2026 HRS Expert Consensus Statement Update on Cardiovascular Implantable Electronic Device Lead Management and Extraction

Yong-Mei Cha, MD, FHRS (Chair),[1,*] Mikhael F. El-Chami, MD, FHRS (Vice Chair),[2,*] Christopher F. Liu, MD, FHRS (Vice Chair),[3,*] Laura J. Andreychuk, BSN, RN,[4,*] Thomas M Beaver, MD, MPH,[5,†] Kelly M. Bergen, MSN, ACNP, FHRS, CCDS,[6,*] Charles I. Berul, MD, MS, FHRS, CEPS-P,[7,‡] Ulrika Maria Birgersdotter-Green, MD, FHRS,[8,*] Alexander Breitenstein, MD,[9,§] Laurence M. Epstein, MD,[10,*] Jay N. Gross, MD, CCDS,[11,*] Larry R. Jackson, II, MD, MHSc, FHRS [12,*] Saima Karim, DO, FHRS,[13,¶] Andrew D. Krahn, MD, FHRS,[14,*] Fred Kusumoto, MD, FHRS,[15,*] Nigel Lever, MD,[16,#] Latoya N. Linton-Frazier, MD, MS,[17,*] Charles J. Love, MD, FHRS, CCDS,[18,*] Douglas Y. Mah, MD, FHRS, CEPS-P,[19,‡] Pamela K. Mason, MD, FHRS,[20,**] M. Travis Maynard,[21,¶¶] Melanie Maytin, MD, FHRS,[22,*] Jay A. Montgomery, MD,[23,*] Jennie Ngai, MD, FASA,[24,‡‡] Ratika Parkash, MD, MS, FHRS,[25,*] Kristen K. Patton, MD, FHRS,[26,*] Naga Venkata K. Pothineni, MD,[27,*] Ulises Rojel-Martínez, Sr., MD, FHRS,[28,§§] M. Rizwan Sohail, MD, FIDSA,[29,¶¶]

DOCUMENT REVIEWERS: [List of peer reviewers to be added after review]

From the [1]Mayo Clinic, Rochester, Minnesota; [2]Emory University, Atlanta, Georgia; [3]Weill Cornell Medicine / New York-Presbyterian Hospital, New York, New York; [4]Sault Area Hospital, Sault Ste Marie, Ontario; [5]University of Florida, College of Medicine, Gainesville, Florida; [6]CaroMont Heart & Vascular, Gastonia, North Carolina; [7]Children's National, Washington, District of Columbia; [8]University of California San Diego, La Jolla, California; [9]University of Heart Center Zurich, Zurich, Switzerland; [10]Northwell Health, Manhasset,

New York; [11]Montefiore Medical Center/ Albert Einstein College of Medicine, New York, New York; [12]Duke University Medical Center, Durham, North Carolina; [13]Case Western Reserve University, Metrohealth Medical Center, Cleveland, Ohio; [14]University of British Columbia, Vancouver, British Columbia; [15]Mayo Clinic Jacksonville, Jacksonville, Florida; [16]Auckland City Hospital, Auckland, New Zealand; [17]Indiana Regional Medical Center, Indiana, Pennsylvania; [18]Johns Hopkins Hospital, Baltimore, Maryland; [19]Boston Children's Hospital, Boston, Massachusetts; [20]University of Virginia, Charlottesville, Virginia; [21]Colorado State University, Fort Collins, Colorado; [22]Brigham & Women's Hospital, Boston, Massachusetts; [23]Vanderbilt University Medical Center, Nashville , Tennessee; [24]NYU Langone, New York, New York; [25]QEII Health Sciences Center, Halifax, Nova Scotia; [26]University of Washington, Seattle, Washington; [27]Kansas City Heart Rhythm Institute, Overland Park, Kansas; [28]South Medical Center, Puebla, Mexico; [29]Baylor College of Medicine/Texas Children's Hospital, Houston, Texas

**Representative of the Heart Rhythm Society (HRS)*

†Representative of the Society of Thoracic Surgeons (STS)

‡Representative of the Pediatric & Congenital Electrophysiology Society (PACES)

§Representative of the European Heart Rhythm Association (EHRA)

¶Representative of the American Heart Association (AHA)

#Representative of the Asia Pacific Heart Rhythm Society (APHRS)

***Representative of the American College of Cardiology (ACC)*

†† Patient Partner

‡‡Representative of the American Society of Anesthesiologists (ASA)

§§Representative of the Latin American Heart Rhythm Society (LAHRS)

¶¶Representative of the Infectious Disease Society of America (IDSA)

*Developed in collaboration with the American College of Cardiology (ACC), the American Heart Association (AHA), the American Society of Anesthesiologists (ASA), the Asia Pacific Heart Rhythm Society (APHRS), the European Heart Rhythm Association (EHRA), the Infectious Disease Society of America (IDSA), the Latin American Heart Rhythm Society (LAHRS), the Pediatric and Congenital Electrophysiology Society (PACES), and the Society of Thoracic Surgeons (STS). Endorsed by XX, YY, ZZ. AA, BB affirmed the value [to be added after endorsement review]. This document is available on the website of the Heart Rhythm Society at https://www.hrsonline.org/publications-resources/resource-library/hrs-documents/. **Reprint requests:** For copies of this document, please contact the Elsevier Inc. Reprint Department (reprints@elsevier.com). **Permissions:** Multiple copies, modification, alteration, enhancement, and/or distribution of this document are not permitted without the express permission of the Heart Rhythm Society. Instructions for obtaining permission are located at https://www.elsevier.com/about/our-business/policies/copyright/permissions. This article has been published with the permission of the Heart Rhythm.*

ABSTRACT

Aim The 2026 HRS Expert Consensus Statement Update on Cardiovascular Implantable Electronic Device (CIED) Lead Management and Extraction provides updated recommendations to guide clinicians in the management of CIED leads.

Background Since the publication of the 2017 HRS Expert Consensus Statement on CIED Lead Management and Extraction, the field has evolved quickly. New evidence on CIED transvenous lead management and the blooming development of new CIED technologies, including leadless pacing and ICD leads implanted outside the vascular system, new lumenless pacing leads and lead extraction tools, have contributed to the field's rapid evolution.

Methods and results A comprehensive literature search was conducted in accordance with the Institute of Medicine standards. The writing committee reviewed evidence gathered by electronic literature searches encompassing clinical trials, original studies, and meta-analyses conducted on human subjects published in English from MEDLINE, PubMed, EMBASE, and the Cochrane Library. The comprehensive literature review supports each evidence-based recommendation and is compiled in the evidence tables. A predefined threshold of > 70% approval for each recommendation was required, with a quorum of two-thirds of the writing committee. The final mean consensus of 108 recommendations was 93.61%.

Discussion The recommendations from the “2017 Expert Consensus Statement on Cardiovascular Implantable Electronic Device Lead Management and Extraction” have been updated with new evidence to guide clinicians. The new recommendations address

the latest CIED technologies with the advantages over transvenous leads, new evidence supporting diagnosis, treatment and prevention for CIED infection, appropriate lead management in transvenous tricuspid valve replacement for tricuspid regurgitation, and standardization of transvenous lead extraction approach, protocol and facilities to improve the outcomes of CIED lead management and extraction.

Top 10 Take-home messages

1. Cardiovascular implantable electronic device (CIED) new technology: Non-vascular ICDs and leadless pacemakers (LP) have emerged as significant parts of our device practice. Their main advantages are related to the elimination of transvenous leads, hence reducing lead-related complications (venous obstruction, system infection) as well as extraction-related complications, and playing a major role in patients with limited vascular access.

2. Risk stratification and prevention for CIED infection: One-time systemic antibiotics delivered before the procedure (prior to incision at a time that allows for adequate tissue levels, typically 1-2 hours) significantly reduces the incidence of device infection; However, additional periprocedural antibiotics, including multicomponent antibiotic regimens or postoperative antibiotics (PADIT trial), provide no significant advantage in preventing device-related infections and are not recommended. Adjunctive use of an antibacterial envelope reduces the incidence of CIED infection in selected high-risk patients and is a new class 2a recommendation.

3. New Strategies for CIED Infection Diagnosis: New diagnostic paradigms emphasize using a probabilistic framework that integrates pathogen specific virulence and biofilm forming capacity, duration of positive cultures, and careful interpretation of imaging findings. This approach reflects the recognized limitations of imaging modalities: transesophageal echocardiography (TEE), while highly sensitive, is non-specific and may not reliably differentiate infection from non-infectious echo densities; similarly, 18F-FDG

PET/CT has limited sensitivity for isolated lead involvement, particularly in the absence of pocket infection.

4. Thoughtfulness on initial lead selection and implantation techniques: When selecting and implanting transvenous leads, it is critical to consider the risk of lead fracture, infection, pocket complications, and the need for future extraction. The updated document recommends minimizing the number of lead(s) as appropriate, selecting single vs dual ICD coils, and practicing meticulous techniques for vascular access and lead placement to mitigate procedural complications (including valvular damage), enhance lead longevity, and facilitate future extraction.

5. Early extraction for infected CIED: In patients with CIED infection undergoing system removal, newer evidence demonstrates that early removal (<7 days) is beneficial compared with delayed extraction, including a reduction in in-hospital mortality, major adverse events, and postprocedural length of stay. Therefore, it is a new class I indication.

6. Lead vegetation debulking and removal: A surgical approach has historically been considered when a very large vegetation (>2.5-3.0cm) was attached to the lead due to a concern for massive pulmonary embolism. Percutaneous mechanical aspiration of vegetations in medium and large sizes utilizing new thrombectomy tools has a high rate of procedural success and a low risk of complications and, therefore, is a new class 2a recommendation.

7. Lead management in the setting of Tricuspid Regurgitation: Transvenous tricuspid valve replacement (TTVR) has evolved as an effective alternative treatment to surgical valve replacement, especially in high-risk patients for surgery and can result in RV lead entrapment between the tricuspid valve and the implanted valve, potentially causing lead malfunction. The updated document recommends RV lead removal in patients with

transvenous leads crossing the tricuspid valve and planned transvenous tricuspid valve intervention to avoid entrapment of the lead and to facilitate the TTVR procedure as a class I indication.

8. Shared decision-making for lead extraction or abandonment: When a CIED lead malfunctions or becomes unnecessary, shared decision-making with the patient as to whether to abandon or remove the lead is recommended.

9. Standardization of multidisciplinary approach, TLE protocol and facility/equipment for lead extraction: The updated document emphasizes prompt referral and access for patients with indications for lead removal to an experienced extraction center and establishing an institutional protocol and a multidisciplinary team approach to guide pre-procedural planning and periprocedural management. The standardized multidisciplinary team approach for TLE and establishing an extraction program with all the necessary equipment and expertise required to manage all potential complications are class I recommendations.

10. Remote monitoring should be mandatory: Modern CIED technology has advanced algorithms for the detection of electrical abnormalities, which can provide early warning for an impending lead malfunction and failure, mitigate adverse events and hospitalization. Therefore, we emphasize that remote monitoring is a Class I recommendation for all CIED systems in this document.

Section 1. Introduction and Methodology

1.1. Preamble

The Heart Rhythm Society (HRS) has developed expert consensus documents that have guided clinical care in the management of cardiac arrhythmias since 1996. This HRS-led clinical practice guideline was developed with international collaboration among ten professional organizations including HRS, American College of Cardiology (ACC), the American Heart Association (AHA), the American Society of Anesthesiologists (ASA), the Asia Pacific Heart Rhythm Society (APHRS), the European Heart Rhythm Association (EHRA), the Infectious Disease Society of America (IDSA), the Latin American Heart Rhythm Society (LAHRS), the Pediatric and Congenital Electrophysiology Society (PACES), and the Society of Thoracic Surgeons (STS). Cardiovascular implantable electronic devices (CIEDs) traditionally use leads that connect the pulse generator to cardiac tissue. Since the publication of the *2017 HRS Expert Consensus Statement on Cardiovascular Implantable Electronic Device Lead Management and Extraction*, the field has evolved quickly with the publication of new evidence on CIED transvenous lead management, development of new CIED technologies that are leadless or employ leads implanted outside the vascular system, wide adoption of leads that do not have a lumen, new lead extraction tools, and new cardiac and vascular procedures that have lead management implications.[1] A holistic approach to CIED selection and use is required, and by extension, consideration of potential lead management implications over a patient's lifetime. This document is intended to help clinicians in their decision-making process for managing

leads and CIED implant considerations and updates the 2017 HRS Expert Consensus on CIED Lead Management and Extraction.[1]

Scientific evidence was systematically reviewed and translated into recommendations to improve the quality of care in CIED lead management. The document was developed in international collaboration and is intended to be relevant to medical practice worldwide. Although Expert Consensus Statements may be used to inform regulatory or payer decisions, the intent is to improve the quality of care, support the appropriate use of therapeutics, and align with patients' interests. Expert Consensus Statements are intended to define practices that meet the needs of patients in most, but not all, circumstances, and are not meant to replace clinical judgment.

1.2. Document scope, objectives, and assumptions

The focus of the current expert consensus statement is to provide an update on practical clinical guidance in the broad field of lead management, including extraction and management of traditional CIEDs that use transvenous leads, CIEDs with extravascular or subcutaneous leads, and leadless CIEDs.

1.3. Editorial independence

This Expert Consensus Statement is sponsored by the HRS and is developed without commercial support; writing group members volunteer their time to the writing and review efforts.

1.4. Organization of the writing committee and stakeholder involvement

The writing group consisted of experts in the field chosen by partnering and collaborating organizations and patient partners. HRS strives to ensure that the guideline writing

committee both contains requisite expertise and is diversely representative of the broader medical community by selecting experts from a broad array of backgrounds representing different geographic regions (from 4 countries), sexes, races, ethnicities, intellectual perspectives, and scopes of clinical practice, and by inviting organizations and professional societies with related interests and expertise to participate as partners or collaborators. HRS has rigorous policies and methods to ensure that documents are developed without bias or improper influence. The complete policy on relationships with industry (RWI) and other entities can be found online.

HRS has rigorous policies and methods to ensure that documents are developed without bias or improper influence. The HRS policy on RWI and other entities can be found at: https://www.hrsonline.org/sites/default/files/2020-06/HRS_Code-of-Ethics.pdf.[2]

Disclosure of any RWI and other entities was required from the writing committee members (**Appendix 1**) and peer reviewers (**Appendix 2**), in accordance with the HRS policies. Of the 28 committee members, 16 (57.14%) had no relevant RWI, including the document Chair and one of the two Vice Chairs. Sections that contain recommendations were written by committee members who were free of any relevant RWI.

1.5. Evidence reviews and formulation of recommendations

This Expert Consensus Statement was developed in accordance with the clinical practice methodology processes detailed in the *HRS Clinical Document Development Methodology Manual and Policies,*[3] and with the aim to aligning with the Institute of Medicine standards.[4] The writing committee reviewed evidence gathered by electronic literature searches (MEDLINE, PubMed, Embase, Cochrane Library). No specific year was chosen for

the oldest literature. Some literature databases allow the use of certain symbols to search for different forms or spellings of a word. The asterisk (*) was used for truncation to search for all forms of a word, the plus (+) symbol was used to search for plural and singular forms of a word, and the pound symbol (#) was used as a wildcard to search for variant spellings or hyphenation of a word. Search terms included, but were not limited to CIED lead management, lead survival and new technologies, diagnostic approaches to suspected lead failure, lead recalls and advisories, indications for lead extraction and periprocedural management. Literature searches focused whenever possible on randomized controlled trials, but systematic reviews, nonrandomized and registry studies, cohort studies, and case series were included. Case reports were not used to support recommendations. Evidence tables are included in **Appendix 3** and summarize the evidence used by the writing committee to formulate recommendations. References are representative of the totality of data and are not meant to be all-inclusive. Limitations of the evidence base are discussed in individual sections.

The writing committee discussed all recommendations with consideration of the risk versus benefit of an intervention and the strength of the evidence. To assess consensus after discussions, the writing committee members participated in surveys. A predefined threshold of > 70% approval for each recommendation was required, with a quorum of two-thirds of the writing committee. An initial failure to reach consensus was resolved by subsequent discussions, revisions as needed, and re-voting. All writing committee members voted on each recommendation. The final consensus over all recommendations was 93.61%, with 39 of 108 recommendations reaching 100% consensus.

1.6. Class of recommendation and level of evidence

The recommendations were formulated according to the ACC/AHA Class of Recommendation (COR) and Level of Evidence (LOE) system (**Table 1**).[5] The COR denotes the strength of the recommendation based on the assessment of the magnitude and certainty of the benefits in proportion to the risks. The LOE reflects the quality of the evidence that supports the recommendation based on the type, quantity, and consistency of data from clinical trials and other sources.

For clarity and usefulness, each recommendation is linked to supportive science through the specific references from the literature used to justify the LOE rating, which are also summarized in the evidence tables (**Appendix 3**). Each recommendation is accompanied by explanatory text. Flow diagrams and appropriate tables provide a summary of the recommendations, intended to assist clinicians at the point of care. A discussion of definitions is provided in **Section 2**.

Table 1 ACC/AHA recommendation system: Applying Class of Recommendation and Level of Evidence to clinical strategies, interventions, treatments, and diagnostic testing in patient care (updated May 2019)*

CLASS (STRENGTH) OF RECOMMENDATION	
CLASS 1 (STRONG)	**Benefit >>> Risk**
Suggested phrases for writing recommendations: • Is recommended • Is indicated/useful/effective/beneficial • Should be performed/administered/other • Comparative-Effectiveness Phrases†: – Treatment/strategy A is recommended/indicated in preference to treatment B – Treatment A should be chosen over treatment B	
CLASS 2a (MODERATE)	**Benefit >> Risk**
Suggested phrases for writing recommendations: • Is reasonable • Can be useful/effective/beneficial • Comparative-Effectiveness Phrases†: – Treatment/strategy A is probably recommended/indicated in preference to treatment B – It is reasonable to choose treatment A over treatment B	
CLASS 2b (WEAK)	**Benefit ≥ Risk**
Suggested phrases for writing recommendations: • May/might be reasonable • May/might be considered • Usefulness/effectiveness is unknown/unclear/uncertain or not well-established	
CLASS 3: No Benefit (MODERATE) **(Generally, LOE A or B use only)**	**Benefit = Risk**
Suggested phrases for writing recommendations: • Is not recommended • Is not indicated/useful/effective/beneficial • Should not be performed/administered/other	
Class 3: Harm (STRONG)	**Risk > Benefit**
Suggested phrases for writing recommendations: • Potentially harmful • Causes harm • Associated with excess morbidity/mortality • Should not be performed/administered/other	

LEVEL (QUALITY) OF EVIDENCE‡	
LEVEL A	
• High-quality evidence‡ from more than 1 RCT • Meta-analyses of high-quality RCTs • One or more RCTs corroborated by high-quality registry studies	
LEVEL B-R	**(Randomized)**
• Moderate-quality evidence‡ from 1 or more RCTs • Meta-analyses of moderate-quality RCTs	
LEVEL B-NR	**(Nonrandomized)**
• Moderate-quality evidence‡ from 1 or more well-designed, well-executed nonrandomized studies, observational studies, or registry studies • Meta-analyses of such studies	
LEVEL C-LD	**(Limited Data)**
• Randomized or nonrandomized observational or registry studies with limitations of design or execution • Meta-analyses of such studies • Physiological or mechanistic studies in human subjects	
LEVEL C-EO	**(Expert Opinion)**
• Consensus of expert opinion based on clinical experience	

COR and LOE are determined independently (any COR may be paired with any LOE).

A recommendation with LOE C does not imply that the recommendation is weak. Many important clinical questions addressed in guidelines do not lend themselves to clinical trials. Although RCTs are unavailable, there may be a very clear clinical consensus that a particular test or therapy is useful or effective.

* The outcome or result of the intervention should be specified (an improved clinical outcome or increased diagnostic accuracy or incremental prognostic information).

† For comparative-effectiveness recommendations (COR 1 and 2a; LOE A and B only), studies that support the use of comparator verbs should involve direct comparisons of the treatments or strategies being evaluated.

‡ The method of assessing quality is evolving, including the application of standardized, widely-used, and preferably validated evidence grading tools; and for systematic reviews, the incorporation of an Evidence Review Committee.

COR indicates Class of Recommendation; EO, expert opinion; LD, limited data; LOE, Level of Evidence; NR, nonrandomized; R, randomized; and RCT, randomized controlled trial.

Modified with permission from the American College of Cardiology (ACC) and the American Heart Association (AHA).

1.7. Document review and approval

The HRS invites public and stakeholder involvement in document development. In addition to patient representation in the writing committee, draft recommendations were posted for

public comment, and contributions were solicited from regulatory agencies and patient organizations.

This Expert Consensus document was approved by the writing committee and underwent internal review by the HRS Clinical Guideline Committee (CGC). The document underwent external peer review by reviewers appointed by HRS and each of the collaborating societies, and revisions were made by the chairs. A record of the writing committee's response to reviewer comments and rationale is maintained by the HRS.

1.8. Updating

The HRS CGC reviews its published clinical practice documents in currency at least every 5 years, or earlier in the event of newly published data. Literature is routinely monitored to evaluate the continued validity of recommendations.

1.9. Other guideline documents and systematic reviews

Clinical practice documents and systematic reviews relevant to the topic of lead management were used to inform the development of this guideline. **Table 2** lists applicable clinical practice documents (eg, guidelines and consensus statements) that the writing committee considered fundamental to the development of this document. Other systematic reviews used to support specific recommendations are referenced in the respective sections.

Table 2 Relevant clinical practice documents

Title	Publication Year

(18)F-FDG PET/CT and radiolabeled leukocyte SPECT/CT imaging for the evaluation of cardiovascular infection in the multimodality context: ASNC Imaging Indications (ASNC I(2)) Series Expert Consensus Recommendations from ASNC, AATS, ACC, AHA, ASE, EANM, HRS, IDSA, SCCT, SNMMI, and STS.	2024
Update on Cardiovascular Implantable Electronic Device Infections and Their Prevention, Diagnosis, and Management: A Scientific Statement from the American Heart Association: Endorsed by the International Society for Cardiovascular Infectious Diseases.	2024
2021 PACES Expert Consensus Statement on the Indications and Management of Cardiovascular Implantable Electronic Devices in Pediatric Patients: Developed in collaboration with and endorsed by the Heart Rhythm Society (HRS), the American College of Cardiology (ACC), the American Heart Association (AHA), and the Association for European Paediatric and Congenital Cardiology (AEPC) Endorsed by the Asia Pacific Heart Rhythm Society (APHRS), the Indian Heart Rhythm Society (IHRS), and the Latin American Heart Rhythm Society (LAHRS).	2021
European Heart Rhythm Association (EHRA) international consensus document on how to prevent, diagnose, and treat cardiac implantable electronic device infections-endorsed by the Heart Rhythm Society (HRS), the Asia Pacific Heart Rhythm Society (APHRS), the Latin American Heart Rhythm Society (LAHRS), the International Society for Cardiovascular Infectious Diseases (ISCVID), and the European Society of Clinical Microbiology and Infectious Diseases (ESCMID) in collaboration with the European Association for Cardio-Thoracic Surgery (EACTS).	2020
2017 HRS expert consensus statement on cardiovascular implantable electronic device lead management and extraction.	2017

Transvenous lead extraction: Heart Rhythm Society expert consensus on facilities, training, indications, and patient management: this document was endorsed by the American Heart Association (AHA).	2009

283

Section 2. General concepts

Over the past seventy years, CIEDs have become an established treatment option for selected patients with bradycardia, tachycardia, and heart failure. In addition, new cardiac and vascular procedures such as transvenous tricuspid valve interventions and central venous stenting have evolved with concurrent lead management implications. It is estimated that in 2022, 800,000 CIEDs were implanted in the United States.[6] The most recent report from Europe found a median number of 607 pacemaker implants and 121 implantable cardioverter defibrillator (ICD) per million people in 2023, with higher numbers observed in more economically advanced countries.[7] The increasing population age in all economically advanced countries suggests that future CIED implant rates will be higher, particularly for permanent pacemakers.[8] When any CIED (including leadless pacemakers) is implanted, future lead management considerations must be considered. At initial CIED implant or subsequently when a generator or lead needs to be replaced or revised, device choice and lead management issues include clinical indication, patient comorbidities, predicted patient lifespan, lead performance, consequences of any future CIED complication, and potential clinical benefit and risks.

Section 3. Definitions

The definitions used in the current document are similar to those developed in the 2017 document and are provided in **Table 3**.[1] In that document clinical success of lead extraction could include the retention of a small part of the lead that did not affect the desired outcome of the procedure. The writing committee defined “small” as < 4 cm for any residual lead portion as unlikely to be clinically significant. To provide an accurate and

consistent description of a clinical procedure that involves the removal of a lead, a lead removal procedure can be further classified as either a lead explant or lead extraction. Lead extraction is defined as a lead removal procedure where at least one lead removal requires the assistance of equipment not typically employed during lead implantation, or at least one lead was implanted for greater than one year. Lead removal can involve transvenous leads, or any lead not placed in the vascular system.

To account for new technologies and better account for potential consequences of transvenous leads that pass through the tricuspid valve, several new definitions have been added to the current document. The first is Intracardiac Leadless CIED Extraction, as this strategy becomes more widely used with a current estimated growth rate of 13-14%.[9] New and established cardiac and vascular interventional procedures, such as transcatheter tricuspid valve replacement (TTVR), can potentially result in lead injury or lead entrapment ("jailing"). This document defines lead entrapment when the deployment of an intravascular or cardiac device results in fixation of a transvenous lead against a vascular wall, cardiac structure, or a previously implanted bioprosthetic valve (TTVR is sometimes deployed on a prior bioprosthetic valve (valve in valve). Finally, lead-induced severe tricuspid regurgitation is a situation where new severe tricuspid regurgitation is identified after transvenous lead implant and imaging documents leaflet impingement by the lead. Lead associated tricuspid regurgitation is identified with no imaging evidence of leaflet-transvenous lead interaction with multifactorial potential causes including enlargement or poor function of right-sided chambers or pulmonary hypertension.

327 **Table 3 Definitions**

Term	Definition
Nonfunctional lead	A lead that is not usable due to electrical dysfunction, whether it is connected to the CIED or not.
Abandoned lead	A functional or nonfunctional lead that is left in place and is not connected to the CIED
Lead Removal Procedure	A procedure involving the removal of a pacing or defibrillator lead using any technique, regardless of time since implantation.
Lead Explant Procedure	Lead removal procedure where all leads were removed without tools or with implantation stylets, and all removed leads were implanted for less than one year.
Lead Extraction	The lead removal procedure, where at least one lead removal required the assistance of equipment not typically employed during lead implantation, or at least one lead was implanted for greater than one year.
Intracardiac leadless CIED extraction	Removal of a leadless CIED that has been placed in the heart.
Surgical lead removal	Lead removal procedure that requires surgical epicardial access.
Lead entrapment	Any cardiac or intravascular implant that results in fixation of a portion of a transvenous lead against a vascular wall, cardiac structure or previously implanted valve.

Transvenous and/or Permanent Epicardial Lead Extraction Procedure Outcomes	**Definition**
Complete Procedural Success	Transvenous and/or permanent epicardial lead extraction procedure with removal of all targeted leads and all lead material from the vascular space, with the absence of any permanently disabling complication or procedure related death.
Complete Procedural Success Rate	Transvenous and/or permanent epicardial lead extraction procedures, where there is complete procedural success / Total number of extraction procedures.
Clinical Success	Transvenous and/or permanent epicardial lead extraction procedures with removal of all targeted leads and lead material from the vascular space, or retention of a small portion of the lead (< 4 cm) that does not negatively impact the outcome goals of the procedure.
Clinical Success Rate	Transvenous and/or permanent epicardial lead extraction procedures, where there is clinical success / Total number of transvenous lead extraction procedures.
Failure	Transvenous and/or permanent epicardial lead extraction procedures when there is the inability to achieve either complete procedural or clinical success, or the development of any permanently disabling complication or procedure related death.

Failure Rate	Transvenous and/or permanent epicardial lead extraction procedures that failed / Total number of transvenous and/or permanent epicardial lead extraction procedures.
Lead Removal with Clinical Success	Transvenous and/or permanent epicardial leads with attempted removal, where the entire lead is taken out of the body, or with retention of a small portion of the lead material (< 4 cm) that does not negatively impact the outcome goals of the procedure.
Lead Removal with Clinical Success Rate	Number of transvenous and/or permanent epicardial leads removed with clinical success during a lead extraction / Total number of transvenous and/or permanent epicardial leads with attempted removal.
Definitions for CIED related tricuspid regurgitation	**Definition**
Lead induced severe tricuspid regurgitation	New finding of severe tricuspid regurgitation following implantation of a transvenous lead crossing the tricuspid valve with imaging evidence of leaflet impingement by the lead limiting valve coaptation and an eccentric jet of tricuspid regurgitation.
Lead associated with severe tricuspid regurgitation	Severe tricuspid regurgitation in the setting of a dilated tricuspid annulus and right atrial dilation, along with the presence of a transvenous lead crossing the tricuspid valve with no imaging evidence of interaction of the lead with the tricuspid valve leaflets.

328

329 **References**

1. Kusumoto FM, Schoenfeld MH, Wilkoff BL, Berul CI, Birgersdotter-Green UM, Carrillo R, Cha YM, Clancy J, Deharo JC, Ellenbogen KA, Exner D, Hussein AA, Kennergren C, Krahn A, Lee R, Love CJ, Madden RA, Mazzetti HA, Moore JC, Parsonnet J, Patton KK, Rozner MA, Selzman KA, Shoda M, Srivathsan K, Strathmore NF, Swerdlow CD, Tompkins C, Wazni O. 2017 HRS expert consensus statement on cardiovascular implantable electronic device lead management and extraction. Heart Rhythm. 2017 Dec;14(12):e503-e551.
2. https://www.hrsonline.org/about-us/structure-and-governance/disclosure-policy
3. Indik JH, Patton KK, Beardsall M, Chen-Scarabelli CA, Cohen MI, Dickfeld TL, Haines DE, Helm RH, Krishnan K, Nielsen JC, Rickard J, Sapp JL Jr, Chung M. **HRS** Clinical Document Development **Methodology** Manual and Policies: Executive summary. Heart Rhythm. 2017 Oct;14(10):e495-e500.
4. https://www.nationalacademies.org/our-work/standards-for-developing-trustworthy-clinical-practice-guidelines
5. https://www.acc.org/Guidelines/About-Guidelines-and-Clinical-Documents/Methodology and https://www.acc.org/Guidelines/About-Guidelinesand-Clinical-Documents/Methodology and https://professional.heart.org/-/media/phd-files/guidelines-and-statements/methodology_manual_and_policies_ucm_319826.pdf
6. https://www.globaldata.com/store/report/usa-cardiac-rhythm-management-procedures-market-analysis/
7. Timmis A, Aboyans V, Vardas P, Townsend N, Torbica A, Kavousi M, Boriani G, Huculeci R, Kazakiewicz D, Scherr D, Karagiannidis E, Cvijic M, Kapłon-Cieślicka A, Ignatiuk B,

Raatikainen P, De Smedt D, Wood A, Dudek D, Van Belle E, Weidinger F; ESC National Cardiac Societies. European Society of Cardiology: the 2023 Atlas of Cardiovascular Disease Statistics. Eur Heart J. 2024 Oct 7;45(38):4019-4062.

8. https://www.who.int/news-room/questions-and-answers/item/population-ageing#:~:text=Globally%2C%20life%20expectancy%20at%20birth,and%20rapid%20in%20developing%20regions.
9. https://www.coherentmarketinsights.com/industry-reports/leadless-pacemakers-market

Section 4. Lead Survival and New Technologies

4.1. New Technologies

Newer technologies in cardiovascular implantable electronic devices (CIED) offer the opportunity to significantly decrease the clinical challenges, morbidity, and mortality associated with intravascular devices. Since the prior consensus statement in 2017, the use of leadless pacing and non-vascular implantable cardioverter defibrillators (NV-ICDs, eg, S-ICD and EV-ICD) has increased substantially, ushering in a new paradigm of non-vascular cardiac rhythm management.

4.1.1. Non-Vascular Implantable Cardioverter Defibrillator Therapies

Recommendations for Non-Vascular ICDs			
COR	**LOE**	**Recommendations**	**References**
1	**C-EO**	**1. In patients who meet indications for primary or secondary prevention implantable cardioverter defibrillator therapy and without an indication for bradycardia pacing or cardiac resynchronization therapy (CRT), shared decision-making is recommended to choose the type of implantable cardioverter defibrillator (transvenous vs non-vascular) based on a patient-centered approach.**	(7)
1	**B-R**	**2. In patients who meet indications for primary or secondary implantable cardioverter defibrillator therapy and without an indication for bradycardia pacing or cardiac resynchronization therapy (CRT), who have inadequate vascular access, a mechanical tricuspid valve, high risk of infection, or history of prior CIED infection, an S-ICD is recommended.**	(1)(2)(3)(5)(6)
2a	**C-LD**	**3. In patients who meet indications for primary or secondary implantable cardioverter defibrillator therapy and without an indication for bradycardia pacing or cardiac resynchronization therapy (CRT) or history of prior sternotomy, who have inadequate**	(9)(10)(11)(12)

		vascular access, high risk of infection, or history of prior CIED infection, an EV-ICD is reasonable.	
1	**B-NR**	**4. In patients who meet indications for primary or secondary prevention implantable cardioverter defibrillator therapy, and without an indication for bradycardia pacing and cardiac resynchronization therapy (CRT), where avoiding a TV lead might be beneficial (ie, younger patients), an S-ICD is recommended.**	(13) (14)
2a	**C-LD**	**5. In patients who meet indications for primary or secondary prevention implantable cardioverter defibrillator therapy, and without an indication for bradycardia pacing and cardiac resynchronization therapy (CRT) or history of prior sternotomy, where avoiding a TV lead might be beneficial (ie, younger patients), an EV-ICD is reasonable.**	(13) (14)

Synopsis

Non-vascular implantable cardioverter defibrillator therapies, including S-ICD and the EV-ICD, are both FDA-approved for primary and secondary prevention strategies to mitigate sudden cardiac death. The use of a non-vascular ICD may be of particular interest for those patients with a history of prior CIED infection or high risk of infection, inadequate vascular access, younger patients requiring long lead dwell time, or a mechanical tricuspid valve.

Recommendation-specific supportive text

Recommendation 1&2: The S-ICD is an entirely subcutaneous ICD system appropriate for candidates who are at risk of sudden cardiac death who do not require brady or antitachycardia pacing (ATP), or cardiac resynchronization therapy.[1] Several studies have demonstrated the safety and efficacy of the S-ICD in both clinical trial settings and real-

world practice.[2-4] Knops et al., in an international randomized non-inferiority trial of S-ICD vs. transvenous defibrillator therapy, showed that S-ICD was non-inferior with respect to the primary endpoint of the composite of device related complications and inappropriate shocks after a median follow-up of 49.1 months (HR 0.99, 95% CI, 0.71 to 1.39; P=0.01 for noninferiority; P=0.995 for superiority).[5] In a multinational, prospective, nonrandomized study of primary prevention patients undergoing de novo implant of an S-ICD who had a left ventricular ejection fraction (LVEF) ≤35%, Gold and colleagues demonstrated among 1116 patients who had an attempted S-ICD implant that the eighteen-month freedom from inappropriate shock was 95.9% (lower confidence limit, 94.8%); the 18-month all-cause shock-free rate was 90.6% (lower confidence limit, 89.0%).[6] The conversion success rate for appropriate, discrete episodes was 98.4%; the complication-free rate at 18 months was 92.7%. The decision to pursue treatment with a non-vascular CIED for sudden cardiac death prevention should be based on a detailed discussion between patient and clinician, including an assessment of preferences and values for treatment in the context of a shared decision-making encounter[7], while reviewing key treatment considerations including patient age, need for cardiac resynchronization therapy, and brady or anti-tachycardia pacing.

In general, the risk of infection with S-ICD is lower than transvenous ICD systems. In a secondary analysis of the PRAETORIAN Trial, S-ICD was associated with a lower rate of overall device-related complications compared to transvenous-ICDs, including lower risk of overall infections [11.1% (4/ 36) vs. 16.3% (8/49)] and systemic infections [(48-month Kaplan Meier cumulative incidence (0 vs. 1.2%, p=0.030)].[4] In an analysis from the S-ICD

post-approval study, Gold and colleagues demonstrated that over a 3-year post-implantation follow-up period, S-ICD infection occurred in 55/1637 (3.3%) of patients, with 69% of the infections occurring within 90 days post-implant; 92.7% of the infections occurred within 1 year after device implantation.[8] Predictors of S-ICD infection included: (HR 1.91; P=.022), younger age (HR 0.98; P =.021), prior TV-ICD implant (HR 4.84; P < .0001), and lower left ventricular ejection fraction (LVEF) (HR 0.98; P =.038).

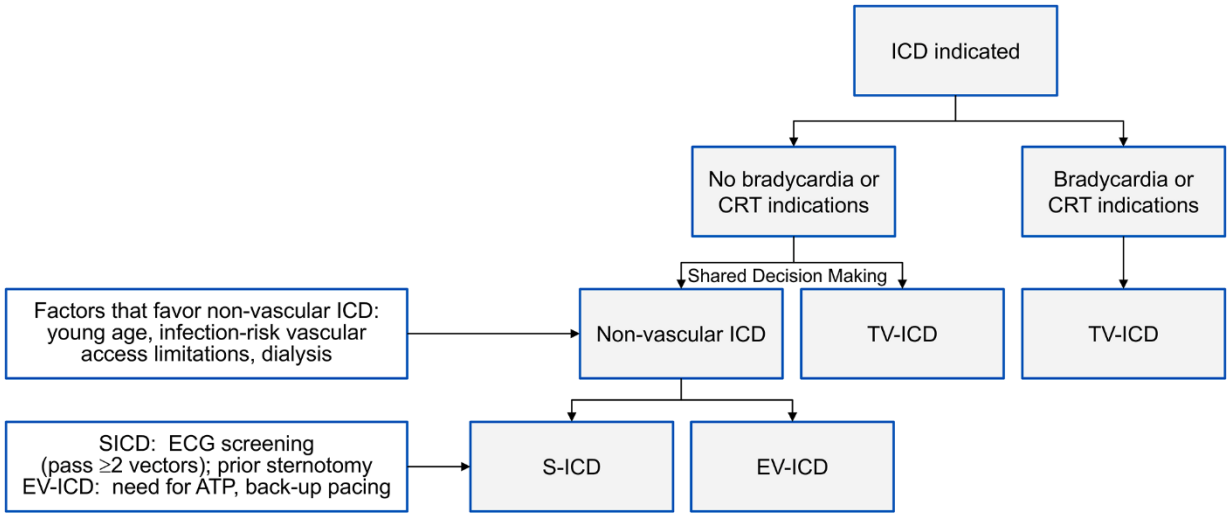
Recommendation 3: The EV-ICD, approved by the Food and Drug Administration (FDA) in October 2023, is used to prevent sudden cardiac death and treat ventricular arrhythmias with defibrillation and ATP in a single device. The EV-ICD utilizes a substernal lead that can offer ATP, post-shock and pause prevention pacing.[9,10] Limited data exist on the safety and efficacy of the EV-ICD in real-world clinical practice.[11] Friedman and colleagues in long-term follow-up from the PIVOTAL study evaluated freedom from major system- or procedure-related complications and appropriate and inappropriate therapy rates through 3 years of follow-up.[12] Antitachycardia pacing was successful in 77.1% (N=37/48) of episodes, and shock therapy was successful in 100% (N=27/27) of discrete, spontaneous ventricular arrhythmias. No major intraprocedural complications were reported, and the estimated freedom from system or procedure-related major complications was 91.9% in 1 year and 89.0% in 3 years.

Both non-vascular ICD systems (S-ICD and EV-ICD) are associated with increased rates of inappropriate shocks/therapies compared to transvenous ICD systems. Inappropriate shocks with the S-ICD have been well-documented and largely addressed via the use of Smart Pass filter (Boston Scientific) and dual zone programming.[13,14] Results from the

PIVOTAL EV-ICD trial demonstrated an inappropriate shock rate of 9.7% (29/299) of patients and a Kaplan Meier estimate for inappropriate shocks at 8.5% at 6 months; the most common causes of inappropriate shocks were p wave oversensing.[10]

Recommendations 4&5: In certain clinical scenarios, avoiding a transvenous lead might be beneficial. Young age is a known risk factor for premature transvenous lead failure.[15,16] These patients are typically more active and expose the lead to more stress. Also, their life expectancy is higher, hence they are expected to require multiple lead revisions, which may necessitate repeated transvenous lead extraction (TLE). Moreover, transvenous lead extraction is typically more challenging in this group of patients due to fibrosis.[15,16] The use of non-vascular ICDs is advantageous in this setting. The S-ICD has been available for more than a decade compared to the EV-ICD, hence the difference in the class of recommendations. **Figure 1** summarizes a proposed algorithm for ICD selection, including transvenous and non-vascular ICDs.

Figure 1. Proposed Algorithm for Implantable Cardioverter Defibrillator Selection



CRT: Cardiac resynchronization Therapy; ICD: Implantable Cardioverter Defibrillator; TV: Transvenous; SICD: Subcutaneous ICD; EV-ICD: Extravascular ICD

4.1.2. Leadless Pacing Therapies

Recommendations for Leadless Pacing			
COR	**LOE**	**Recommendations**	**References**
1	**C-EO**	**6. In patients who require bradycardia pacing support, shared decision-making is recommended to choose the type of pacemaker implanted based on a patient-centered approach.**	(17)(18)(19)(20) (21)(22)
1	**B-NR**	**7. In patients who require pacing for bradycardia, with a history of transvenous cardiovascular implantable electronic device infection(s), limited vascular access, or dialysis, treatment with a leadless pacemaker is recommended.**	(17)(18)(19)(20) (21)(22)

2a	**B-NR**	**8. In patients who require pacing for bradycardia, treatment with a leadless pacemaker is reasonable as an alternative to a transvenous pacemaker.**	(21)(23) (24)(25)(26)
2b	**C-LD**	**9. In younger patients who require pacing for bradycardia, a leadless pacemaker may be reasonable.**	(13)(27)
3: Harm	**C-EO**	**10. In patients with a history of mechanical tricuspid valve who require pacing support, treatment with a leadless pacemaker is NOT recommended.**	(21)(28)(29)

Synopsis

Bradycardia pacing with leadless pacing systems has rapidly expanded since initial FDA approval in 2016. Given the advantages and growing utilization of leadless pacing, contemporary leadless pacing systems have become an important alternative in the pacing armamentarium for select populations.

Recommendation-specific supportive text

Recommendation 6&7: Two single-component leadless pacemakers are currently available for implant: the Micra™ Transcatheter Pacing System-VR (Medtronic) and the AVEIR™ VR (Abbott). The Micra™ VR system employs nitinol tines (estimated median battery longevity ~12-13 years, VR2 longevity ~16.7 years)[17,18] while the AVEIR system has a screw-like, active fixation mechanism and has an estimated battery longevity of ~12 years

and 16 years for the atrial device and ventricular device, respectively, but the i2i communication adds significant drain on the battery longevity.[19] A common theme to all LP studies is the reduction in complications during follow-up, driven by the reduction in need for reintervention. Numerous studies have demonstrated the safety and efficacy of the Micra™ VR system compared to either historical controls or a contemporary cohort of patients receiving transvenous single ventricular chamber pacemakers.[20,21] In a study from the Longitudinal Coverage With Evidence Development Study on Micra Leadless Pacemakers (Micra CED), Piccini et al. showed no significant difference in the overall acute complication rate between the leadless VVI pacemaker vs transvenous VVI pacemakers (7.7% vs. 7.4%; risk difference, 0.3; 95% CI, -0.6 to 1.3; P=0.49); pericardial effusion/perforation within 30 days was significantly higher in the leadless VVI pacemaker group (adjusted, 0.8% vs 0.4%; risk difference, 0.4; 95% CI, 0.1 to 0.7; P=.004).[21] El-Chami et al., in a 2-year follow-up from the Micra™ CED study, demonstrated that leadless VVI patients had significantly fewer reinterventions [adjusted HR 0.62, 95% CI 0.45-0.85, P=.003] and chronic complications [adjusted HR 0.69, 95% CI 0.60-0.81, P<0.0001] compared to transvenous VVI patients.[22] In addition, data from the Micra™ transcatheter pacing system Post Approval Registry, demonstrated that among 1809 patients with a median follow period of 51.1 months the major complication rate was 4.5% at 60 months [95% CI: 3.6%-5.5%] and 4.1% at 36 months, significantly lower than the 8.5% rate for transvenous systems (HR: 0.47, 95% CI: .36-.61; P <.001).[23] Importantly, there were no Micra™ removals due to infection noted over the duration of follow-up. Similarly, data from the Micra™ AV Coverage with Evidence Development study showed that LP patients had

lower complication rates [adjusted 5.3 vs. 9.6%, HR: 0.54, 95% CI 0.49-0.61, P<0.0001)] and lower re-intervention rates [adjusted 3.5 vs. 5.6%, HR 0.62, 95% CI 0.54-0.72, P<0.0001] than dual chamber transvenous pacemaker patients.[24] Importantly, all-cause mortality rates remained higher in Micra™ AV than in dual chamber transvenous patients (unadjusted HR: 2.48, 95% CI 2.35-2.62, P<0.0001; adjusted HR: 1.53, 95% CI 1.44-1.62, P<0.0001).[24] The increased mortality seen in the Micra™ AV vs. dual chamber transvenous cohort is most likely attributable to a higher burden of comorbid medical conditions in the Micra™ AV cohort and differences in patient characteristics.[24]

While the real-world data of AVEIR™ is limited, early reports demonstrate comparable success and safety. Reddy et al. demonstrated that 95.1% of patients met the effectiveness criteria of acceptable pacing thresholds ($\leq$ 2.0 V at 0.4 milliseconds) and R-wave amplitudes ($\leq$ 5.0 mV or greater than or equal to the value at implantation) through 1-year of follow-up with the AVEIR™ VR [(95% CI: 91.2%-97.6%), of which the lower bound exceeded the performance goal of 80% (P < 0.0001)].[19] The primary safety endpoint of 1-year freedom from serious adverse device effects was met in 93.2% (95% CI: 88.7%-95.9%), of which the lower bound exceeded the performance goal of 83% (P < 0.0001).

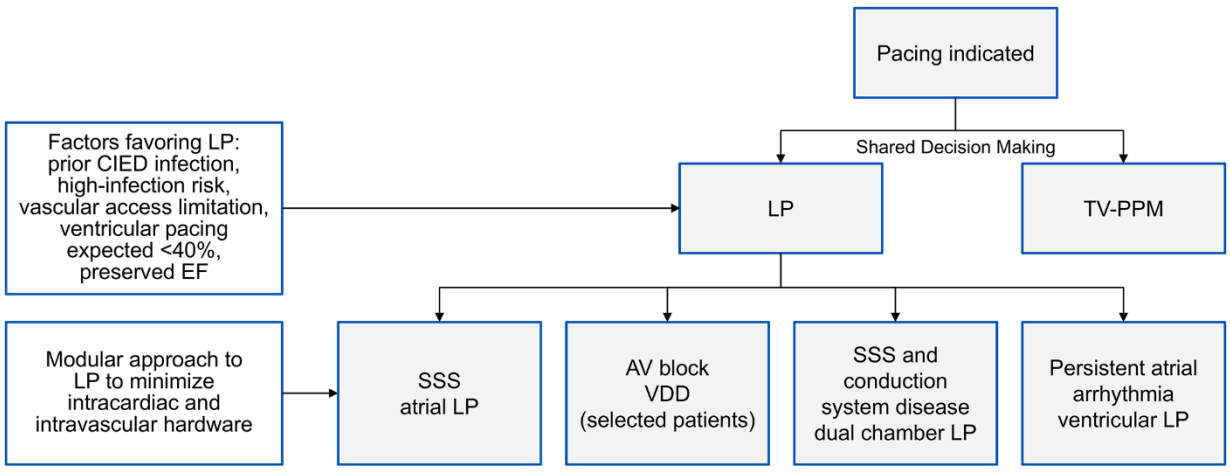
Recommendation 8: Several studies have demonstrated the safety of LP implantation after TLE of an infected CIED.[23,25,26] Remarkably, no LP-related infection was seen in these patients. The 5-year follow-up data from the Micra™ Post Approval Registry have shown no device-related infection in around 1800 patients followed for 5 years. This illustrates the advantage of LP in patients at high risk for infection.[23] Similarly, LP is the desired pacing therapy for patients on hemodialysis or with limited vascular access, and several studies

have demonstrated its safety.[27,28] Hence, for patients with a history of CIED-related infection or a high risk for infection, LP is the preferred choice over transvenous PM.

Recommendation 9: Young patients have a higher incidence of transvenous pacing lead failure, are more likely to require multiple lead revisions during their lifetime and are more likely to require TLE.[15,29] Leadless pacing might be a reasonable option for young patients, especially those who wish to mitigate the long-term sequelae of transvenous leads.

Recommendation 10: Leadless pacing studies have excluded patients with a mechanical tricuspid valve.[23,30,31] Crossing the mechanical prosthesis might lead to delivery system entrapment or valve malfunction. **Figure 2** is a summary of the proposed algorithm for leadless pacemaker selection.

Figure 2: Proposed algorithm for Leadless Pacemaker



AV: Atrioventricular; CIED: cardiovascular Implantable Electronic Devices; EF: Ejection Fraction; LP: Leadless Pacing: PPM: Pacemaker; SSS: Sick Sinus Syndrome; TV: Transvenous

4.2 Extraction of CIEDs in Newer CIED Technologies

4.2.1 Extraction of Nonvascular Implantable Cardioverter Defibrillators

Both the S-ICD and EV-ICD employ the use of a tunneling tool for defibrillator coil deployment, either in a subcutaneous parasternal orientation to the sternum or below the sternum, respectively. Several retrospective observational analyses have demonstrated the efficacy of utilizing manual traction in removing the defibrillator lead of the S-ICD and EV-ICD. De Filippo and colleagues demonstrated among 71 consecutive patients who underwent complete S-ICD extraction that simple manual traction of the S-ICD lead through the xiphoid incision was sufficient to remove the lead in 59 (84%), while eleven patients (15%) required the use of a non-powered mechanical sheath (eg, Byrd dilator sheath) to remove lead adhesions around the coil.[32] Sagi et al. demonstrated that of the 347 patients who underwent successful EV-ICD implantation across the 3 studies, 29 underwent lead removal with a primary indication for lead dislodgment.[33] Lead removal was successful in 27/29 (93.1%) cases; simple traction was used in 22/26 (84.6%), and extraction tools were used in 4/26 (15.4%). Based on the limited available data, the use of manual traction should be the initial strategy when removing the EV-ICD or S-ICD lead in patients who require explant or extraction due to infection, lead/malfunction/failure, or lead malposition.

4.2.2 Retrieval and Extraction of Leadless Pacemakers

Recommendations for Leadless Pacing Retrieval and Extraction

COR	LOE	Recommendations	References
1	B-NR	**11. In patients with a proven leadless device infection, device removal using contemporary extraction techniques is recommended.**	(21)(32)(33) (34)
1	B-NR	**12. In patients with micro or macro dislodgement of a leadless pacemaker, device removal is recommended.**	(35)(36)(37)(38)
2a	B-NR	**13. In patients with suboptimal pacing parameters early on after implantation, device removal is reasonable.**	(35)(36)(37)(38)

2a	**C-LD**	**14. In patients with a leadless pacemaker who require battery replacement or device upgrade years after implantation, a strategy of either device removal or abandonment is reasonable using a patient-centered approach and shared decision-making.**	(21)(39)(40) (41)(402)(43) (44) (45)
1	**C-EO**	**15. In patients undergoing leadless pacemaker extraction, the extraction procedure should be performed in a center with expertise in snaring and contemporary extraction techniques.**	(42)(46)

Synopsis

The widespread adoption of LP in routine clinical practice has concurrently led to an increase in scenarios where these devices need to be retrieved or extracted. Data on the safety and efficacy of techniques needed to retrieve or extract these devices is accumulating. In addition, the appropriateness of device retrieval and/or extraction will be based on clinical and patient characteristics, including indication for retrieval/extraction, patient demographics, and medical comorbidities.

Recommendation-specific supportive text

Recommendation 11: Leadless pacing infection is a rare event. Data from the 5-year follow-up Micra™ PAR showed no device-related infection requiring device removal.[23]

However, several case reports of LP infections have been described.[34-36] When proven, LP infection is an absolute indication for LP extraction.

Recommendations 12 &13: Experience with Micra™ and AVEIR™ LP early retrieval is well described. A multicenter study by Afzal et.al described successful retrieval of 40 Micra™ devices.[37] The most common indication was elevated pacing thresholds. Another multicenter study of 40 patients reported 100% success of Micra™ removal.[38] The mean age of extracted Micra™ LPs was 46 days, and no complications were encountered. Neuzil et al. and Morita et al. document successful retrieval of the Nanostim LP and AVEIR, using either the AVEIR retrieval system or the double snare technique, respectively.[39,40] Given the mounting evidence of success and safety of early retrieval of LP, extraction is recommended in the context of dislodgment and is preferable when early suboptimal pacing characteristics are encountered.

Recommendation 14: The Micra™ PAR reported nearly 1800 patients implanted and followed for 5 years. Eighty-two patients required a device modification (upgrade to CRT, battery at EOL, etc.). The majority (72 patients) were managed with device abandonment, and the remainder by device extraction.[23] No complications were observed with either approach. Evidence regarding the extraction of LPs with long dwell times continues to mount. In a study from Prague, chronically implanted Micra™ LPs were successfully extracted in 88.9% (8/9 patients), despite dwell times of 7 to 9 years[41] Additionally, several case reports have similarly described the successful extraction of chronically implanted

559 Micra™ LPs.[41-47] **Table 1** presents examples of clinical scenarios to help guide LP

560 management and decision-making.

561 **Recommendation 15:** Extraction of LPs requires a unique skill set of femoral snaring.

562 Physicians who perform these procedures should have expertise in TLE, particularly in

563 different snaring techniques, including the double snare technique.[44,48]

564 **Table 1**: Clinical scenarios and Leadless Pacemaker (LP) management options

An 86-year-old with a history of permanent atrial fibrillation and complete heart block (CHB) received a leadless pacemaker 12 years ago. The device has reached the elective replacement indicator (ERI).	- Option 1: Abandon the old LP and re-implant a new LP. - Option 2: Abandon the old LP and re-implant a TV-pacemaker (PPM) - Option 3: Extract the LP and re-implant a new LP	Option 1 or 2 would be more reasonable since this patient is 86 years old and is unlikely to require a 3rd device.
A 65-year-old with a history of mitral valve replacement 8 years ago, with post op complete heart block s/p LP with atrioventricular synchrony (AV) that reached ERI.	- Option 1: Abandon the old LP and re-implant a new LP. - Option 2: Abandon the old LP and re-implant a TV-PPM - Option 3: Extract the LP and re-implant a new LP	Options 1,2, and 3 are all reasonable. The patient is 65 years old and will likely require more than 1 device during their lifetime. The prior sternotomy is likely protective during LP extraction. Shared decision-making is an essential step in the decision-making process.
A 78-year-old with a history of heart block is s/p LP implant 7 years ago. She has developed a decline in her EF to 40%.	- Option 1: Abandon the old LP and upgrade to cardiac resynchronization therapy-pacemaker (CRT-P) or	The patient is 78 years old, and it might be reasonable to abandon the LP and implant a CRT-P/CSP.

	conduction system pacing (CSP) - Option 2: Extract the LP and upgrade to CRT-P or CSP	
A 75-year-old with a history of sinus node dysfunction status post dual chamber LP 5 years ago. His atrial LP has reached ERI, but his ventricular LP still has 6 years left on the battery.	- Option 1: Abandon the atrial LP and re-implant a new atrial LP. - Option 2: Extract the atrial LP and implant a new one. - Option 3: Extract the LP and re-implant a TV PPM.	This scenario has the potential to become a common situation in the future. The right atrium has limited real estate for multiple LP. Therefore, LP extraction might be reasonable in this situation.

References

1. Bardy GH, Smith WM, Hood MA, et al. An entirely subcutaneous implantable cardioverter-defibrillator. The New England journal of medicine 2010;363(1):36-44, doi:10.1056/NEJMoa0909545
2. Burke MC, Gold MR, Knight BP, et al. Safety and Efficacy of the Totally Subcutaneous Implantable Defibrillator: 2-Year Results From a Pooled Analysis of the IDE Study and EFFORTLESS Registry. Journal of the American College of Cardiology 2015;65(16):1605-1615, doi:10.1016/j.jacc.2015.02.047
3. Weiss R, Knight BP, Gold MR, et al. Safety and efficacy of a totally subcutaneous implantable-cardioverter defibrillator. Circulation 2013;128(9):944-53, doi:10.1161/CIRCULATIONAHA.113.003042
4. Knops RE, Pepplinkhuizen S, Delnoy P, et al. Device-related complications in subcutaneous versus transvenous ICD: a secondary analysis of the

PRAETORIAN trial. European heart journal 2022;43(47):4872-4883, doi:10.1093/eurheartj/ehac496

5. Knops RE, Olde Nordkamp LRA, Delnoy PHM, et al. Subcutaneous or Transvenous Defibrillator Therapy. The New England journal of medicine 2020;383(6):526-536, doi:10.1056/NEJMoa1915932

6. Gold MR, Lambiase PD, El-Chami MF, et al. Primary Results From the Understanding Outcomes With the S-ICD in Primary Prevention Patients With Low Ejection Fraction (UNTOUCHED) Trial. Circulation 2021;143(1):7-17, doi:10.1161/CIRCULATIONAHA.120.048728

7. Al-Khatib SM, Stevenson WG, Ackerman MJ, et al. 2017 AHA/ACC/HRS Guideline for Management of Patients With Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society. Circulation 2018;138(13):e272-e391, doi:10.1161/CIR.0000000000000549

8. Gold MR, Aasbo JD, Weiss R, et al. Infection in patients with subcutaneous implantable cardioverter-defibrillator: Results of the S-ICD Post Approval Study. Heart rhythm : the official journal of the Heart Rhythm Society 2022;19(12):1993-2001, doi:10.1016/j.hrthm.2022.07.031

9. Crozier I, Haqqani H, Kotschet E, et al. First-in-Human Chronic Implant Experience of the Substernal Extravascular Implantable Cardioverter-Defibrillator. JACC Clin Electrophysiol 2020;6(12):1525-1536, doi:10.1016/j.jacep.2020.05.029

10. Friedman P, Murgatroyd F, Boersma LVA, et al. Efficacy and Safety of an Extravascular Implantable Cardioverter-Defibrillator. The New England journal of medicine 2022;387(14):1292-1302, doi:10.1056/NEJMoa2206485
11. Crozier I, Haqqani H, Kotschet E, et al. Three-year chronic follow-up from the pilot study of a substernal extravascular implantable cardioverter-defibrillator. Europace : European pacing, arrhythmias, and cardiac electrophysiology : journal of the working groups on cardiac pacing, arrhythmias, and cardiac cellular electrophysiology of the European Society of Cardiology 2023;25(10), doi:10.1093/europace/euad301
12. Friedman P, Murgatroyd F, Boersma LVA, et al. Performance and Safety of the Extravascular Implantable Cardioverter Defibrillator Through Long-Term Follow-Up: Final Results From the Pivotal Study. Circulation 2025;151(4):322-332, doi:10.1161/CIRCULATIONAHA.124.071795
13. Theuns D, Brouwer TF, Jones PW, et al. Prospective blinded evaluation of a novel sensing methodology designed to reduce inappropriate shocks by the subcutaneous implantable cardioverter-defibrillator. Heart rhythm : the official journal of the Heart Rhythm Society 2018;15(10):1515-1522, doi:10.1016/j.hrthm.2018.05.011
14. Gold MR, Weiss R, Theuns DA, et al. Use of a discrimination algorithm to reduce inappropriate shocks with a subcutaneous implantable cardioverter-defibrillator. Heart rhythm : the official journal of the Heart Rhythm Society 2014;11(8):1352-8, doi:10.1016/j.hrthm.2014.04.012

15. Atallah J, Erickson CC, Cecchin F, et al. Multi-institutional study of implantable defibrillator lead performance in children and young adults: results of the Pediatric Lead Extractability and Survival Evaluation (PLEASE) study. Circulation 2013;127(24):2393-402, doi:10.1161/CIRCULATIONAHA.112.001120
16. El-Chami MF, Sayegh MN, Patel A, et al. Outcomes of lead extraction in young adults. Heart rhythm : the official journal of the Heart Rhythm Society 2017;14(4):537-540, doi:10.1016/j.hrthm.2017.01.030
17. Carretta DM, Tomasi L, Tondo C, et al. Leadless Micra pacemakers: Estimating long-term longevity. A real word data analysis. International journal of cardiology 2025;426(133062, doi:10.1016/j.ijcard.2025.133062
18. Sheldon T EK, Fagan D. Device longevity and AV synchrony algorithm modeling of a leadless pacemaker family: A virtual patient analysis. Medtronic Data on File 2023;
19. Reddy VY, Exner DV, Doshi R, et al. 1-Year Outcomes of a Leadless Ventricular Pacemaker: The LEADLESS II (Phase 2) Trial. JACC Clin Electrophysiol 2023;9(7 Pt 2):1187-1189, doi:10.1016/j.jacep.2023.01.031
20. El-Chami MF, Al-Samadi F, Clementy N, et al. Updated performance of the Micra transcatheter pacemaker in the real-world setting: A comparison to the investigational study and a transvenous historical control. Heart rhythm : the official journal of the Heart Rhythm Society 2018;15(12):1800-1807, doi:10.1016/j.hrthm.2018.08.005
21. Piccini JP, El-Chami M, Wherry K, et al. Contemporaneous Comparison of Outcomes Among Patients Implanted With a Leadless vs Transvenous Single-

Chamber Ventricular Pacemaker. JAMA Cardiol 2021;6(10):1187-1195, doi:10.1001/jamacardio.2021.2621

22. El-Chami MF, Bockstedt L, Longacre C, et al. Leadless vs. transvenous single-chamber ventricular pacing in the Micra CED study: 2-year follow-up. European heart journal 2022;43(12):1207-1215, doi:10.1093/eurheartj/ehab767

23. El-Chami MF, Garweg C, Clementy N, et al. Leadless pacemakers at 5-year follow-up: the Micra transcatheter pacing system post-approval registry. European heart journal 2024;45(14):1241-1251, doi:10.1093/eurheartj/ehae101

24. El-Chami MF, Higuera L, Longacre C, et al. Two-year outcomes of Micra AV leadless pacemakers in the Micra AV CED study. Europace : European pacing, arrhythmias, and cardiac electrophysiology : journal of the working groups on cardiac pacing, arrhythmias, and cardiac cellular electrophysiology of the European Society of Cardiology 2024;26(11), doi:10.1093/europace/euae273

25. Bicong L, Allen JC, Arps K, et al. Leadless pacemaker implantation after lead extraction for cardiac implanted electronic device infection. Journal of cardiovascular electrophysiology 2022;33(3):464-470, doi:10.1111/jce.15363

26. Beccarino NJ, Choi EY, Liu B, et al. Concomitant leadless pacing in pacemaker-dependent patients undergoing transvenous lead extraction for active infection: Mid-term follow-up. Heart rhythm : the official journal of the Heart Rhythm Society 2023;20(6):853-860, doi:10.1016/j.hrthm.2023.02.003

27. El-Chami MF, Clementy N, Garweg C, et al. Leadless Pacemaker Implantation in Hemodialysis Patients: Experience With the Micra Transcatheter Pacemaker. JACC Clin Electrophysiol 2019;5(2):162-170, doi:10.1016/j.jacep.2018.12.008

28. Panico A, Flahault A, Guillemin F, et al. Improved outcomes with leadless vs. single-chamber transvenous pacemaker in haemodialysis patients. Europace : European pacing, arrhythmias, and cardiac electrophysiology : journal of the working groups on cardiac pacing, arrhythmias, and cardiac cellular electrophysiology of the European Society of Cardiology 2024;26(11), doi:10.1093/europace/euae257

29. Kutarski A, Jachec W, Tulecki L, et al. Disparities in transvenous lead extraction in young adults. Sci Rep 2022;12(1):9601, doi:10.1038/s41598-022-13769-y

30. Reynolds D, Duray GZ, Omar R, et al. A Leadless Intracardiac Transcatheter Pacing System. The New England journal of medicine 2016;374(6):533-41, doi:10.1056/NEJMoa1511643

31. Garweg C, Chinitz JS, Marijon E, et al. A leadless ventricular pacemaker providing atrioventricular synchronous pacing in the real-world setting: 12-Month results from the Micra AV post-approval registry. Heart rhythm : the official journal of the Heart Rhythm Society 2024;21(10):1939-1947, doi:10.1016/j.hrthm.2024.06.008

32. De Filippo P, Migliore F, Palmisano P, et al. Procedure, management, and outcome of subcutaneous implantable cardioverter-defibrillator extraction in clinical practice. Europace : European pacing, arrhythmias, and cardiac electrophysiology : journal of the working groups on cardiac pacing, arrhythmias, and cardiac cellular electrophysiology of the European Society of Cardiology 2023;25(6), doi:10.1093/europace/euad158

33. Sagi V, Murgatroyd F, Boersma LVA, et al. Comprehensive analysis of substernal lead removal: experience from EV ICD Pilot, Pivotal, and Continued Access Studies. Europace : European pacing, arrhythmias, and cardiac electrophysiology : journal of the working groups on cardiac pacing, arrhythmias, and cardiac cellular electrophysiology of the European Society of Cardiology 2024;26(9), doi:10.1093/europace/euae225
34. Bernardes-Souza B, Mori S, Hingorany S, et al. Late-Onset Infection in a Leadless Pacemaker. JACC Case Rep 2022;4(24):101645, doi:10.1016/j.jaccas.2022.09.015
35. Ellison K, Hesselson A, Ayoub K, et al. Retrieval of an infected leadless pacemaker. HeartRhythm Case Rep 2020;6(11):863-866, doi:10.1016/j.hrcr.2020.08.022
36. Koay A, Khelae S, Wei KK, et al. Treating an infected transcatheter pacemaker system via percutaneous extraction. HeartRhythm Case Rep 2016;2(4):360-362, doi:10.1016/j.hrcr.2016.04.006
37. Afzal MR, Daoud EG, Cunnane R, et al. Techniques for successful early retrieval of the Micra transcatheter pacing system: A worldwide experience. Heart rhythm : the official journal of the Heart Rhythm Society 2018;15(6):841-846, doi:10.1016/j.hrthm.2018.02.008
38. Dar T, Akella K, Murtaza G, et al. Comparison of the safety and efficacy of Nanostim and Micra transcatheter leadless pacemaker (LP) extractions: a multicenter experience. Journal of interventional cardiac electrophysiology : an

international journal of arrhythmias and pacing 2020;57(1):133-140, doi:10.1007/s10840-019-00684-y

39. Neuzil P, Petru J, Chovanec M, et al. Retrieval and replacement of a helix-fixation leadless pacemaker at 9 years post-implant. HeartRhythm Case Rep 2023;9(4):258-262, doi:10.1016/j.hrcr.2023.01.012

40. Morita J, Kondo Y, Kasai Y, et al. Retrieval of the Aveir™ leadless pacemaker with the double-snare technique. Eur Heart J-Case Rep 2024;8(6), doi:ARTN ytae267 10.1093/ehjcr/ytae267

41. Funasako M, Hala P, Janotka M, et al. Transcatheter non-acute retrieval of the tine-based leadless ventricular pacemaker. Europace : European pacing, arrhythmias, and cardiac electrophysiology : journal of the working groups on cardiac pacing, arrhythmias, and cardiac cellular electrophysiology of the European Society of Cardiology 2024;26(10), doi:10.1093/europace/euae256

42. Callahan TDt, Wilkoff BL. Extraction of a 5-year-old leadless pacemaker using a competing manufacturer's removal tool. HeartRhythm Case Rep 2023;9(7):441-444, doi:10.1016/j.hrcr.2023.04.004

43. El-Chami MF, Merchant FM. Femoral extraction of transvenous leads and leadless pacemakers-A review of the data, tools, and procedural steps. Pacing and clinical electrophysiology : PACE 2019;42(9):1248-1252, doi:10.1111/pace.13766

44. Goyal R, Markowitz SM, Ip JE. Double-Snare Technique for Capturing a Wandering Leadless Pacemaker. JACC Clin Electrophysiol 2019;5(7):872-873, doi:10.1016/j.jacep.2019.02.010

45. Kiani S, Merchant FM, El-Chami MF. Extraction of a 4-year-old leadless pacemaker with a tine-based fixation. HeartRhythm Case Rep 2019;5(8):424-425, doi:10.1016/j.hrcr.2019.05.002

46. Minami K, Shtembari J, Petru J, et al. Successful Retrieval of a 4-Year-Old Micra Transcatheter Pacemaker System in a Patient With Leadless Biventricular Pacing Therapy. JACC Case Rep 2020;2(14):2249-2252, doi:10.1016/j.jaccas.2020.09.019

47. Neuzil P, Petru J, Sediva L, et al. Retrieval and replacement feasibility of 7-year-old implanted leadless pacemaker with tines fixation. HeartRhythm Case Rep 2024;10(1):2-5, doi:10.1016/j.hrcr.2023.10.007

48. Ip JE. Double-snare technique for helix-fixation leadless cardiac pacemaker retrieval. Heart rhythm: the official journal of the Heart Rhythm Society 2024;21(5):677-678, doi:10.1016/j.hrthm.2024.01.019

Section 5. Diagnostic Approach to Suspected Lead Failure

Introduction

Pacemaker lead failure can occur due to conductor fractures or insulation breaches, causing either failure to capture or inappropriate inhibition of pacing due to oversensing of electrical noise. Defibrillation high-voltage lead failure can result in catastrophic failure to shock or ineffective shock, inappropriate shocks due to oversensing or undersensing, as well as failure to detect tachyarrhythmias and/or successfully defibrillate due to conductor fracture.

Section 5 Recommendation Table

	Recommendations for Remote Monitoring		
COR	**LOE**	**Recommendations**	**References**
1	**B-NR**	**1. Remote Monitoring with Lead Monitoring Algorithms is recommended for all patients with CIED.**	31,32,33,34,35,36
2a	**B-NR**	**2. For patients with abnormal findings on remote monitoring, it is reasonable to have an in-person clinic evaluation.**	

Synopsis

Pacemaker and defibrillator lead failure can present in various ways, from asymptomatic detection on remote monitoring or in-person device interrogation to symptoms due to

abnormal performance of the CIED system to failure to pace or defibrillate. Understanding the basic mechanisms of conductor fractures or insulation breaches and the value of embedded software algorithms and remote monitors can mitigate the potential clinical consequences of lead failure.

Recommendation-specific Supportive Text

Recommendation 1: The availability of remote monitoring capabilities for most pacemakers and defibrillators allows for easy access to care in addition to early warning of potential lead abnormalities. Remote monitoring can provide reassurance and correlate rhythm and device functionality with perceived symptoms or arrhythmias. It can also offer more frequent CIED electrical parameter assessments between in-person clinical visits.

Recommendation 2: The early warning value of remote monitoring should be followed up with an in-person clinic visit for device evaluation. Currently, CIED parameters cannot be reprogrammed remotely, and, moreover, additional assessments can be performed in person to further determine the etiology of remote monitor-detected abnormalities.

5.1. Clinical Presentation

The lead failure modes are pace-sense malfunction and shock component malfunction. In pace-sense circuits, insulation breach typically presents as oversensing of rapid, nonphysiologic signals, resulting in inappropriate shocks or pacing inhibition, whereas conductor fracture can lead to failure to capture.[1] In older generation ICDs, the most common presentation of pace-sense lead fracture was inappropriate shocks.[2,3] Due to improvements in device diagnostics that incorporate the detection of short intervals and changes in impedance and the more widespread use of remote monitoring, an increasing

number of patients are now presenting with pre-symptomatic lead alerts, enabling early recognition of lead failure before the onset of adverse clinical events.[4] Despite these advances, patients can still present with multiple inappropriate shocks, as the fracture may only become apparent after the first shock therapy. Fortunately, high-voltage coil conductor failure is quite rare, but can result in failure to deliver an appropriate (potentially lifesaving) shock when needed.

Shock component malfunction typically presents with shock impedance change, less commonly as failed defibrillation or in association with coexisting pace-sense failures. Insulation failure with a shorting of the high-voltage circuit can result in catastrophic failure of the defibrillator pulse generator. The introduction of remote monitoring and enhanced lead diagnostics has fortunately improved the early recognition of both pace-sense lead failure and shock-component malfunction.

Family members and health care providers who provide initial care for patients with CIEDs should understand the urgent use of magnets for suspending therapy. Placing a magnet over a pacemaker will inhibit the sensing part, leading to asynchronous pacing (AOO, VOO, DOO) while the magnet is immediately present over the device. Magnet application over an ICD will inhibit shock therapies without disabling sensing or altering the pacing mode. Once the magnet is removed from the field, the pacemaker or ICD will revert to its prior non-magnet programmed parameters and therapies.

Several studies have aimed to determine the prevalence of lead failures, including the impact of electrical abnormalities on mortality. In one large prospective observational study, all consecutive adult-aged patients undergoing CIED implantation were included

over a 3-year period. During follow-up (median 57 months), they observed 283 complications in 263 of 2811 consecutive patients (71 ± 14 years of age, 67% male). Early complications (≤30 days) were associated with significantly lower cumulative survival from cardiovascular death in comparison with late complications and with freedom from complications. On multivariate analysis, early complication, pneumothorax, and pocket hematoma were significantly associated with a higher risk of all-cause death, while device infection remained the only complication significantly associated with a higher risk of cardiovascular death.[5] In a large, retrospective chart-review study over 8 years, patients were identified with lead failure and segregated by patient clinical characteristics and device manufacturer. There were 2996 unique patients (35% female) included with 4600 leads (57% Abbott, 43% Medtronic). Electrical lead abnormalities were observed in 135 (3%) leads over 4.5-year follow-up, including 124 (92%) Abbott and 10 (7%) Medtronic leads (hazard ratio 9.25, $P < .001$). Risks associated including smaller lead French size, atrial location, and Abbott leads. Lead revision was required in 28% of cases. Patients with lead abnormalities had 38% more in-clinic visits per patient year of follow-up compared with those without ($P < .001$).[6] To assess the clinical and radiographic factors associated with lead failure, subjects were compared with lead failure within 10 years of implantation with an implant-year-matched group without lead failure. Among the failure group, the meantime from implantation to device lead failure was 4.7 ± 2.9 years. Older age at implantation was associated with a lower likelihood of lead failure (Odds Ratio (OR) = 0.28 (75 vs 42 years old), 95% CI 0.12-0.63, $P = .002$). A larger smallest loop diameter on the chest radiograph was also associated with a lower likelihood of lead failure (OR = 0.51 (31

vs 14 mm), 95% CI 0.27-0.97, P = .04). CIED type (defibrillator vs pacemaker) was not significantly associated with lead failure. Among lead-specific parameters, defibrillation lead vs pace-sense lead was associated with lead failure (OR = 3.91, 95% CI 1.95-7.81, P < .001). Younger age, defibrillation leads, and small lead loops are associated with lead failure in CIEDs. Techniques to avoid tight loops in the pocket could potentially reduce the risk of lead failure and bear important implications for the implanting physician.[7] The Tendril family of pacing leads (Abbott) has been shown in several studies to have an increased risk of insulation breach leading to lead failure. [8] In a single-center observational study following 1111 leads in 700 patients over an average of 54 months, the Tendril leads had significantly higher failure rates (HR 9.6), manifested by low impedances and electrical noise. [9] Similarly, a single-center study of 408 Tendril 2088 leads implanted in 335 patients revealed a failure rate of 6.2% at 4 years follow-up, significantly higher than published product performance reports.[10]

A propensity-matched survival analysis of the ICD Registry was performed to evaluate 4 ICD leads in patients aged ≥18 years who underwent an implant of an ICD between April 2011 and March 2016. Monitoring safety continued for up to 5 years. A difference was defined as twice (or more) the lead failure rate observed in the propensity-matched comparator patients. Among 374,132 patients who received a new ICD implant, no safety alerts were triggered for the primary safety endpoint of lead failure for any of the high-energy leads studied. Estimated rates of freedom from lead failure at 5 years ranged from 97.7% to 98.9% for the 4 high-energy leads.[11]

A single-connector defibrillator lead (DF4) is more streamlined by removing the separate yoke joining the 2 defibrillation conductors into an inline format, reducing the bulk and complexity at the pin end. The chronic performance of DF4 leads has been evaluated and demonstrates relatively stable reliability over 3-5 years dwell time and 96-98% lead survival at follow-up.[12,13]

5.2. Special Populations: Children and Patients with Congenital Heart Disease

Implanting a device in children or in young adults with congenital heart disease has special considerations, including patient size, longitudinal growth, level of physical activity, and the need for potentially decades-long requirement for pacing, defibrillation, and lead management. The Pediatric Lead Extractability and Survival Evaluation (PLEASE) study was a 24-center international registry of 878 pediatric and congenital heart disease ICD patients (44% with congenital heart disease).[14] The mean age at implantation was 18.6±9.8 years. Of 965 total leads, 54% were thin (≤7F), of which 57% were Fidelis, and 23% were coated with expanded polytetrafluoroethylene. There were 139 ICD lead failures (14%) in 132 patients (15%) at a mean lead age of 2.0±1.4 years, causing shocks in 53 patients (40%). Independent predictors of lead failure included younger implantation age and Fidelis leads. Actuarial analysis showed an incremental risk of lead failure with younger age at implantation: <8 years compared with >18 years (P=0.01). Extraction was performed on 143 leads (80% thin, 7% expanded polytetrafluoroethylene coated), with lead age as the only independent predictor for advanced extraction techniques. There were 6 major extraction complications (4%) but no procedural mortality. This study demonstrates that ICD leads in children and congenital heart disease patients have an age-related

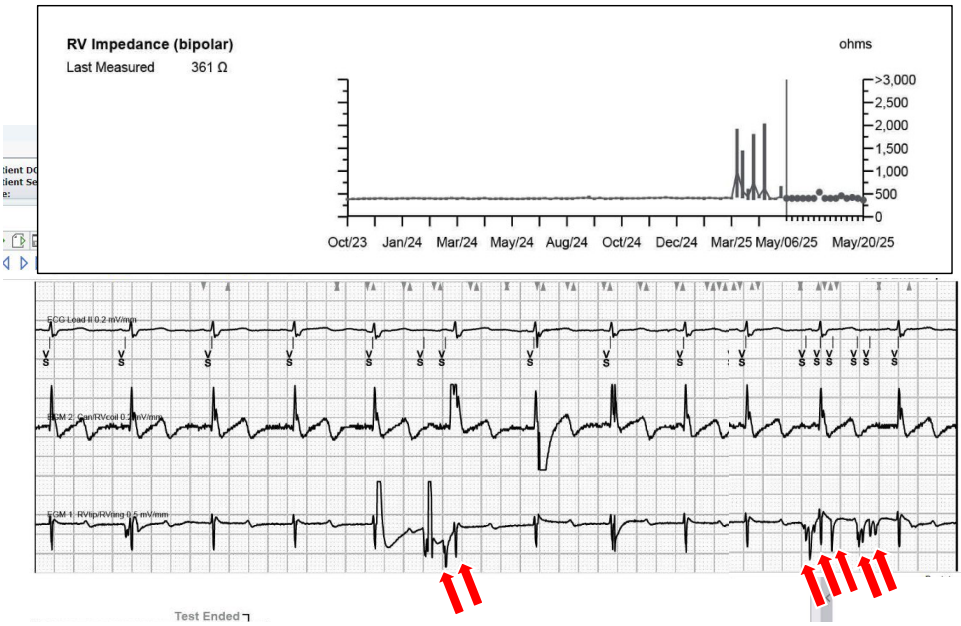
suboptimal performance, further compounded by a high failure rate of thin ICD leads.[14] Lead failure may be higher in younger patients, which is likely multifactorial including increased levels of physical activity and continued linear growth after lead implantation. [15] It is critically important to consider the implications of implanting a device in young patients who will have a lifetime need for cardiac rhythm management. Children and patients with congenital heart disease may have life expectancy of 50-100 years after their first CIED implantation, therefore it is imperative to preserve venous patency and maintain vascular access for future device needs. [16,17] Epicardial systems may be preferable in the smallest patients and those with intracardiac shunts or other congenital abnormalities that preclude transvenous access to the heart. Novel pediatric epicardial devices are currently under clinical investigation. [18] Lead extraction has higher relative risk in young patients due in part to greater fibrosis and lower volumes for extractors and centers. [19] Cardiac surgical backup is mandatory for pediatric lead extractions. The role of leadless pacemakers and non-transvenous defibrillator systems (S-ICD, EV-ICD, pericardial and hybrid approaches) may reduce the reliance on transvenous endocardial systems in the young. [20]

5.3. Device Electrograms in Pace-Sense Failures

Device electrogram (EGM) analysis is important in the diagnostic approach to suspected lead failure, especially pace/sense circuit failures, because oversensing (electrical noise) is the most common observation in this failure mode. It is important to distinguish lead failure–related oversensing from other sources, such as electromagnetic interference, myopotentials, P- or T-wave oversensing, R-wave double counting, and lead-lead interactions. Cyclical oversensing, which refers to sensing non-QRS components with

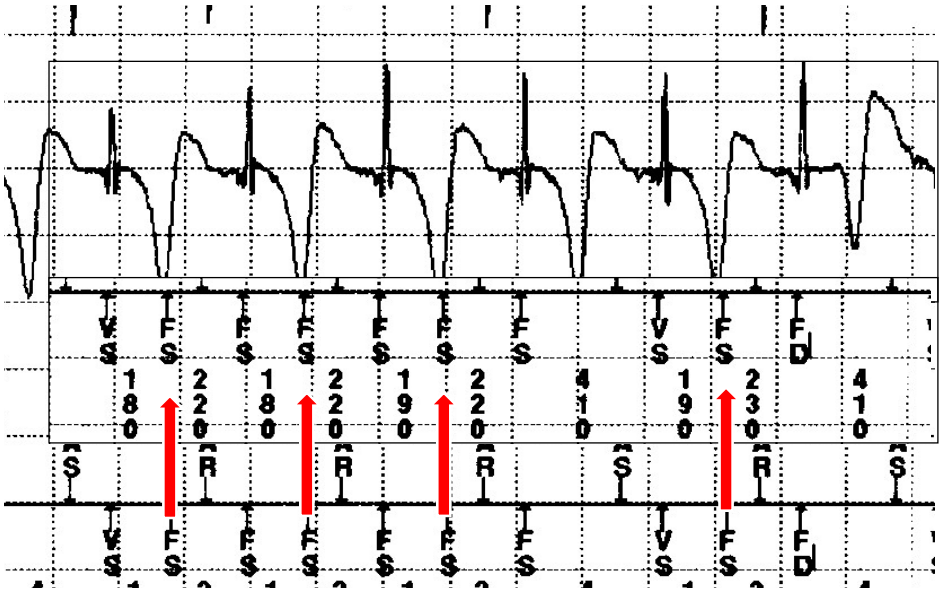
every cardiac cycle, typically indicates an intracardiac source of over sensed signals. **Figure 1A** illustrates an ICD recorded electrogram from a patient who had an ICD lead fracture with nonphysiologic cyclical oversensing, and **Figure 1B** is an example of physiologic T-wave oversensing. The morphology and pattern of typical nonphysiological EGMs in conductor fractures have been validated by returned product analysis of explanted leads.[21] The typical characteristics of conductor-fracture EGMs are signals that are (1) intermittent with a high dominant frequency; (2) highly variable (amplitude, morphology, frequency); and (3) not recorded on the high-voltage or shock channel. The EGMs are typically noncyclical, exhibit extremely short nonphysiological R-R intervals (<160 ms), are unlikely to represent ventricular depolarization, and might saturate the sensing amplifier, resulting in a truncated signal on the sensing channel. Atypical EGM patterns can occur in pace-sense conductor fractures, including oversensing that is precipitated by pacing and cyclical oversensing patterns.[21,22] Lead-header connection problems can also present with similar EGM patterns and are difficult to distinguish from conductor fractures. However, connection problems are most often temporally associated with an invasive CIED procedure such as implantation or generator replacement. Data regarding EGM characteristics in insulation breaches of pace-sense circuits are limited to observational clinical series and returned product analysis validation. In contrast to conductor fractures, insulation failures do not typically generate abnormal signals but result in sensing of physiological signals from surrounding structures, which are typically generated from the interaction of conductors. As such, EGM patterns in insulation breaches vary depending on the signal source.[23]

Figure 1A



917

Figure 1B



918

919 **Figure 1A** illustrates a 41-year-old who received an ICD for long-QT syndrome. 10 years
920 later, the remote monitor shows intermittent elevated lead impedance and inappropriate
921 noise detection. The ventricular sensing is nonphysiologic, with features of high-frequency,
922 short (150ms) interval oscillation, consistent with oversensing the noise due to lead
923 fracture. Red arrows point out the noise detection. **Figure 1B** shows a patient who develops

T-wave oversensing, double-counting R wave and T wave, resulting in ventricular fibrillation detection as the rate meets the VF detection. This is consistent with inappropriate physiologic T-wave oversensing.

5.4. Impedance and Impedance Trends in Lead Failure

CIEDs periodically measure the entire circuit's resistance to direct current, which applies Ohm's law (VxR/I) and reflects the electrical circuit integrity. The pace-sense conductors' resistance to current typically contributes less than 20% of the entire circuit's resistance; therefore, impedance assessment and monitoring lacks sensitivity in pace-sense failures. In fact, gradual impedance abnormalities occur in only a minority of pace-sense lead failures before the abnormalities are identified by oversensing diagnostics or inappropriate detection of ventricular tachycardia (VT) or ventricular fibrillation (VF) – often leading to inappropriate shock in ICD systems. In contrast, the observation of abrupt, relative changes in impedance trends is more specific and is about as sensitive as an out-of-range impedance. A single abrupt change could, however, be spurious, and a gradual rise in impedance without oversensing typically reflects increased resistance to current at the lead-myocardium interface, which by itself does not require lead revision in the absence of sensing and pacing abnormalities. A pacing impedance of less than 200 ohms in a bipolar configuration or abrupt significant decrease in lead impedance can indicate an insulation breach of the pace-sense component. Abrupt increase in pacing lead impedance, especially when greater than 2000 ohms, suggests impending conductor failure, and >3000 ohms impedance indicates pace-sense conductor fracture. Impedance measurements remain the primary diagnostic tool for high-voltage conductors. There are numerous

considerations for the low-voltage, painless measurement of shock circuit impedance, including (1) typical low impedances for high-voltage cables and shock electrodes; (2) tissue resistance, which is inversely proportional to voltage, thereby affecting the estimate of high-voltage impedance based on painless measurement; and (3) the greater effect of respiratory variability with low-voltage measurements. An abrupt increase in shock impedance or a shock impedance value greater than 120 ohms likely indicates shock conductor fracture, based on the returned product analysis.[24] Elevated shock-impedance values could also reflect a faulty connection of shock components. High-voltage insulation breaches result in low impedance values, but shock impedance trends may be variable, and no threshold values have been defined.

5.5. Device Diagnostics to Mitigate Adverse Consequences of Pace-Sense Failure

5.5.1. Counts of Extremely Short R-R Intervals

Intervals near the ventricular blanking period are unlikely to represent successive ventricular activation, even in VF. Some devices keep track of nonphysiological sensed intervals in place of lead integrity. The utility of this feature has been studied systematically with the Medtronic Sensing Integrity Count, which stores the count of R-R intervals shorter than 130 ms. The most common cause of isolated, short-sensed R-R intervals is benign over sensed physiological signals or detection of environmental electromagnetic interference. A rapidly increasing sensing integrity count is a sensitive early indicator of conductor fracture, which in isolation has low specificity. It has been noted that elevated sensing integrity count values are more common with intact integrated bipolar leads than with intact dedicated bipolar leads.[25] Increasing episodes of non-sustained VT, particularly

if characterized by rapid rates, should also arouse suspicion for possible lead failure and careful review of intracardiac EGMs is essential to differentiate true non-sustained VT from electrical noise oversensing.

5.5.2. Algorithms That Incorporate Sensing and Impedance Monitoring

Lead Integrity Alert (Medtronic)

This was the first lead-alert algorithm to incorporate oversensing metrics and is the most extensively studied. The algorithm combines a rapidly increasing sensing integrity count with repetitive rapid oversensing and abrupt impedance changes.[26] Monitoring both rapid oversensing and impedance trends provides earlier warning of lead failure than a fixed impedance threshold. This algorithm has been validated by returned product analysis, and multiple studies have assessed its clinical utility and shown relatively low false positive rates.

Prospective and retrospective observational data indicate that lead integrity alerts (LIA) improve early detection of the now-recalled thin defibrillator (Fidelis) lead fractures and reduce inappropriate shocks compared with monitoring impedance alone.[26,27]

Retrospective, observational, clinical studies have found that this algorithm identifies failures in defibrillation leads from various manufacturers.[28]

Latitude Lead Check (Boston Scientific)

This algorithm is qualitatively similar to Medtronic's LIA and alerts for either rapid, repetitive oversensing or out-of-range pace-sense impedance. A potential advantage of this algorithm is that it is incorporated within the remote monitoring system network, not the

ICD; thus, it can be regularly updated for all patients. To date, no peer-reviewed publications have assessed this algorithm's clinical performance.[1,29,30]

5.5.3. Algorithms That Compare Sensing and Shock EGMs

Two currently employed algorithms—Medtronic's Lead Noise Algorithm (LNA) and Abbott's Secure- Sense—identify over sensed, non-physiological, pace-sense signals as those that do not correlate temporally with EGMs on the shock channel. There are differences in the design of LNA and SecureSense, but both withhold shocks if sufficient evidence of oversensing occurs.[31,32] Algorithm failures can be caused by a false-negative assessment, resulting in failure to withhold inappropriate therapies for true lead failure or a false-positive assessment with the algorithm being triggered by conditions other than lead failure. In the latter, failure to deliver appropriate therapy for life-threatening arrhythmia is of greatest concern. Neither algorithm identifies right ventricular (RV) coil fractures in integrated bipolar leads or simultaneous nonphysiological signals on sensing and shock channels, such as those caused by cable-coil abrasions. The differences in design of these algorithms might account for the variability in algorithm failure modes. In bench testing, SecureSense identified simulated lead failure signals (97% of sustained episodes, 90% of nonsustained episodes) and did not withhold shocks from 100% of induced VF episodes.[32] These sensing algorithms have been tested in small series, with rare delay in delivering shock therapies, and even rarer withholding of ICD shocks.[33,34]

5.6. Role of Remote Monitoring

Devices with wireless telemetry automatically detect and transmit stored data, including lead alerts. Observational studies support the use of remote monitoring to facilitate

diagnosis of lead failure and data suggest that wireless remote monitoring, when combined with LIA, reduces inappropriate shocks more than LIA alone.[35] The role and importance of remote monitoring in the diagnosis of lead failure and monitoring at-risk leads have been endorsed by consensus statements from the HRS and the Canadian Heart Rhythm Society.[36,37] The value of routine remote monitoring has been evaluated and shown to be effective at identifying lead failures earlier than in-office visits, although compliance with regular use may be impacted by external factors such as patient age and location. However, a substantial portion of remote monitoring warnings and abnormalities may not represent true lead failure necessitating intervention. [38] When patients go on vacation, they often leave their bedside transmitters at home and thereby lose remote monitoring capabilities.[39] A recent survey from the Pediatric and Congenital Electrophysiology Society (PACES) showed high variation in compliance with remote monitoring in young patients. Fifteen of 22 reporting centers (68%) reported that >80% of their CIED patients are enrolled in RM and only two centers reported <50% participation. The number of centers achieving high compliance differed by device type: 36% for pacemakers, 50% for ICDs, and 55% for Implantable Cardiac Monitors. All centers reported at least 50% adherence to recommended follow-up for PM and ICD.[40] A prospective study combining remote monitoring with or without lead noise alerts to mitigate adverse events was performed using 5 different manufacturers' alert algorithms. During follow-up of 4,457 patients, 64 lead failures occurred. Sixty-one (95%) of the diagnoses were made before any clinical complication occurred. Inappropriate shocks were delivered in only one patient of each group (3%), with an annual rate of 0.04%. All high voltage conductor failures were identified

remotely by a dedicated impedance alert in 10 patients. Pace-sense component failures were correctly identified by a dedicated alert in 77% (17 of 22) of the remote monitor-lead noise group versus 25% (8 of 32) of the remote monitor only group (P = <0.01). The absence of a lead noise alert was associated with a 16-fold increase in the likelihood of initiating either a shock or ATP (OR: 16.0, 95% CI 1.8–143.3; P = 0.01).[4,41]

Summary

Pacemakers and defibrillators lead failure can present in a variety of clinical scenarios, ranging from pre-symptomatic detection on remote monitoring or in-person device interrogation, to symptomatic abnormal performance of the CIED system, to catastrophic failure to pace or defibrillate. Understanding the basic mechanisms of conductor fractures or insulation breaches and the value of embedded software algorithms and remote monitors can mitigate the potential clinical consequences of lead failure.

References

1. Swerdlow CD, Ploux S, Poole JE, Nair SG, Himes A, Ellenbogen KA. Interpreting device diagnostics for lead failure. Heart Rhythm. 2022;19:154-164. PMID: 34597770

2. Hauser RG, Kallinen AK, Almquist AK, Gornick CC, Katsiyiannis WT. Early failure of a small-diameter high-voltage implantable cardioverter-defibrillator lead. Heart Rhythm 2007;4:892–896.

3. Ellenbogen KA, Wood MA, Shepard RK, Clemo HF, Vaughn T, Holloman K, Dow M, Leffler J, Abeyratne A, Verness D. Detection and management of implantable cardioverter defibrillator lead failure: incidence and clinical implications. J Am Coll Cardiol 2003;41:73–80.

4. Ploux S, Swerdlow CD, Strik M, Welte N, Klotz N, Ritter P, Haïssaguerre M, Bordachar P. Towards eradication of inappropriate therapies for ICD lead failure by combining comprehensive remote monitoring and lead noise alerts. J Cardiovasc Electrophysiol. 2018;29:1125-1134. PMID: 29858871

5. Palmisano P, Guerra F, Dell'Era G, Ammendola E, Ziacchi M, Laffi M, Troiano F, Prenna E, Russo V, Angeletti A, Guido A, Occhetta E, Nigro G, Biffi M, Gaggioli G, Capucci A, Accogli M; Italian Association of Arrhythmology and Cardiac Pacing (AIAC). Impact on all-cause and cardiovascular mortality of cardiac implantable electronic device complications: Results from the POINTED registry. JACC Clin Electrophysiol. 2020;6:382-392. PMID: 32327071

6. Roberts H, Matheson K, Sapp J, Gardner M, Gray C, AbdelWahab A, Lee D, MacIntyre C, Parkash R. Prevalence and management of electrical lead abnormalities in cardiac

implantable electronic device leads. Heart Rhythm O2. 2023;4:417-426. PMID: 37520017

7. Kim EJ, Davogustto G, Huang S, Crossley GH 3rd, Montgomery JA. Clinical and radiographic predictors of cardiovascular implantable electronic device lead failure at the time of initial implantation. J Arrhythm. 2021;37:1086-1092. PMID: 34386136

8. El-Chami MF, Rao B, Shah AD, Wood C, Sayegh M, Zakka P, Ginn K, Pallotta L, Evans B, Hoskins MH, Delurgio D, Lloyd M, Langberg J, Leon AR, Merchant FM. Long-term performance of a pacing lead family: A single-center experience. Heart Rhythm. 2019;16:572-578. PMID: 30366161

9. Adelstein E, Zhang L, Nazeer H, Loka A, Steckman D. Increased incidence of electrical abnormalities in a pacemaker lead family. J Cardiovasc Electrophysiol. 2021;32:1111-1121.

10. Segan L, Samuel R, Lim M, Ridley D, Sen J, Perrin M. Incidence of premature lead failure in 2088 TendrilTM pacing leads. Heart Lung Circ. 2021;30:986-995. PMID: 33288446

11. Resnic FS, Majithia A, Dhruva SS, Ssemaganda H, Robbins S, Marinac-Dabic D, Hewitt K, Ohno-Machado L, Reynolds MR, Matheny ME. Active Surveillance of the Implantable Cardioverter-Defibrillator Registry for Defibrillator Lead Failures. Circ Cardiovasc Qual Outcomes. 2020;13:e006105. PMID: 32283971

12. Sarrazin JF, Philippon F, Sellier R, André P, O'Hara G, Molin F, Nault I, Blier L, Champagne J. Clinical performance of different DF-4 implantable cardioverter

defibrillator leads. Pacing Clin Electrophysiol. 2018. doi: 10.1111/pace.13400. PMID: 29856075

13. Ibrahim R, Al-Gibbawi M, Mekary W, Bhatia NK, Kiani S, Westerman SB, Shah AD, Lloyd MS, Leal M, De Lurgio DB, Patel AM, Tompkins C, Leon AR, Merchant FM, El-Chami MF. Long-term performance of single-connector (DF4) implantable defibrillator leads. Europace. 2023;25:euad347. PMID: 38000900

14. Atallah J, Erickson CC, Cecchin F, Dubin AM, Law IH, Cohen MI, LaPage MJ, Cannon BC, Chun T, Freedenberg V, Gierdalski M, Berul CI on behalf of PACES. A multi-institutional study of implantable defibrillator lead performance in children and young adults: Results of the pediatric lead extractability and survival evaluation (PLEASE) study. Circulation 2013;127:2393-2402.

15. Fortescue EB, Berul CI, Cecchin F, Walsh EP, Triedman JK, Alexander ME. Patient, procedural, and hardware factors associated with pacemaker lead failures in pediatrics and congenital heart disease. Heart Rhythm. 2004;1:150-9. PMID: 15851146

16. Hong J, Choi NH, Ramwell CB, Lewis AR, Barber JR, Sherwin ED, Berul CI, Moak JP. Pacing and defibrillator lead longevity extends beyond 15-20 years after implantation in pediatric and congenital heart disease patients. JACC:EP 2025;11:132-142.

17. Shah MJ, Silka MJ, Avari J, Balaji S, Beach C, Benjamin M, Berul CI, Cannon B, Cecchin F, et al. 2021 PACES Expert consensus statement on the indications and management of cardiovascular implantable electronic devices in pediatric patients. Simultaneously published: Heart Rhythm 2021;18:1888-1924; Cardiology in the Young

2021;3:1738-1769; JACC Electrophysiology 2021;7:1437-1473; Indian Pacing Electrophysiol J. 2021:21;367-93.

18. Berul CI, Haack L, Sherwin ED, Whitehill RD, Nash D, Dasgupta S, Johnsrude C, Chandler SF, LeGras MD, Clark BC, Jimenez E, Giacone HM, Ceresnak S, Goya G, Jackson LB, Pham TD, Valdes SO, Rhee E, Brucker R, Olson S, Whitman T. Multicenter results of a novel pediatric pacemaker in neonates and infants. Circulation: EP 2025;18: e013436

19. Cooper J, Stephenson, EA, Berul CI, Walsh EP, Epstein LM. Laser assisted ICD lead extraction in children and young adults with congenital heart disease. Journal Cardiovascular Electrophysiology 2003;14:344-349.

20. Stephenson EA, Batra AS, Knilans TK, Gradaus R, Balagi S, Dubin AM, Rhee EK, Thøgersen AM, Walsh EP, Berul CI. A multicenter experience with novel implantable cardioverter defibrillator configurations in the pediatric and congenital heart disease population. Journal Cardiovascular Electrophysiology 2006;17:41-46.

21. Parkash R, Crystal E, Bashir J, Simpson C, Birnie D, Sterns L, Exner D, Thibault B, Connors S, Healey JS, Champagne J, Cameron D, Mangat I, Verma A, Wolfe K, Essebag V, Kus T, Ayala-Paredes F, Davies T, Sanatani S, Gow R, Coutu B, Sivakumaran S, Stephenson E, Krahn A. Complications associated with revision of Sprint Fidelis leads: report from the Canadian Heart Rhythm Society Device Advisory Committee. Circulation 2010;121:2384–2387.

22. Swerdlow CD, Sachanandani H, Gunderson BD, Ousdigian KT, Hjelle M, Ellenbogen KA. Preventing overdiagnosis of implantable cardioverter-defibrillator lead fractures using device diagnostics. J Am Coll Cardiol 2011;57: 2330–2339.

23. Chung EH, Casavant D, John RM. Analysis of pacing/defibrillator lead failure using device diagnostics and pacing maneuvers. Pacing Clin Electrophysiol 2009;32:547–549.

24. Swerdlow CD, Asirvatham SJ, Ellenbogen KA, Friedman PA. Troubleshooting implanted cardioverter defibrillator sensing problems. Circ Arrhythm Electrophysiol 2014;7:1237–61.

25. Thiyagarajah A, Strik M, Ploux S, Bordachar P. Diagnostic approach to suspected lead failure. Card Electrophysiol Clin. 2024;16:359-371. PMID: 39461827

26. Tsurugi T, Matsui S, Nakajima H, Nishii N, Honda T, Kaneko Y. Various mechanisms and clinical phenotypes in electrical short circuits of high-voltage devices: report of four cases and review of the literature. Europace 2015;17:909–914.

27. Swerdlow CD, Gunderson BD, Ousdigian KT, Abeyratne A, Sachanandani H, Ellenbogen KA. Downloadable software algorithm reduces inappropriate shocks caused by implantable cardioverter-defibrillator lead fractures: a prospective study. Circulation 2010;122:1449–55.

28. Ellenbogen KA, Gunderson BD, Stromberg KD, Swerdlow CD. Performance of Lead Integrity Alert to assist in the clinical diagnosis of implantable cardioverter defibrillator lead failures: analysis of different implantable cardioverter defibrillator leads. Circ Arrhythm Electrophysiol 2013;6:1169–1177.

29. Steinberg C, Padfield GJ, Hahn E, et al. Lead integrity alert is useful for assessment of performance of Biotronik Linox leads. J Cardiovasc Electrophysiol 2015;26:1340–1345.

30. Pron G, Ieraci L, Kaulback K; Medical Advisory Secretariat, Health Quality Ontario. Internet-based device-assisted remote monitoring of cardiovascular implantable electronic devices: an evidence-based analysis. Ont Health Technol Assess Ser. 2012;12:1-86.

31. Wilkoff BL, Fauchier L, Stiles MK, Morillo CA, Al-Khatib SM, Almendral J, Aguinaga L, Berger RD, Cuesta A, Daubert JP, Dubner S, Ellenbogen KA, Estes NA 3rd, Fenelon G, Garcia FC, Gasparini M, Haines DE, Healey JS, Keegan R, Kolb C, Kuck KH, Marinskis G, Martinelli M, Mcguire M, Molina LG, Okumura K, Proclemer A, Russo AM, Singh JP, Swerdlow CD, Teo WS, Uribe W, Viskin S, Wang CC, Zhang S. 2015 HRS/EHRA/APHRS/SOLAECE expert consensus statement on optimal implantable cardioverter-defibrillator programming and testing. Europace. 2016;18:159-83. PMID: 26585598

32. Gunderson BD, Gillberg JM, Wood MA, Vilayaraman P, Shepard RK, Ellenbogen KA. Development and testing of an algorithm to detect implantable cardioverter-defibrillator lead failure. Heart Rhythm 2006;3:155–162.

33. Beau S, Greer S, Ellis CR, Keeney J, Asopa S, Arnold E, Fischer A. Performance of an ICD algorithm to detect lead noise and reduce inappropriate shocks. J Interv Card Electrophysiol 2016;45:225–232.

34. Mulpuru SK, Noheria A, Cha YM, Friedman PA. Nonsustained lead noise alert associated with repeating pattern of signals on the ventricular channel: is there true concern for lead malfunction? Heart Rhythm 2014;11:526–528.

35. Wollmann CG, Lawo T, Kühlkamp V, Becker R, Garutti C, Jackson T, Brown ML, Mayr H. Implantable defibrillators with enhanced detection algorithms: detection performance and safety results from the PainFree SST study. Pacing Clin Electrophysiol 2014;37:1198–1209.

36. Yee R, Verma A, Beardsall M, Fraser J, Philippon F, Exner DV. Canadian Cardiovascular Society/Canadian Heart Rhythm Society joint position statement on the use of remote monitoring for cardiovascular implantable electronic device follow-up. Can J Cardiol 2013;29:644–651.

37. Slotwiner D, Varma N, Akar JG, et al. HRS Expert Consensus Statement on remote interrogation and monitoring for cardiovascular implantable electronic devices. Heart Rhythm 2015;12:e69–e100.

38. Caughron H, Bowman H, Raitt MH, Whooley MA, Tarasovsky G, Shen H, Matheny ME, Selzman KA, Wang L, Major J, Odobasic H, Dhruva SS. Cardiovascular implantable electronic device lead safety: Harnessing real-world remote monitoring data for medical device evaluation. Heart Rhythm. 2023;20:512-519. PMID: 36586706

39. Kowal D, Baszko A, Czyż K, Bobkowski W, Mitkowski P, Rubiś B. Pacemaker remote monitoring challenges in pediatric population: Single center long term experience. Kardiol Pol. 2024;82:308-314. PMID: 38493457

40. Clark BC, Olen M, Dechert B, Brateng C, Jarosz B, Smoots K, Connell P, Dupanovic ST, Fenrich A, Hill AC, LaPage M, Mah D, McCanta A, Malloy-Walton L, Pflaumer A, Radbill A, Tanel R, Whitehill R, Dalal A; Pediatric and Congenital Electrophysiology Society (PACES). Current State of Cardiac Implantable Electronic Device Remote Monitoring in Pediatrics and Congenital Heart Disease: A PACES-Sponsored Quality Improvement Initiative. Pediatr Cardiol. 2024;45:114-120. PMID: 38036754

41. Poole JE, Swerdlow CD, Tarakji KG, Mittal S, Ellenbogen KA, Greenspon AJ, Kennergren C, Philbert BT, Moore J, Jones RC, Schaller RD, Hansalia R, Simmers T, Mihalcz A, DeBus B, Lexcen DR, Gunderson B, Wilkoff BL. Clinical performance of implantable cardioverter-defibrillator lead monitoring diagnostics. Heart Rhythm. 2022;19:363-371. PMID: 34767985

Section 6: Lead Recalls and Advisories

Recommendations for Lead Recalls			
COR	**LOE**	**Recommendations**	**References**
1	**C-EO**	1. Patients with leads under FDA advisory/recalls should be informed about the potential for lead malfunction/abnormalities and advised about the different management strategies in a shared decision-making process. Patients who do not need urgent/immediate intervention should be monitored remotely or in person.	

Synopsis

Implantable cardioverter-defibrillator (ICD) and pacemaker leads are critical components of the CIED system with mechanisms to ensure proper sensing, pacing, and defibrillation therapy. Over time, certain lead models have been subject to recalls or advisories due to lead malfunction/abnormalities that may lead to inappropriate shocks or ineffective therapy. Unlike device generator recalls, lead recalls pose greater clinical challenges, as extraction can carry significant procedural risk. Collaboration between clinicians, patients, and device manufacturers is essential to ensure informed decision-making and optimal management. An awareness of lead performance trends, adherence to surveillance

recommendations, and shared decision-making remain the foundation of safe and effective care in the setting of lead recalls and advisories.

Recommendation-specific supportive text

Recommendation 1: There should be widespread use of enhanced surveillance with remote monitoring as this allows for early detection of potential lead abnormalities. In addition, patients should be informed about the advisory with an emphasis of individualized risk assessment and shared decision-making with regards to lead management

6.1 Background

6.1.1. Introduction

Lead recalls or advisories confer a safety concern to the patient, healthcare professional, manufacturer, and regulatory agencies that a lead has failed to meet the prespecified expectations for performance.[1] This failure notification is based on returned product analysis, customer-reported failures, post-marketing registry reports, or remote monitoring.[1,2]

The precise terminology is primarily determined by regulatory language, as the vast majority of leads are not extracted and returned to the manufacturer. Component failure describes an unavoidable, rare failure that does not reflect a systematic failure mechanism over-represented in a particular lead model. Advisories are typically reported when a lead manifests a specific mechanism of component failure, attributed to a component or an assembly flaw that lead failure, which can involve any of the lead

components (insulation, conductors or connectors). The advisory typically outlines the nature of the problem, recommended clinical actions, and any required follow-up.

A ”recall” is a regulatory action used by the United States Food & Drug Administration (FDA), describing an action taken by a company to correct or remove from the market an FDA-regulated product that violates U.S. laws and regulations. Most recalls involve removing violative FDA-regulated products from the market, but there are instances where a violation can be corrected without removing the products from distribution. In the context of implanted products, including CIEDs, a recall has complex implications, since clinicians and patients then need to decide whether to continue to use the product, place a new implant, and/or remove the recalled implant. There are three classes of recall, ranging from most to least serious. Class I recalls demand immediate attention due to the reasonable probability that using or being exposed to the defective product will cause serious adverse health consequences or even death. Class II recalls may result in temporary or medically reversible adverse health consequences, but the probability of serious health consequences is low. Class III recalls are the least serious and are not likely to cause any adverse health consequences. Class III recalls generally focus on addressing minor defects or quality issues. Since some recalls do not necessitate cessation of the use of the device or removal from the market, and do not dictate a change in clinical management in all cases, some experts recommend using the word “advisory” instead. Manufacturers and regulatory agencies, such as the FDA, collaborate to ensure patient safety through surveillance, public notifications, and recommended clinical actions.

6.1.2 Lead Surveillance History

CIED implants are commonplace, and there is now greater ease of surveillance with remote monitoring. This provides the ongoing ability for lead issue detection and reporting. Lead manufacturers generate detailed and rigorous lead performance reports, such that the sheer volume of leads in registries and information available via remote and in-person surveillance is easily accessible, even if rare issues arise.[1,2] Therefore, all removed/extracted malfunctioning leads should be returned to the manufacturer for analysis.

6.1.3 Historical Lessons

The landmark recall of the Teletronics Accufix leads in 1994 was the impetus for the formation of a multicenter clinical study and a global registry that tracked clinical failure-related events and complications of interventions when leads were extracted as there were two fatal events and non-fatal injuries with the lead.[3] Not too long after, there was an unacceptable rate of failure in a specific bipolar tined polyurethane ventricular pacing lead, such as the Medtronic 4004/4004M lead. This failure was manifested by failure to capture, sensing abnormalities, early battery depletion, and abnormal impedance measurements.[4] This problem highlighted the roles of lead component materials and surgical technique on lead performance.

Implantable Cardioverter Defibrillator (ICD) leads are considered the “weakest link” in a defibrillator system because of the high rates of failure and recall.[5] A retrospective study evaluating the Medtronic 6936 in the 1990s was pivotal in the identification of the late failure mechanism. This has led to the development of lead failure recognition algorithms characterized by the detection of non-physiologic short sensing intervals.[6] The last two

major lead advisories were the Medtronic Fidelis and the St. Jude (now Abbott) Riata ICD leads. In October 2007, the Medtronic Sprint Fidelis lead was recalled by the United States FDA. The reason for the recall was due to chronic conductor fractures occurring at two primary locations, leading to inappropriate shocks and several deaths.[7-9] In 2011, there was a Class I recall of the St. Jude (now named Abbott) Riata ICD lead (multiple models exist). This recall was characterized by insulation breaches resulting in an increased risk of lead malfunction.[10]

6.2 Thresholds and Targets for Lead Performance

Monitoring lead performance has steadily improved over time. Robust data gathering and extensive lead follow-up provide information for post-marketing surveillance so that evidence of unsatisfactory lead function is detected expeditiously.[11] Despite these stringent standards, there is no clear consensus regarding acceptable thresholds for annual failure rates for pacing or ICD leads. While the expectation of a lead's performance is not 100%, there is a performance threshold that is acceptable due to the risk of malignant bradycardia and tachyarrhythmias. Hence, manufacturers, regulatory bodies, healthcare providers, and patients are all vested in acceptable and reliable lead performance. Historical data for the long-term performance of available transvenous leads suggest that annual failure rates should not exceed 0.4% and 0.2% per year for the first 10 years of ICD and pacemaker leads, respectively.[12-15]

A recalled S-ICD lead provides an interesting case to illustrate the decision for recall due to a systematic failure mechanism despite acceptable overall performance. To date, approximately 47,000 Emblem 3501 S-ICD leads have been implanted worldwide. The

cumulative occurrence rate for this specific electrode body fracture location is reported to be 0.2% at 41 months, with a potential for life-threatening harm of 1 in 25,000 (0.004%) at 10 years.[16] The probability of longevity of the S-ICD lead was higher when compared to transvenous leads and not significantly lower than that of its predecessor, model 3401 (not subjected to safety notification).[17] Even though this failure rate would be considered acceptably low and comparable to the standard transvenous leads, the fact that a systematic failure mechanism was identified led to the recall of this lead (see below in 6.4.4).

6.3 U.S. Food and Drug Administration

6.3.1 U.S. Food and Drug Administration Premarketing Assessment

In the United States, the Office of Device Evaluation (ODE) within the U.S. Food and Drug Administration (FDA) is responsible for approving CIEDs and CIED leads. Premarketing assessment (bench, animal or clinical investigation) involves ensuring reasonable safety and effectiveness of leads. Bench testing is required and can include mechanical and electrical performance, biocompatibility, interchangeability, and flex-fatigue testing. Pre-market requirements are not standardized and are determined on a case-by-case basis based on lead-specific concerns and differences to products already in the market. Given the lead recalls discussed in this section, the FDA has continued to modify its premarket requirements and post-marketing surveillance for new ICD and pacemaker leads.

6.3.2 U.S. Food and Drug Administration Postmarketing Surveillance Identification

The FDA is also responsible for post-marketing surveillance to monitor safety signals in approved devices and leads. This is to ensure that all devices, including leads, perform as

intended without harm to the patient over time. Device manufacturers are required to report lead-related failures that cause or may cause death or serious injury. The FDA receives several hundred thousand reports annually on device-related adverse events, which are submitted and saved to the Manufacturer and User Facility Device Experience (MAUDE) database. Since 2008, manufacturers have been required to conduct a 5-year, 1000-patient minimum, post-approval study on all new or substantially modified ICD leads to reliably capture all lead failures in a large patient cohort and to hopefully detect failures that either occur late or with relative infrequency.[18] On July 22, 2022, the FDA established a Unique Device Identification (UDI) system to adequately identify medical devices sold in the United States, which requires all medical devices and packages to carry a unique numeric or alphanumeric code. The UDI code includes a device identifier, which identifies the model and includes the production identifier (manufacturer's lot number, serial number, expiration date, and manufacturing date). With full implementation, the label of most devices will include a unique device identifier (UDI) in human- and machine-readable form, which will ultimately improve patient safety, modernize device postmarket surveillance, and facilitate medical device innovation. [1,17-19]

6.4 Lead Recalls

6.4.1 General notifications

If a device manufacturer determines that a device recall is warranted, the FDA will be notified and may issue a public notification along with the manufacturer’s notification to ensure widespread awareness of the recall. The FDA classifies recalls as class I, II, or III, depending on the severity and likelihood of the health risk.[11,18-20] Medtronic Sprint Fidelis,

St. Jude Medical (now Abbott) Riata ICD lead, St. Jude Medical (now Abbott) Nanostim and most recently, Boston Scientific's Model 3501 advisories were classified as class I recalls. As of the writing of this document, Boston Scientific just issued a Safety Advisory for its Reliance Gore-coated ICD leads, but an official recall has yet to be issued (the lead models are no longer on the market as of 2021).

A Class I recall indicates that the lead model can no longer be implanted but does not necessitate lead extraction or replacement. Consistent and routine patient monitoring and management strategies are required for Class I recalls. The FDA can make general recommendations based on the available information at the time of the recall and will update the recommendations as new information is received. The manufacturers and professional societies will also issue their own recommendations to patients and physicians. In summary, healthcare professionals, manufacturers, and regulatory agencies work together to manage recalls effectively and ensure patient safety. Information on recalled leads is posted on the FDA website, the manufacturer's website, and HRSonline safety alerts, which contains physician-written recommendations regarding lead advisories, recalls, and factors to consider when formulating a plan for individual patients.

6.4.2. Sprint Fidelis and Riata Leads

The approach to the management of the recalled Sprint Fidelis and Riata leads has previously been documented. In summary, patients should be followed with remote monitoring. All patients with Medtronic ICDs should have the Lead Integrity Alert (LIA) turned on to prevent inappropriate therapies and high-voltage lead impedance alert

programmed “on” with a maximum setting of 100 Ω (pace/sense impedance alerts can also be narrowed from nominal) to facilitate earlier detection of lead failure.[6,8] If a lead fracture is suspected or confirmed, immediate patient attention is strongly recommended to discuss the approach of lead management. Implantation of a new high-voltage lead is recommended. If the decision is made to extract the affected lead, the Heart Rhythm Society and Medtronic Independent Physician Quality Panel recommend that this be performed by a physician with extensive lead extraction experience.[6, 9-11] If the lead is normally functioning, the recommendation is to continue remote monitoring. Similarly, if there is no evidence of a lead fracture at the time of generator change or device upgrade, multiple approaches should be considered regarding the Fidelis lead. This includes continuing to use the lead, implanting a new ICD lead and capping the Fidelis lead, implanting a new pace-sense lead (although there is an increased risk of subsequent high-voltage conductor fracture in a lead with a prior pace-sense conductor fracture), or extraction of the Fidelis lead and implantation of a new lead depending on the clinical scenario. Similarly, patients with the St Jude Medical (now Abbott) Riata leads should be followed with remote monitoring. Strategies to monitor for lead compromise (eg, short, non-physiologic RR intervals) include: using the SecureSense noise discrimination to monitor for lead noise, programming the pacing lead impedance range to 200– 1000 Ω and the high-voltage (HV) lead impedance to 25 Ω above and below the stable HV impedance range, programming an unused electrogram (EGM) channel to RV coil to the superior vena cava to store EGMs that might detect noise, increasing detection criteria for VF detection intervals from 24 to 30 intervals, turning off the SVC coil in dual coil leads, turning RV

autocapture to “on” or to “monitor” to closely monitor the pacing lead thresholds, turning “on” vibratory patient alert triggers, ensuring that the episode trigger for ventricular tachycardia (VT) / ventricular fibrillation (VF) episodes are set to “high.” If conductor externalization is noted but the lead is electrically intact, continued monitoring is recommended without replacement. This is true at the time of generator change but the operator should consider implanting a device that has an automatic vector switching capability that allows the shock vector to be automatically changed if a short circuit is detected. The Riata lead should be replaced if it exhibits electrical failure by implanting a new ICD lead and either capping or extraction of the Riata lead (depending on the shared decision making based on underlying comorbidities and the expertise of the medical center and the physician).

6.4.3. SJM (Abbott) Nanostim leadless pacemaker

The Nanostim leadless pacemaker was a pioneering device that offered an alternative to traditional transvenous pacemakers. The device was recalled 4 years after its launch due to premature battery depletion, with failure of output and communication from the device. Failure rates approached 41%. There have also been reports of undersensing and issues with pacing. It should also be noted that in 94% of the cases of premature battery depletion, patients had normal lead parameters 3 months before battery failure, therefore the changes were sudden and unexpected.[21] A second advisory was also released stating that there was a 0.28% docking button detachment rate, rendering the device irretrievable.[21,22] The batteries that were retrieved for premature depletion showed an increase in resistance caused by insufficient electrolyte availability at the cathode/anode

interface. Retrieval of these devices can be safely performed with a demonstrated success rate of ~90%.[23] In patients who need removal, the overall success of Nanostim leadless pacemaker extraction is high, with a low risk of extraction attempt. The average time of extraction of Nanostim was 1,040+467 days, noted in one series, and [21] and 256 days in others.[24] Two out of 73 patients had serious adverse events with Nanostim extraction in one series.[24] It is a reasonable approach to retrieve or abandon the leadless pacemaker with the implantation of a new pacing system in high-risk device-dependent patients. Among low-risk patients without device dependence, watchful monitoring is recommended. Patients should be followed remotely with remote monitoring (Merlin.net) with a suggested frequency of every 3 months.

6.4.4. Model 3501 S-ICD lead

There have been marked advancements in implantable cardioverter defibrillator therapy, one of which has been heralded by the use of a non-vascular (subcutaneous) ICD lead (S-ICD). This S-ICD system is an effective alternative for the prevention of sudden cardiac death.[25] In December 2020, the FDA issued a Class I recall of the Boston Scientific Emblem Model 3501 subcutaneous ICD lead following 27 reports of lead fracture not related to trauma and 1 reported death.[26] Mechanical stress at a location just distal to the proximal ring electrode on the lead may potentially cause a “fatigue crack” that initiates from the outer lumen. Over time, this crack may propagate inward toward the distal sense conductor, eventually leading to a fracture of both high-voltage conductors.[26] The current recommendations for the Model 3501 S-ICD lead issued by the FDA and supported by the HRS are listed in Appendix 1.

6.4.5. Boston Scientific RELIANCE ePTFE lead

The most recent lead advisory comes from Boston Scientific (BSC) regarding their RELIANCE ePTFE (GORE)-coated coil(s) defibrillation lead manufactured from 2002 to 2021. While no longer on the market or available for implantation, BSC estimates that approximately 354,000 remain in service, of which 250,000 are in the United States. The expanded polytetrafluoroethylene (ePTFE/GORE) leads were initially developed to prevent tissue ingrowth. However, its presence on the lead coil may cause a gradual change in low or high-voltage shock impedance (LVSI/HVSI) due to shock coil calcification. High out-of-range LVSI and/or HVSI measurements have the potential for reduced shock efficacy. There is a natural and acceptable rise in LVSI in the post-implantation period, and it can also be seen in other lead performance issues (eg, lead fractures and insulation issues). It is, therefore, crucial to identify a gradual rise in LVSI consistent with lead calcification. This includes a 20Ω rise from baseline, at least three (3) years post-implant, to a minimum of 90Ω for single coil (SC) leads, 70Ω for dual coil (DC) leads, excluding rises in excess of 30Ω per quarter.

If HVSI exceeds 145Ω, BSC defibrillators, by design, limit the shock duration of the first shock phase to 20ms. If this occurs, the shock's bi-phasic waveform is truncated, and a monophasic shock is delivered, potentially reducing shock efficacy. A high delivered shock impedance alert (Fault Code-1005) is seen on the device check after these shock instances. This phenomenon can occur irrespective of lead polarity. However, FC-1005 is 4.5x more likely in reversed (RV+) polarity compared to Initial (RV-) polarity. The caveat is that this applies to ePTFE RELIANCE defibrillation leads connected to BSC generators.

Presently, the criteria for leads connected to ICD generators from other manufacturers remain less certain.

The association of calcified defibrillation lead coil(s) with a pattern of gradually rising LVSI measurements has been reported in the past [27-32]. This impedance rise could reduce shock efficacy, and instances of failed shock therapy have been reported[32]. Sensing and pacing performance are not known to be compromised. Patient complications have also been reported from extraction procedures – possibly related to long dwell times. The current recommendations for the Model RELIANCE ePTFE lead issued by Boston Scientific and supported by the HRS are available online [HRSonline safety alert].

References

1. Maisel, W.H. Hauser, R.G. Hammill, S.C. Recommendations from the Heart Rhythm Society Task Force on Lead Performance Policies and Guidelines: developed in collaboration with the American College of Cardiology (ACC) and the American Heart Association (AHA). Heart Rhythm. 2009; 6:869-885

2. Carlson, M.D. Wilkoff, B.L. Maisel, W.H. Recommendations from the Heart Rhythm Society Task Force on Device Performance Policies and Guidelines. Endorsed by the American College of Cardiology Foundation (ACCF), the American Heart Association (AHA), and the International Coalition of Pacing and Electrophysiology Organizations (COPE) Heart Rhythm. 2006; 3:1250-1273

3. Kay, G.N. Brinker, J.A. Kawanishi, D.T. ... Risks of spontaneous injury and extraction of an active fixation pacemaker lead: report of the Accufix Multicenter Clinical Study and Worldwide Registry Circulation. 1999; 100:2344-2352

4. Hayes, D.L. Graham, K.J. Irwin, M. Multicenter experience with a bipolar tined polyurethane ventricular lead . Pacing Clin Electrophysiol. 1995; 18:999-1004

5. Swerdlow, C.D. Ellenbogen, K.A. Implantable cardioverter-defibrillator leads: design, diagnostics, and management Circulation. 2013; 128:2062-2071

6. Ellenbogen, K.A. Gunderson, B.D. Stromberg, K.D. Performance of Lead Integrity Alert to assist in the clinical diagnosis of implantable cardioverter defibrillator lead failures: analysis of different implantable cardioverter defibrillator leads. Circ Arrhythm Electrophysiol. 2013; 6:1169-1177

7. Krahn, A.D. Champagne, J. Healey, J.S. Outcome of the Fidelis implantable cardioverter-defibrillator lead advisory: a report from the Canadian Heart Rhythm Society Device Advisory Committee Heart Rhythm. 2008; 5:639-642

8. Swerdlow, C.D. Gunderson, B.D. Ousdigian, K.T. Downloadable software algorithm reduces inappropriate shocks caused by implantable cardioverter-defibrillator lead fractures: a prospective study Circulation. 2010; 122:1449-1455

9. Birnie, D.H. Parkash, R. Exner, D.V. Clinical predictors of Fidelis lead failure: report from the Canadian Heart Rhythm Society Device Committee Circulation. 2012; 125:1217-1225

10. Parkash, R. Tung, S. Champagne, J. Insight into the mechanism of failure of the Riata lead under advisory Heart Rhythm. 2015; 12:574-579

11. Maisel, W.H. Moynahan, M. Zuckerman, B.D. Pacemaker and ICD generator malfunctions: analysis of Food and Drug Administration annual reports JAMA. 2006; 295:1901-1906

12. Providencia, R. Kramer, D.B. Pimenta, D. Transvenous implantable cardioverter-defibrillator (ICD) lead performance:a meta-analysis of observational studies J Am Heart Assoc. 2015; 4:e002418

13. Arnsbo, P. · Møller, M. Updated appraisal of pacing lead performance from the Danish Pacemaker Register: the reliability of bipolar pacing leads has improved Pacing Clin Electrophysiol. 2000; 23:1401-1406

14. de Voogt, W.G. Pacemaker leads: performance and progress Am J Cardiol. 1999; 83:187D-191D

15. van Rees, J.B. van Welsenes, G.H. Borleffs, C.J.W. Update on small-diameter implantable cardioverter-defibrillator leads performance Pacing Clin Electrophysiol. 2012; 35:652-658

16. Remole SC; Kohli U; Hassan S, Boston Scientific Emblem S-ICD (Model 3501) lead advisory: an illustrative patient report. J Interv Card Electrophysiol] [2021]; 443-444

17. Boston Scientific Rhythm Management Product Performance Report. Q4 Editionhttps://www.bostonscientific.com/content/dam/bostonscientific/quality/ppr/2021/q4/Q4%202021%20CRM%20Product%20Performance%20Report%20Rev%20A.pdfPublished November 8, 2021

18. Hauser, R.G. Almquist, A.K. Learning from our mistakes? Testing new ICD technology. N Engl J Med. 2008; 359:2517-2519

19. Shein, M.J. Schultz, D.G. Testing new ICD technology N Engl J Med. 2008; 359:2610

20. https://www.fda.gov/medical-devices/medical-device-recalls/ boston-scientific-recalls-emblem-s-icd-subcutaneous-electrode- model-3501-due-risk-fractures. Accessed 20 May 2021

21. Erik F.J. Oosterwerff, Dominic A.M.J. Theuns, Alexander H. Maass, Lieselot van Erven, MD, Remarkably high and accelerating failure rate of a widely used implantable cardioverter-defibrillator lead: A large-scale manufacturer-independent multicenter study with long accurate follow-up. Heart Rhythm O2, Volume 5, Issue 9, 614 - 622

22. Czulada E, Kabadi R, Basyal B, Hadadi C, Thomaides A. Challenging Extraction and Replacement of an Eight-year-old Nanostim Leadless Pacemaker and AVEIR Implant. J Innov Card Rhythm Manag. 2024 Dec 15;15(12):6126-6129.

23. Lakkireddy D, Knops R, Atwater B, Neuzil P, Ip J, Gonzalez E, Friedman P, Defaye P, Exner D, Aonuma K, Doshi R, Sperzel J, Reddy V. A worldwide experience of the management of battery failures and chronic device retrieval of the Nanostim leadless pacemaker. Heart Rhythm. 2017 Dec;14(12):1756-1763. doi: 10.1016/j.hrthm.2017.07.004. Epub 2017 Jul 10. PMID: 28705736.

24. Dar T, Akella K, Murtaza G, Sharma S, Afzal MR, Gopinathannair R, Augostini R, Hummel J, Lakkireddy D. Comparison of the safety and efficacy of Nanostim and Micra transcatheter leadless pacemaker (LP) extractions: a multicenter experience. J Interv Card Electrophysiol. 2020 Jan;57(1):133-140. doi: 10.1007/s10840-019-00684-y. Epub 2020 Jan 6. PMID: 31907831.

25. Knops R.E., Olde Nordkamp L.R.A., Delnoy P.H.M., et. al.: Subcutaneous or transvenous defibrillator therapy. N Engl J Med 2020; 383: pp. 526-536.

26. https://www.bostonscientific.com/content/dam/bostonscientific/quality/dlt/ reg code-228/2020Dec_BSC_EmblemElectrode3501_PhysLtr_Final. pdf. Accessed 20 May 2021.

27. Monkhouse C, Cambridge A, Chow AWC, Behar JM. High-voltage impedance rise; mechanism and management in patients with transvenous implantable cardioverter-defibrillators: a case series. Eur Heart J Case Rep. 2019 Dec;3(4):1-8. doi:10.1093/ehjcr/ytz220. Epub 2019 Dec 19. PMID: 31911989; PMCID: PMC6939807.

28. Swerdlow CD, Koneru JN, Gunderson B, Kroll MW, Ploux S, Ellenbogen KA. Impedance in the Diagnosis of Lead Malfunction. Circ Arrhythm Electrophysiol. 2020 Feb;13(2):e008092. doi10.1161/CIRCEP.119.008092. Epub 2020 Jan 27. PMID:31985260.

29. Swerdlow CD, Ploux S, Poole JE, Nair SG, Himes A, Ellenbogen KA. Interpreting device diagnostics for lead failure. Heart Rhythm. 2022 Jan;19(1):154-164. doi:10.1016/j.hrthm.2021.09.027. Epub 2021 Sep 28. PMID: 34597770.

30. Narayanan, Chockalingam et al. PO-05-084 Management of Gradual Elevated Shock Impedance in ENDOTAK RELIANCE ICD Leads Heart Rhythm, Volume 20, Issue 5, S722 - S723. https://doi.org/10.1016/j.hrthm.2023.03.1497.

31. Malik A, Sousa A, et al. PO-06-127 Progressive High-Voltage Impedance Rise in Boston Scientific ENDOTAK RELIANCE ICD Leads. HeartRhythm, Volume 22, Issue 4, S687. https://doi.org/10.1016/j.hrthm.2025.03.1668

32. Koneru, Jayanthi N. et al. PO-06-203 Implantable Cardioverter Defibrillator Failure Due to High-Voltage Impedance Abnormality Causing Monophasic Shocks and Defibrillation Failure. Heart Rhythm, Volume 22, Issue 4, S722 – S723. http://dx.doi.org/10.1016/j.hrthm.2025.03.1743.

Section 7. Clinical Considerations in Cardiovascular Implantable Electronic Device Lead Management

Careful consideration is required when patients with existing CIED systems require additional procedures, including generator changes, lead revisions, and device upgrades. Patient device needs can evolve over time, and alternate management strategies have different risks and benefits. One hallmark of existing CIED management is shared decision-making with patients, reviewing not only the acute risks and benefits of various strategies but also the potential long-term ramifications.

Recommendations for Management of Patients with Existing CIEDs

COR	LOE	Recommendations	References
1	C-EO	**1. Leaving the lead in a condition that will permit future extraction and prevent retraction into the vessel is recommended for any abandoned lead.**	
1	C-EO	**2. When considering whether to abandon or remove a nonfunctional or unnecessary lead, shared decision-making with the patient is recommended to include immediate and long-term risks and benefits of each option, taking into account the patient's preference, comorbidities, future vascular access, and available programming options.**	49,50,52,53,54,55, 56,57,59

1	**C-EO**	**3. It is recommended that patients with CIED leads across the tricuspid valve who are referred for transvenous tricuspid valve replacement be evaluated by a multi-disciplinary heart team, including an electrophysiologist with lead extraction and lead management expertise.**	63

Synopsis

In patients with CIEDs, lead management should be guided by an assessment of current and future risks, anticipated benefits, and the clinical significance of potential outcomes. Shared decision-making is essential in determining whether a lead is best retained, abandoned, or extracted.

Recommendation-specific supportive text

Recommendation 1: Transected leads should not be allowed to retract into the vasculature, as they may put patients at risk for arrhythmias or thrombosis and make future extraction more difficult. Capping and suturing the stump of a transected lead in the pocket would improve future access to the lead, as well as shield the lead stump from possible MRI heating. Capping a transected lead may prevent future helix retraction in active fixation leads. However, in leads prone to inside-out erosion, transection could facilitate cable extrusion. Preserving the lead terminal connector may prevent these challenges with future extraction, but it increases the amount of hardware in the pocket.

Recommendation 2: Shared decision-making with the patient, reviewing the risks and benefits of each strategy, is required prior to the decision to extract or abandon a lead due to malfunction, replacement by an alternate lead (eg, pacemaker upgrade to ICD), or change in clinical situation (eg, atrial lead in patients with permanent atrial fibrillation). The risks of extraction include venous or cardiac perforation and depend on multiple device and patient factors, including quantity of leads, lead type, lead manufacturer, duration of implant, patient's age and health, presence of prior sternotomy, and operator and team experience. The benefits of removal include the elimination of unneeded hardware that might be more difficult to remove in the future for mandatory extraction indications, such as infection, to facilitate MRI at some institutions, and to allow for access in patients with vascular occlusions. Some studies have shown that abandoned hardware is associated with an increased risk of future infections. A large retrospective Medicare claims study showed that patients undergoing lead extraction for noninfectious indications had similar long-term survival to those who pursued an abandonment approach, although extraction was associated with a lower risk of device infection at 5 years. Overall, studies are limited by their observational nature, and many are single-center.

Recommendation 3: In patients with transvenous right ventricular leads, surgical or percutaneous tricuspid valve procedures can "jail" the lead. This may affect the lead function and prevent extraction even in the event of infection. Management of these patients is complex and requires evaluation of many patient and device factors, such as patient's age and health, device type, pacemaker dependency, and surgical risk. In patients with the right ventricular CIED leads, the multi-disciplinary team devising a

comprehensive treatment plan should include an electrophysiologist who has expertise in lead extraction and management, as this is an important consideration for these patients.

7.1 Lead Management during Cardiovascular Implantable Electronic Device Replacement

Normally functioning, non-recalled leads are generally retained during routine generator exchange procedures. There is a lower rate of complications for routine generator exchanges compared to lead extraction or revision procedures. Proceduralists should be prepared to respond to unexpected findings that may require lead removal or revision during the planned generator exchange.

7.1.1 Complications of Generator Exchange

The risks associated with routine generator exchange procedures are substantial, both in the acute perioperative period and during the first several months of follow-up. Minor complications include superficial infections treatable with antibiotics, hematoma, and pain. Major complications include lead dislodgment requiring revision (0.07-3.2%), pocket or lead-related infections (0-5.2%), and hematoma requiring evacuation (0-5.2%). Direct peri-procedural complications occur in approximately 1 to 2% of cases. This risk increases to approximately 4% (0.6-8.2%) during short term follow up. The risk of death at the time of a generator change is negligible (0-0.4%).[1-3]

Generator exchange is associated with a 2.2-fold increased risk of pocket-related complications compared to initial CIED implantation procedures. In addition, the risk of pocket complications rises with each subsequent procedure. In a population of ICD procedures, the rate increased to 8.1% by the fourth subsequent procedure.[4] Based upon

these findings, a basic premise of CIED and lead management is that the number of required generator exchanges in a patient should be minimized. Devices with superior battery longevity may help achieve this goal. Optimal thresholds should be attained during the original device implantation, and unnecessary leads avoided. Appropriate attention should be given to device programming using strategies to decrease current drain and minimize unnecessary pacing and use of ICD therapies. Battery longevity can vary greatly based upon a variety of factors, including device type, device manufacturer, lead parameters, and patient usage, and may be difficult to predict.[5,6] Subcutaneous ICDs seem to have a low risk of complications at the time of generator change.[3] There are no data yet regarding substernal ICDs.

7.1.2. Risk Factors for Complications and Mortality

Risk factors for complications and mortality at the time of generator exchange depend on patient, procedural, and CIED system characteristics. Patient factors and comorbidities that have been associated with adverse procedural events include angina, heart failure, antiarrhythmic drug use, valvular heart disease, renal failure, diabetes, anticoagulation/antiplatelet use, corticosteroid use, chronic pulmonary disease, cerebrovascular disease, malignancy, fever, recent hospitalization, and dermatologic disorders. Prior CIED infection is also associated with increased risk for future infection. While mortality is extremely low around the time of generator changes, in one large registry study, older age, atrial fibrillation, heart failure, diabetes, renal dysfunction, lung disease, and cerebrovascular disease were associated with an increased risk of death.[1,3,7,8] Additionally, low implant volume, lack of antibiotic prophylaxis, temporary pacing, and

ICDs or cardiac resynchronization therapy (CRT) devices (as compared to single or dual-chamber pacemakers) raise the risk of adverse events.[1]

7.1.3. Risk of Lead Failure after Generator Exchange

Data are limited and conflicting as to whether patients have an increased risk of lead failure after a generator exchange. In a series of over 60,000 ICD patients in the Boston Scientific Latitude remote monitoring platform, lead alerts significantly increased after generator change compared to the remainder of the population, most within the first three months after generator change (Hazard ratio 5.19 [95% CI 3.45-7.84].[9] Risks are likely associated with procedural technique and the specific lead models. A study of the recalled Riata defibrillator lead did not show increased risks of lead malfunction after generator changes[10]. Two series of patients with recalled Sprint Fidelis leads reported conflicting results, with one showing a significant increase in lead failures at the time of generator exchange and the other showing no difference compared to the general population.[11,12]

7.1.4 Shared Decision-Making

The decision to replace an ICD generator should involve a comprehensive discussion between the patient and the providers regarding the risks and benefits of the procedure, as well as the patient's values and preferences.[13] This is particularly important in patients who are very elderly or who have significant comorbidities. In these patients, the benefits of the device may not justify the potential procedural complications. In addition, tachyarrhythmia therapies may no longer be in line with the patient's wishes.[14] An observational study of ICD generator changes in septuagenarians and octogenarians

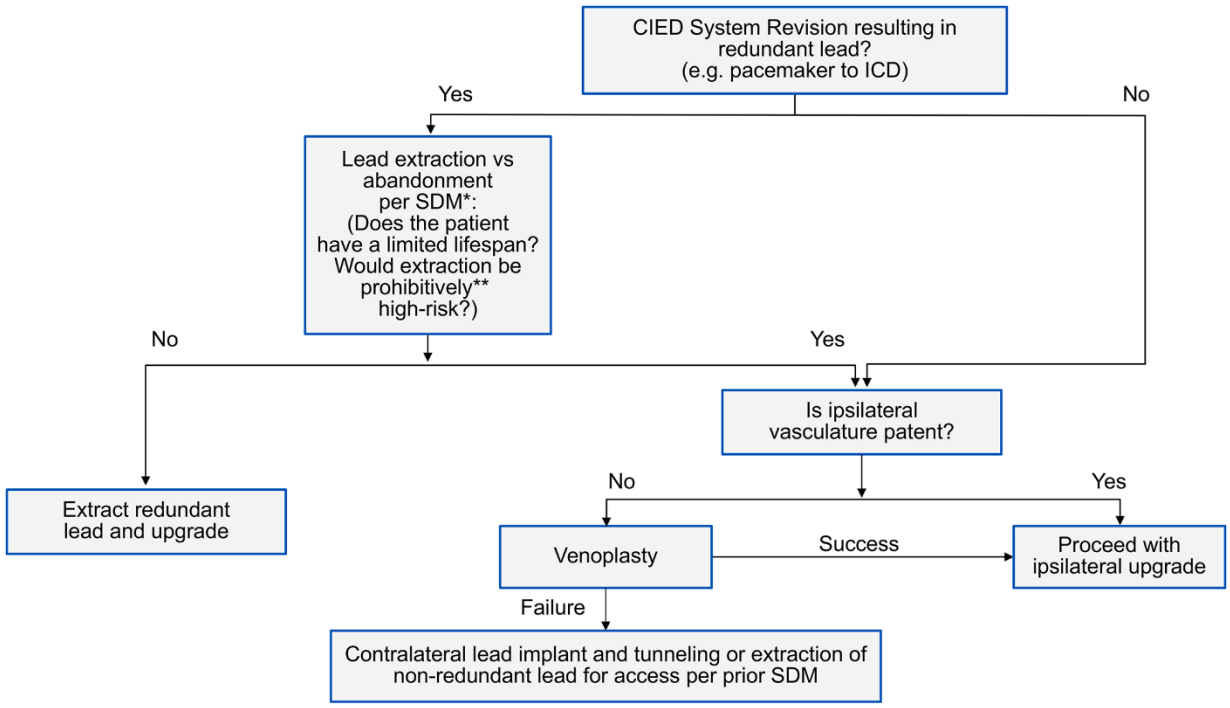
showed the procedure to be safe, though more patients died during follow-up from non-cardiac causes than had appropriate shocks.[15] Rarely, there may be select pacemaker patients who do not elect for pacemaker generator change after shared decision-making (eg, those with minimal pacing). Small observational studies have shown that pacemaker generator changes can be performed safely in the extremely elderly.[16]

7.2 Lead Management during Cardiovascular Implantable Electronic Device Upgrade

7.2.1. Upgrade Procedure Preparation

A CIED system is upgraded when one or more leads are added to an existing system. This can include converting a single-chamber device to a dual-chamber device, a pacemaker to an ICD, or a standard pacemaker or ICD to a cardiac resynchronization device. Many of the risks and considerations reviewed in the generator exchange section are applicable to patients undergoing upgrade procedures. The process through which an upgrade procedure proceeds depends on whether a lead will become redundant, the presence of venous patency, patient age and comorbidities, and shared decision-making in light of patient values (See **Figure 1**).

Figure 1: Flowchart of the decision-making on the device upgrade procedure.



7.2.2. Complications of Lead Upgrade and Revision Procedures

The risk of acute and short-term procedural complications is higher for upgrade procedures compared to generator exchanges. This is true for both pacemaker and ICD upgrade procedures. In the Danish Multicenter Randomized Study on AAI versus DDD Pacing in Sick Sinus Syndrome (DANPACE), the incidence of complications in patients undergoing addition of an atrial, right ventricular, or coronary sinus lead to an existing system was 16.7%.[17] In the REPLACE registry, the rate of all complications was 15.3% in the upgrade population and 4% in the generator exchange population. The most common complication was lead dislodgement (7.9%), which may account for the increased complication rate in upgrades compared to generator exchanges. Other complications included prolonged hospitalization (2.5%), hematoma (1.5%), death (1.1%), hospital

readmission (1.1.%), infection (0.8%) and perforation (0.7%).[1] The rate of lead dislodgement is now lower in the era of quadripolar leads.[18]

A large, two-center study comparing de novo implants, generator exchanges, and upgrades found that there were similar rates of complications in patients with new pacemaker implants and generator changes (1.7%), but ICD implants (3.5%) and upgrade procedures (6.1.%) had higher rates of complications, with a much higher rate in patients receiving an LV lead (9.5%).[19] However, in a more recent single-center, retrospective study comparing patients undergoing de novo CRT implantation compared to those undergoing upgrade, the procedure success and 90-day complications were similar despite a higher rate of vascular occlusion in the upgrade population.[20]

7.2.3. Venous Occlusion

Single-center and observational studies have shown a high rate of central vein stenosis in patients with indwelling pacemaker and ICD systems. Complete occlusion is seen in 3-26%, more than 75% stenosis in 10%, and 50-75% stenosis in 6-37%. Clinical factors that are associated with stenosis include lead number, lead type (eg, ICD vs pacemaker), lead dwell time, and number of procedures. Venogram can be considered prior to device upgrades for procedural planning.[21-23] With a stepwise approach, ipsilateral access may often be salvaged in patients with significant stenosis or occlusion.[24]

7.2.4. Lead Choices

The decision to add a lead to an existing CIED system requires careful consideration of multiple patient and device factors. The risks and benefits to the patient should be assessed with consideration of long-term management of the CIED system and potential

long-term complications. Patient considerations include age, comorbidities, and specific CIED needs. Lead considerations include active versus passive fixation leads, location of the new lead, the chamber, and single versus dual-coil ICD leads. In general, dual-coil ICD leads should be avoided as the risks of future extraction outweigh the benefits for defibrillation efficacy in most patients.[25] MRI conditionality is reasonable to preserve whenever possible.

7.2.5. Incorporating Preexisting Leads

As described above, upgrades have a higher risk of complications compared to generator exchanges, and much of this additional risk is related to the addition of new leads. Increased numbers of leads are associated with higher risks for future infection and vascular occlusion. Thus, it is prudent to include functional indwelling leads in an upgraded system when practical. Small observational studies have shown that patients do well with this approach.[23]

7.2.6 Addition of a Pace-Sense Lead

When ICD leads malfunction, the failure mechanism may sometimes be localized to the pace-sense portion while the high-voltage components remain intact. For DF-1 connector ICD leads, there are separate connector pins for the pace-sense components and high-voltage components. For these leads, a new pace-sense lead can be added, connected to the generator along with the high-voltage components of the ICD lead, and the pace-sense portion of the ICD lead capped.[26] Many of these leads are still in service, but DF-4 connector ICD leads have become the standard for new implantations with the pace-

sense and high voltage components integrated such that the addition of a pace-sense lead is not an option.

In the past, small observational studies in patients with non-advisory ICD lead malfunction evaluating pace-sense lead addition and ICD lead replacement have suggested that both strategies are feasible.[27-29] Modelling data of the recalled Sprint Fidelis lead suggests replacing the ICD lead is associated with fewer adverse outcomes and is cost-effective.[30]

7.3 Device Downgrade

Planned generator exchanges due to battery depletion present an opportunity to reevaluate CIED needs with the patient in a shared decision-making process. Factors that may influence the decision to "downgrade" a device include patient comorbidities and longevity, changes in pacing needs, and, for ICD patients, changes in left ventricular systolic function.[31] For patients with permanent atrial fibrillation, a single lead ventricular pacemaker can be placed and the atrial lead capped. However, this may affect MRI access. Use of a dual chamber generator, programmed to a ventricular pacing and sensing mode, can facilitate MRI access and may provide increased battery longevity. Some models of pacemaker generators have greater battery life than others, and patient age and comorbidities should be considered in selecting those devices.[32]

At the time of generator exchange for primary prevention ICDs, important considerations include the original indication, left ventricular ejection fraction, patient comorbidities and prognosis, and patient preferences. There are limitations in using ejection fraction as the main indication for ICD implantation.[33,34] There is controversy as to the risk of sudden death in patients who experience improvement in their ejection fraction after placement of

primary prevention ICDs. Studies have suggested that these patients have lower rates of tachyarrhythmia therapies and mortality, but residual risk remains.[35-37] If exchange for an ICD is deferred, the patient's pacing needs, including cardiac resynchronization, should be assessed. In general, even if the ejection fraction has improved, cardiac resynchronization should be maintained.

When converting an ICD to a pacemaker, including a cardiac resynchronization pacemaker, the lead types and compatibility must be carefully considered. A DF-1 connector ICD lead can easily be converted to a standard right ventricular pacing lead by placing the pace-sense pin in the ventricular port of a pacemaker generator and capping the high voltage pins. DF-4 connector ICD leads do not have this option, as there are no available DF-4 to IS-1 connectors. A new pace-sense lead can be placed. Another option may be to connect this lead to the left ventricular port of a cardiac resynchronization pacemaker if it is a quadripolar connector. Finally, the lead can be connected to an ICD generator with the shock therapies disabled. Factors, including the risks of abandoned leads, device size, and patient condition and preference, will determine the best choice for any individual patient.

7.4. Nonfunctional and Abandoned Leads

All transvenous leads have some rate of malfunction, with older models showing failure rates of 7-16% at 8-10 years of follow-up.[37,38] When a lead malfunctions, a decision must be made regarding management, specifically whether the lead will be removed and replaced or abandoned when a new lead is implanted. This decision depends on many patient and device factors. The acute risks of extraction must be balanced with the long-term risks of

abandonment. There may be settings in which replacement of functional leads may be considered, particularly very old leads or leads under advisory. The potential risks of abandonment include limiting access to MRI, venous thrombosis and stenosis, lead-lead interaction, tricuspid regurgitation, and increased risk of infection. Historically, MRIs have not been performed in patients with abandoned leads, particularly due to concerns about lead heating.[39] However, observational studies and registries have not found adverse effects in the clinical setting.[40-42] Interactions between an abandoned lead and a new lead causing oversensing are rare. Friction between the two leads can lead to erosion of the insulation. Adding a second lead across the tricuspid valve is associated with increased tricuspid regurgitation.[43,44]

Both present and future vascular access affects the decision to abandon or extract a lead. At the time of the first ICD generator change, 25% of patients had some form of stenosis, with 9% having complete occlusion.[45] In 227 patients referred for CIED revision or upgrade after a median implant time of 67 months, 27% had stenosis of >75% of the vessel diameter, with 6% having total occlusion.[24] The rate of venous stenosis rises with increased numbers of transvenous leads.[46,47], Patients are generally asymptomatic due to the formation of collateral vessels, but in severe cases, patients can develop SVC syndrome, which can be challenging to resolve.[48] There is no set number of leads that is considered the maximum in all patients to prevent venous stenosis.

Patients with abandoned leads may be at higher risk for infection. A large retrospective Medicare claims study showed that patients who had undergone lead extraction had a lower risk of device infection at 5 years compared to those who had leads abandoned,

although the overall long-term mortality was the same in both groups.[49] There is a discrepancy in many of the smaller observational studies. Some, particularly with shorter follow-up times, show a low risk associated with abandonment of leads.[50-53] Others suggest an increased risk of infection and subsequent difficulty in future device management, particularly if future extraction is needed.[54-59]

The decision regarding whether to abandon a lead or extract is a complex one, and there is divergence of opinion among experts as to the risks and benefits of each strategy. Table 1 outlines clinical scenarios highlighting the nuances in caring for individual patients. Important device considerations include lead age, number, type (pacemaker vs. ICD), and model. Important patient considerations include age, comorbidities, prognosis, status of vascular access, and preference. Patient age is a key factor, with many physicians preferring to remove leads in younger patients with normal expected lifespan to spare them the long-term complications of transvenous leads, which are no longer providing benefit. Conversely, a lead that is already very high-risk for extraction (eg, Medtronic 4195 Starfix) may be abandoned if no longer functional in an older patient, as high-risk extraction of this lead may never be necessary.

7.5 Lead Management at the Time of Transcatheter Tricuspid Valve Replacement

Newer transcatheter tricuspid valve replacement options have raised awareness regarding transvenous right ventricular leads, including both their influence on tricuspid valve function and lead management around the time of these procedures.[60,61] If a right ventricular lead is left in place at the time of a TTVR, it can be “jailed” by the valve. This has important implications for lead function and future extraction, especially if the patient

develops an indication for mandatory extraction, such as infection.[62] Data are incomplete as to the long-term outcomes of TTVR jailed leads, but there seems to be a significant short-term lead complication rate. One database review showed that of 28 jailed leads, one patient experienced RV lead dislodgement during the procedure, and two patients had lead failure during follow-up of 15.2 months.[63] Another single-center study showed that of 14 patients with jailed leads, 3 had major lead-related complications (2 lead fractures and 1 infection) during 10.5 months of follow-up, with an additional patient dying suddenly at home in the setting of high-grade heart block.[64]

TTVR is an evolving field, and an understanding of the different valve models and how they interact with the conduction system and CIEDs will be critical. The influence of various valves on lead function is likely different. In addition, models are available that may jail other leads (in the superior vena cava) in addition to the right ventricular lead or restrict access to the coronary sinus.[65] As this patient population is often quite ill, patient management is complex. A multi-disciplinary team approach is needed to ensure that a comprehensive treatment plan is in place. This team should include an electrophysiologist with lead extraction experience, as this is an important consideration for these patients.[66] Options for new or revised CIED implant after TTVR may include leadless pacing, coronary sinus lead implant, or a lead across the valve. Each option has benefits and drawbacks, and all could potentially be made more complex by the presence of the valve itself.

Table 1 presents 6 patient scenarios that may help with a case-by-case assessment and management of leadless pacemakers at the end of life, lead malfunction, lead extraction

vs abandonment, device upgrade/downgrade, and lead interaction with transcatheter tricuspid valve replacement.

Table 1: Lead Management Scenario

Patient Scenario	Management Strategies	Key Points
An 85-year-old woman with prior back surgery, sick sinus syndrome, complete heart block, and normal ejection fraction initially underwent pacemaker implantation 23 years ago, and the most recent generator change was one year prior. She developed an abrupt increase in impedance associated with elevated pacing threshold in the 23-year-old RV pacing lead and episodic electrical noise leading to inhibition of pacing.	-Assess the possibility of reprogramming to unipolar -Consider the likelihood of ipsilateral venous occlusion, which would limit management options -Options include attempting to continue to use the lead, possibly in unipolar pacing and sensing mode, adding a new RV lead and abandoning the old lead, extracting and replacing the old lead, or abandoning the system and placing a leadless pacemaker -The patient preferred to avoid unnecessary short-term risk and selected lead addition without extraction, even if it required lead tunneling from the right. This was completed via a severely stenosed left subclavian vein facilitated by balloon venoplasty.	-Age and comorbidities contribute to the lead management shared decision-making -Long dwell time increases the risk and complexity of lead extraction, which influences the risk side of the risk-benefit analysis -If the ipsilateral venous system is occluded, tunneling increases the risk of jeopardizing both prepectoral accesses in the event of future infection -A one-year-old pulse generator factors into the cost consideration of switching to a leadless pacemaker -Lead abandonment may restrict access to MRI at some centers
A 50-year-old man with complete heart block after a prior mechanical mitral valve replacement who had a His bundle pacemaker placed after valve replacement 5 years prior presents with high pacing threshold and generator at	-Management options include generator change only, pacing lead addition with abandonment of the His bundle lead, and extraction and replacement of the lead -The patient preferred to have the best long-term	-While His bundle pacing is potentially an attractive option for chronic ventricular pacing in young patients, this patient now has a very short battery life and no longer has His capture.

the elective replacement interval. Myocardial capture threshold is 4.0V at 1.0ms with QRS duration 165 ms. His bundle capture is not present at maximal output and left ventricular ejection fraction has decreased from 70% to 52% in the intervening five years with continuous ventricular pacing.	pacing system, even if this resulted in more short-term risk and complexity. -Based on all of this, the decision was made to proceed with the extraction of the lead with placement of a left bundle pacing lead on continuous anticoagulation with INR 2-2.5, with no post-procedural bridging if possible	-This patient's young age suggests a large potential benefit of reducing future generator changes and achieving improved ventricular synchrony if possible. -Extraction on continuous anticoagulation can be considered in those at high risk for stopping anticoagulation, as heparin bridging may be associated with worsened outcomes after CIED interventions
A 42-year-old woman with Long QT Syndrome Type 1 presents due to RV ICD lead fracture. She has never had a ventricular arrhythmia or syncope and is on nadolol. She had a single-chamber ICD placed at age 17, and her dual-coil Sprint Fidelis lead was abandoned and replaced due to fracture three years later with another dual-coil ICD lead. She has voiced increasing dissatisfaction with the experience of having an ICD. She was recently denied an MRI due to the presence of the abandoned lead.	-Management options include placement of a third ICD lead, extraction of both indwelling leads with replacement, abandoning the leads with or without generator removal and with or without placement of a non-vascular ICD -The patient is very clear that she does not want an ICD of any sort. She also does not want any remaining ICD hardware. Her referring genetic arrhythmia specialist is understanding of the situation and believes she is low risk for cardiac arrest with nadolol therapy -She understands that extraction will be relatively high-risk, but that future extraction, if needed, would likely be of higher risk -She would like to have no barrier to future MRI -The decision was made to proceed with extraction,	-In a scenario of multiple potential reasonable options, patient preference is key -Two dual-coil leads with a combined lead age of 47 years will be a high-risk extraction, and the operator should be prepared to use many different strategies and manage complications -This lead extraction is higher risk due to the decision to abandon a lead that was only indwelling for three years in a young patient; this would rarely be a prudent decision -While MRI could likely be performed with leads or lead fragments left in place, access to MRI may be limited in many centers. Complete system extraction would obviate this potential restriction. -Removal of only the ICD generator is an option, though the risk of lead-

	which was complex and eventually required removal of a lead fragment via the femoral route.	related infection (among others) would be lifelong.
An 82-year-old woman with permanent atrial fibrillation, severe tricuspid regurgitation, and complete heart block with a pacemaker placed 7 years prior presents as part of a heart team discussion during workup for transcatheter tricuspid valve intervention. She is not a candidate for open surgical repair. No escape rhythm is found on underlying rhythm check.	-Transcatheter valve replacement would jail the pacing lead on which this patient is dependent. -If it is determined that transcatheter valve replacement is her only option, then management considerations will first need to consider whether the lead will be extracted or jailed. -Because she is dependent on the lead, the risk of lead failure was deemed too great to rely on a jailed lead -She elected to undergo lead extraction and replacement with a leadless pacemaker prior to the planned tricuspid valve replacement	-Jailing right ventricular pacing leads during transcatheter tricuspid valve replacement carries a high risk of lead fracture and makes future extraction potentially impossible -Transcatheter edge-to-edge repair is favored in these scenarios if possible -If the RV lead were not essential (eg, sick sinus syndrome with no ventricular pacing), then the decision-making would hinge primarily on future extraction considerations in the event of infection -CIED endocarditis without the possibility of lead removal may very well prove fatal

References

1. Poole JE, Gleva MJ, Mela T, et al. Complication rates associated with pacemaker or implantable cardioverter-defibrillator generator replacements and upgrade procedures: results from the REPLACE registry. Circulation 2010;122(16):1553-61. DOI: 10.1161/CIRCULATIONAHA.110.976076.

2. Kramer DB, Kennedy KF, Noseworthy PA, et al. Characteristics and outcomes of patients receiving new and replacement implantable cardioverter-defibrillators: results from the NCDR. Circ Cardiovasc Qual Outcomes 2013;6(4):488-97. DOI: 10.1161/CIRCOUTCOMES.111.000054.

3. Krahn AD, Lee DS, Birnie D, et al. Predictors of short-term complications after implantable cardioverter-defibrillator replacement: results from the Ontario ICD Database. Circ Arrhythm Electrophysiol 2011;4(2):136-42. DOI: 10.1161/CIRCEP.110.959791.

4. Borleffs CJ, Thijssen J, de Bie MK, et al. Recurrent implantable cardioverter-defibrillator replacement is associated with an increasing risk of pocket-related complications. Pacing Clin Electrophysiol 2010;33(8):1013-9. DOI: 10.1111/j.1540-8159.2010.02780.x.

5. Thijssen J, Borleffs CJ, van Rees JB, et al. Implantable cardioverter-defibrillator longevity under clinical circumstances: an analysis according to device type, generation, and manufacturer. Heart Rhythm 2012;9(4):513-9. DOI: 10.1016/j.hrthm.2011.11.022.

6. von Gunten S, Schaer BA, Yap SC, et al. Longevity of implantable cardioverter defibrillators: a comparison among manufacturers and over time. Europace 2016;18(5):710-7. DOI: 10.1093/europace/euv296.

7. Prutkin JM, Reynolds MR, Bao H, et al. Rates of and factors associated with infection in 200 909 Medicare implantable cardioverter-defibrillator implants: results from the National Cardiovascular Data Registry. Circulation 2014;130(13):1037-43. DOI: 10.1161/CIRCULATIONAHA.114.009081.

8. Biffi M, Ammendola E, Menardi E, et al. Real-life outcome of implantable cardioverter-defibrillator and cardiac resynchronization defibrillator replacement/upgrade in a contemporary population: observations from the multicentre DECODE registry. Europace 2019;21(10):1527-1536. DOI: 10.1093/europace/euz166.

9. Lovelock JD, Cruz C, Hoskins MH, et al. Generator replacement is associated with an increased rate of ICD lead alerts. Heart Rhythm 2014;11(10):1785-9. DOI: 10.1016/j.hrthm.2014.06.018.

10. Lovelock JD, Premkumar A, Levy MR, et al. Pulse Generator Exchange Does Not Accelerate the Rate of Electrical Failure in a Recalled Small Caliber ICD Lead. Pacing Clin Electrophysiol 2015;38(12):1434-8. DOI: 10.1111/pace.12734.

11. Lovelock JD, Patel A, Mengistu A, et al. Generator exchange is associated with an increased rate of Sprint Fidelis lead failure. Heart Rhythm 2012;9(10):1615-8. DOI: 10.1016/j.hrthm.2012.06.009.

12. Salgado R, Martin J, Martinez J, et al. Small-Caliber Lead Failure After Generator Exchange. J Cardiovasc Electrophysiol 2016;27(7):846-50. DOI: 10.1111/jce.12994.

13. Chung MK, Fagerlin A, Wang PJ, et al. Shared Decision Making in Cardiac Electrophysiology Procedures and Arrhythmia Management. Circ Arrhythm Electrophysiol 2021;14(12):e007958. DOI: 10.1161/CIRCEP.121.007958.

14. Barra S, Goonewardene M, Heck P, et al. Implantable cardioverter-defibrillator elective generator replacement: a procedure for all? J Interv Card Electrophysiol 2016;45(2):209-18. DOI: 10.1007/s10840-015-0087-0.

15. Andresen H, Pagonas N, Eisert M, et al. Defibrillator exchange in the elderly. Heart Rhythm O2 2023;4(6):382-390. DOI: 10.1016/j.hroo.2023.05.001.

16. Loirat A, Feneon D, Behaghel A, et al. Pacemaker replacement in nonagenarians: Procedural safety and long-term follow-up. Arch Cardiovasc Dis 2015;108(6-7):367-74. DOI: 10.1016/j.acvd.2015.01.014.

17. Kirkfeldt RE, Johansen JB, Nohr EA, Jorgensen OD, Nielsen JC. Complications after cardiac implantable electronic device implantations: an analysis of a complete, nationwide cohort in Denmark. Eur Heart J 2014;35(18):1186-94. DOI: 10.1093/eurheartj/eht511.

18. Yang M, Li X, Liang J, et al. Outcomes of cardiac resynchronization therapy using left ventricular quadripolar leads. Pacing Clin Electrophysiol 2018. DOI: 10.1111/pace.13388.

19. Palmisano P, Accogli M, Zaccaria M, et al. Rate, causes, and impact on patient outcome of implantable device complications requiring surgical revision: large

population survey from two centres in Italy. Europace 2013;15(4):531-40. DOI: 10.1093/europace/eus337.

20. Nemer DM, Patel DR, Madden RA, et al. Comparative Analysis of Procedural Outcomes and Complications Between De Novo and Upgraded Cardiac Resynchronization Therapy. JACC Clin Electrophysiol 2021;7(1):62-72. DOI: 10.1016/j.jacep.2020.07.022.

21. Abu-El-Haija B, Bhave PD, Campbell DN, et al. Venous Stenosis After Transvenous Lead Placement: A Study of Outcomes and Risk Factors in 212 Consecutive Patients. J Am Heart Assoc 2015;4(8):e001878. DOI: 10.1161/JAHA.115.001878.

22. Pieper CC, Weis V, Fimmers R, et al. Venous Obstruction in Asymptomatic Patients Undergoing First Implantation or Revision of a Cardiac Pacemaker or Implantable Cardioverter-Defibrillator: A Retrospective Single Center Analysis. Rofo 2015;187(11):1029-35. DOI: 10.1055/s-0035-1553351.

23. Sweeney MO, Shea JB, Ellison KE. Upgrade of permanent pacemakers and single chamber implantable cardioverter defibrillators to pectoral dual chamber implantable cardioverter defibrillators: indications, surgical approach, and long-term clinical results. Pacing Clin Electrophysiol 2002;25(12):1715-23. DOI: 10.1046/j.1460-9592.2002.01715.x.

24. Morani G, Bolzan B, Valsecchi S, Morosato M, Ribichini FL. Chronic venous obstruction during cardiac device revision: Incidence, predictors, and efficacy of percutaneous techniques to overcome the stenosis. Heart Rhythm 2020;17(2):258-264. DOI: 10.1016/j.hrthm.2019.08.012.

25. Aoukar PS, Poole JE, Johnson GW, et al. No benefit of a dual coil over a single coil ICD lead: evidence from the Sudden Cardiac Death in Heart Failure Trial. Heart Rhythm 2013;10(7):970-6. DOI: 10.1016/j.hrthm.2013.03.046.

26. Scott PA, Chungh A, Zeb M, Yue AM, Roberts PR, Morgan JM. Is the use of an additional pace/sense lead the optimal strategy for the avoidance of lead extraction in defibrillation lead failure? A single-centre experience. Europace 2010;12(4):522-6. DOI: 10.1093/europace/eup406.

27. Wollmann CG, Bocker D, Loher A, et al. Incidence of complications in patients with implantable cardioverter/defibrillator who receive additional transvenous pace/sense leads. Pacing Clin Electrophysiol 2005;28(8):795-800. DOI: 10.1111/j.1540-8159.2005.00169.x.

28. Wollmann CG, Bocker D, Loher A, et al. Two different therapeutic strategies in ICD lead defects: additional combined lead versus replacement of the lead. J Cardiovasc Electrophysiol 2007;18(11):1172-7. DOI: 10.1111/j.1540-8167.2007.00940.x.

29. Bode F, Himmel F, Reppel M, Mortensen K, Schunkert H, Wiegand UK. Should all dysfunctional high-voltage leads be extracted? Results of a single-centre long-term registry. Europace 2012;14(12):1764-70. DOI: 10.1093/europace/eus202.

30. Bashir J, Cowan S, Raymakers A, et al. A cost-effectiveness analysis of a proactive management strategy for the Sprint Fidelis recall: a probabilistic decision analysis model. Heart Rhythm 2013;10(12):1761-7. DOI: 10.1016/j.hrthm.2013.09.067.

31. Kusumoto FM, Schoenfeld MH, Wilkoff BL, et al. 2017 HRS expert consensus statement on cardiovascular implantable electronic device lead management and extraction. Heart Rhythm 2017;14(12):e503-e551. DOI: 10.1016/j.hrthm.2017.09.001.

32. Montgomery JA, Ellis CR. Longevity of Cardiovascular Implantable Electronic Devices. Card Electrophysiol Clin 2018;10(1):1-9. DOI: 10.1016/j.ccep.2017.11.001.

33. Bilchick KC, Wang Y, Cheng A, et al. Seattle Heart Failure and Proportional Risk Models Predict Benefit From Implantable Cardioverter-Defibrillators. J Am Coll Cardiol 2017;69(21):2606-2618. DOI: 10.1016/j.jacc.2017.03.568.

34. Adabag S, Patton KK, Buxton AE, et al. Association of Implantable Cardioverter Defibrillators With Survival in Patients With and Without Improved Ejection Fraction: Secondary Analysis of the Sudden Cardiac Death in Heart Failure Trial. JAMA Cardiol 2017;2(7):767-774. DOI: 10.1001/jamacardio.2017.1413.

35. Russo AM, Stainback RF, Bailey SR, et al. ACCF/HRS/AHA/ASE/HFSA/SCAI/SCCT/SCMR 2013 appropriate use criteria for implantable cardioverter-defibrillators and cardiac resynchronization therapy: a report of the American College of Cardiology Foundation appropriate use criteria task force, Heart Rhythm Society, American Heart Association, American Society of Echocardiography, Heart Failure Society of America, Society for Cardiovascular Angiography and Interventions, Society of Cardiovascular Computed Tomography,

and Society for Cardiovascular Magnetic Resonance. Heart Rhythm 2013;10(4):e11-58. DOI: 10.1016/j.hrthm.2013.01.008.

36. Kusumoto FM, Calkins H, Boehmer J, et al. HRS/ACC/AHA expert consensus statement on the use of implantable cardioverter-defibrillator therapy in patients who are not included or not well represented in clinical trials. J Am Coll Cardiol 2014;64(11):1143-77. DOI: 10.1016/j.jacc.2014.04.008.

37. Kleemann T, Becker T, Doenges K, et al. Annual rate of transvenous defibrillation lead defects in implantable cardioverter-defibrillators over a period of >10 years. Circulation 2007;115(19):2474-80. DOI: 10.1161/CIRCULATIONAHA.106.663807.

38. Zhang Y, Guallar E, Blasco-Colmenares E, et al. Changes in Follow-Up Left Ventricular Ejection Fraction Associated With Outcomes in Primary Prevention Implantable Cardioverter-Defibrillator and Cardiac Resynchronization Therapy Device Recipients. J Am Coll Cardiol 2015;66(5):524-31. DOI: 10.1016/j.jacc.2015.05.057.

39. Langman DA, Goldberg IB, Finn JP, Ennis DB. Pacemaker lead tip heating in abandoned and pacemaker-attached leads at 1.5 Tesla MRI. J Magn Reson Imaging 2011;33(2):426-31. DOI: 10.1002/jmri.22463.

40. Austin CO, Landolfo K, Parikh PP, Patel PC, Venkatachalam KL, Kusumoto FM. Retained cardiac implantable electronic device fragments are not associated with magnetic resonance imaging safety issues, morbidity, or mortality after orthotopic heart transplant. Am Heart J 2017;190:46-53. DOI: 10.1016/j.ahj.2017.04.011.

41. Higgins JV, Gard JJ, Sheldon SH, et al. Safety and outcomes of magnetic resonance imaging in patients with abandoned pacemaker and defibrillator leads. Pacing Clin Electrophysiol 2014;37(10):1284-90. DOI: 10.1111/pace.12419.

42. Schaller RD, Brunker T, Riley MP, Marchlinski FE, Nazarian S, Litt H. Magnetic Resonance Imaging in Patients With Cardiac Implantable Electronic Devices With Abandoned Leads. JAMA Cardiol 2021;6(5):549-556. DOI: 10.1001/jamacardio.2020.7572.

43. Postaci N, Eksi K, Bayata S, Yesil M. Effect of the number of ventricular leads on right ventricular hemodynamics in patients with permanent pacemaker. Angiology 1995;46(5):421-4. DOI: 10.1177/000331979504600509.

44. de Cock CC, Vinkers M, Van Campe LC, Verhorst PM, Visser CA. Long-term outcome of patients with multiple (> or = 3) noninfected transvenous leads: a clinical and echocardiographic study. Pacing Clin Electrophysiol 2000;23(4 Pt 1):423-6. DOI: 10.1111/j.1540-8159.2000.tb00821.x.

45. Lickfett L, Bitzen A, Arepally A, et al. Incidence of venous obstruction following insertion of an implantable cardioverter defibrillator. A study of systematic contrast venography on patients presenting for their first elective ICD generator replacement. Europace 2004;6(1):25-31. DOI: 10.1016/j.eupc.2003.09.001.

46. Czajkowski M, Jachec W, Polewczyk A, et al. Risk Factors for Lead-Related Venous Obstruction: A Study of 2909 Candidates for Lead Extraction. J Clin Med 2021;10(21). DOI: 10.3390/jcm10215158.

47. Suga C, Hayes DL, Hyberger LK, Lloyd MA. Is there an adverse outcome from abandoned pacing leads? J Interv Card Electrophysiol 2000;4(3):493-9. DOI: 10.1023/a:1009860514724.

48. Arora Y, Carrillo RG. Lead-related superior vena cava syndrome: Management and outcomes. Heart Rhythm 2021;18(2):207-214. DOI: 10.1016/j.hrthm.2020.09.006.

49. Pokorney SD, Mi X, Lewis RK, et al. Outcomes Associated With Extraction Versus Capping and Abandoning Pacing and Defibrillator Leads. Circulation 2017;136(15):1387-1395. DOI: 10.1161/CIRCULATIONAHA.117.027636.

50. Kwon S, Lee E, Choi EK, Lee SR, Oh S, Choi YS. Long-term outcomes of abandoned leads of cardiac implantable electronic devices. Heart Rhythm 2023;20(12):1639-1646. DOI: 10.1016/j.hrthm.2023.07.068.

51. Alqarawi W, Coppens J, Aldawood W, et al. A Strategy of Lead Abandonment in a Large Cohort of Patients With Sprint Fidelis Leads. JACC Clin Electrophysiol 2019;5(9):1059-1067. DOI: 10.1016/j.jacep.2019.07.006.

52. Elgaard AF, Johansen JB, Nielsen JC, et al. Long-term follow-up of abandoned transvenous defibrillator leads: a nationwide cohort study. Europace 2020;22(7):1097-1102. DOI: 10.1093/europace/euaa086.

53. Bracke F, Rademakers LM. When pacing or defibrillator leads become redundant: Extract or abandon? Heart Rhythm 2025;22(2):405-410. DOI: 10.1016/j.hrthm.2024.07.113.

54. Hussein AA, Tarakji KG, Martin DO, et al. Cardiac Implantable Electronic Device Infections: Added Complexity and Suboptimal Outcomes With Previously

Abandoned Leads. JACC Clin Electrophysiol 2017;3(1):1-9. DOI: 10.1016/j.jacep.2016.06.009.

55. Merchant FM, Tejada T, Patel A, et al. Procedural outcomes and long-term survival associated with lead extraction in patients with abandoned leads. Heart Rhythm 2018;15(6):855-859. DOI: 10.1016/j.hrthm.2018.01.018.

56. Boyle TA, Uslan DZ, Prutkin JM, et al. Impact of Abandoned Leads on Cardiovascular Implantable Electronic Device Infections: A Propensity Matched Analysis of MEDIC (Multicenter Electrophysiologic Device Infection Cohort). JACC Clin Electrophysiol 2018;4(2):201-208. DOI: 10.1016/j.jacep.2017.09.178.

57. Segreti L, Rinaldi CA, Claridge S, et al. Procedural outcomes associated with transvenous lead extraction in patients with abandoned leads: an ESC-EHRA ELECTRa (European Lead Extraction ConTRolled) Registry Sub-Analysis. Europace 2019;21(4):645-654. DOI: 10.1093/europace/euy307.

58. Jachec W, Polewczyk A, Segreti L, Bongiorni MG, Kutarski A. To abandon or not to abandon: Late consequences of pacing and ICD lead abandonment. Pacing Clin Electrophysiol 2019;42(7):1006-1017. DOI: 10.1111/pace.13715.

59. Lee JZ, Talaei F, Tan MC, et al. Long-term outcomes with abandoning versus extracting sterile leads: A 10-year population-based study. Pacing Clin Electrophysiol 2024;47(5):626-634. DOI: 10.1111/pace.14940.

60. Nakajima H, Seo Y, Ishizu T, et al. Features of Lead-Induced Tricuspid Regurgitation in Patients With Heart Failure Events After Cardiac Implantation of Electronic

Devices - A Three-Dimensional Echocardiographic Study. Circ J 2020;84(12):2302-2311. DOI: 10.1253/circj.CJ-20-0620.

61. Park SJ, Gentry JL, 3rd, Varma N, et al. Transvenous Extraction of Pacemaker and Defibrillator Leads and the Risk of Tricuspid Valve Regurgitation. JACC Clin Electrophysiol 2018;4(11):1421-1428. DOI: 10.1016/j.jacep.2018.07.011.

62. Dhindsa DS, Mekary W, El-Chami MF. Pacing and Defibrillation Consideration in the Era of Transcatheter Tricuspid Valve Replacement. Curr Cardiol Rep 2024;26(5):331-338. DOI: 10.1007/s11886-024-02032-7.

63. Anderson JH, McElhinney DB, Aboulhosn J, et al. Management and Outcomes of Transvenous Pacing Leads in Patients Undergoing Transcatheter Tricuspid Valve Replacement. JACC Cardiovasc Interv 2020;13(17):2012-2020. DOI: 10.1016/j.jcin.2020.04.054.

64. Mekary W, Ibrahim R, Lloyd MS, et al. Pacing considerations in patients undergoing transcatheter tricuspid valve replacement: Insights from a tertiary care center. Heart Rhythm 2025. DOI: 10.1016/j.hrthm.2025.02.004.

65. Chandran K, Long A, Bishop J, et al. First In-Man Experience With TricValve Transcatheter Bicaval Valve System in Left Ventricular Assist Device Heartmate II Patient for High-Risk Tricuspid Regurgitation. Circ Heart Fail 2023;16(6):e010027. DOI: 10.1161/CIRCHEARTFAILURE.122.010027.

66. Deharo JC, Dreyfus J, Bongiorni MG, et al. Management of patients with transvalvular right ventricular leads undergoing transcatheter tricuspid valve interventions: a scientific statement of the European Heart Rhythm Association and

the European Association of Percutaneous Cardiovascular Interventions of the ESC endorsed by the Heart Rhythm Society, the Asian Pacific Heart Rhythm Society and the Canadian Heart Rhythm Society. Europace 2025;27(5). DOI: 10.1093/europace/euaf061.

67. Knops RE, Reddy VY, Ip JE, et al. A Dual-Chamber Leadless Pacemaker. N Engl J Med 2023;388(25):2360-2370. DOI: 10.1056/NEJMoa2300080.

68. Reynolds D, Duray GZ, Omar R, et al. A Leadless Intracardiac Transcatheter Pacing System. N Engl J Med 2016;374(6):533-41. DOI: 10.1056/NEJMoa1511643.

69. Li J, Hou WB, Cao MK, et al. Safety and efficacy of leadless pacemaker retrieval. J Cardiovasc Electrophysiol 2019;30(9):1671-1678. DOI: 10.1111/jce.14076.

70. Garweg C, Chinitz JS, Marijon E, et al. A leadless ventricular pacemaker providing atrioventricular synchronous pacing in the real-world setting: 12-Month results from the Micra AV post-approval registry. Heart Rhythm 2024;21(10):1939-1947. DOI: 10.1016/j.hrthm.2024.06.008.

71. Reddy VY, Miller MA, Knops RE, et al. Retrieval of the Leadless Cardiac Pacemaker: A Multicenter Experience. Circ Arrhythm Electrophysiol 2016;9(12). DOI: 10.1161/CIRCEP.116.004626.

72. Russo AM, Desai MY, Do MM, et al. ACC/AHA/ASE/HFSA/HRS/SCAI/SCCT/SCMR 2025 Appropriate Use Criteria for Implantable Cardioverter-Defibrillators, Cardiac Resynchronization Therapy, and Pacing. J Am Coll Cardiol 2025;85(11):1213-1285. DOI: 10.1016/j.jacc.2024.11.023.

Section 8. Diagnosis, Management, and Prevention of CIED Infection

CIED infection is one of the most feared and serious complications of device therapy due to associated morbidity, prolonged hospitalizations, need for costly and repeated interventions, and increased mortality.[1] Although removal of infected hardware has been the fundamental and logical cornerstone of CIED infection management for several decades, establishing a clear diagnosis can be challenging due to the lack of any single diagnostic test that is considered definitive. In the setting of obvious CIED pocket abnormalities (eg, incisional dehiscence, purulence, drainage, erosion), device infection may be a relatively straightforward diagnosis. However, when a patient presents with bacteremia and no local signs of pocket infection, confirming CIED involvement can be difficult. Reliance on TTE or TEE imaging must be constrained by the inability to reliably distinguish non-infected echo densities from infectious vegetations.[2] Further complicating the diagnostic challenges, CIED lead infection may be present in the absence of abnormalities on echocardiographic or nuclear medicine imaging, and abnormal pocket findings overlap with superficial infection or inflammation due to non-infectious causes.[3] Establishing the diagnosis is time-sensitive, since evidence shows early definitive antimicrobial treatment combined with system removal is associated with improved outcomes. This includes early involvement by expert centers with multidisciplinary extraction teams.

8.1. Initial Evaluation and Diagnosis of CIED Infection

Recommendations for Initial Evaluation and Diagnosis of CIED Infection

COR	LOE	Recommendations	References
1	C-LD	**1. In patients with a suspected CIED pocket or systemic infection, drawing ≥ 2 sets of blood cultures before initiation of antibiotic therapy is recommended to enhance microbial detection and distinguish true bloodstream infection from blood culture contamination from skin flora.**	4, 5, 6
2b	C-LD	**2. In stable patients with suspected CIED pocket infection (without fever, hypotension, leukocytosis, or other systemic signs and symptoms, it may be reasonable to withhold antibiotic therapy until device removal to improve the yield of pocket tissue culture**	7
1	C-LD	**3. In patients with suspected CIED pocket or bloodstream infection, transthoracic echocardiogram is recommended as initial imaging to assess lead-related echo densities and concurrent native or prosthetic valvular involvement.**	8,9, 6
1	C-LD	**4. In patients with suspected CIED infection, transesophageal echocardiogram is recommended to identify the presence, size and mobility of lead vegetation if findings on transthoracic echocardiogram are negative or**	10,6, 2, 11

		inconclusive, and there is high suspicion of systemic infection.	
2a	**B-NR**	**5. In patients with a suspected CIED infection and inconclusive echocardiographic imaging findings, 18-F-FDG PET/CT is reasonable to improve diagnostic accuracy, particularly for pocket involvement.**	12, 13

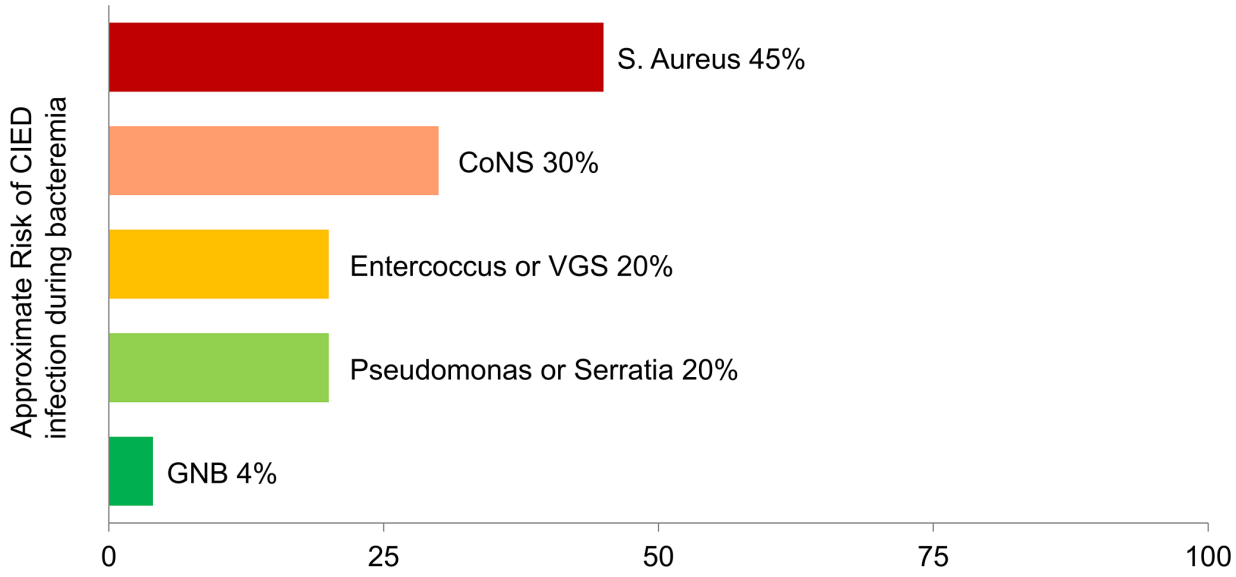
Synopsis

Timely and accurate diagnosis is the foundational principle for optimal management of suspected CIED infection, yet there is no gold standard for diagnosis, and establishing definite CIED infection is often challenging. Initial evaluation should include a focused history, including the timeline and scope of device interventions, symptoms, and laboratory evaluation consisting of infectious and inflammatory markers. Blood cultures are essential in all patients with suspected CIED infection, even if the origin of infection is the CIED pocket. Blood cultures should be obtained prior to the initiation of antibiotic therapy for the best yield. Obtaining ≥ 2 blood cultures enhances diagnostic accuracy and helps differentiate true bacteremia from contamination, particularly when the organism detected in blood culture is an uncommon cause of CIED infection or part of normal skin flora. Imaging, whether echocardiographic or nuclear, has assumed increasing importance in establishing the diagnosis of CIED infection.

Recommendation-specific supportive text

Recommendation 1: Although no studies specific to CIED infection and timing or number of blood cultures have been performed, standard clinical care and extrapolated evidence support obtaining ≥ 2 sets of blood cultures prior to administration of antibiotic therapy to optimize the diagnostic yield of cultures. A multicenter observational study of patients with sepsis showed blood culture positivity decreased by nearly 50% within 2 hours of antibiotic administration (31% positive vs. 19% positive)[4]. While not specific to CIED infection, these data highlight the importance of early blood culture acquisition. In CIED infection, bloodstream involvement is common; in a registry of 39 CIED infections of 2029 implants, 90% of whom had abnormal pocket findings, 54% had positive blood cultures.[5] However, concordance between blood and lead tip cultures was only 35%. In a cohort of patients with clinical signs of pocket infection, 65% had evidence of lead-associated endocarditis, highlighting the risk of systemic infection in patients presenting with pocket infection.[6] Early blood cultures are critical to the diagnosis of bloodstream infection and to guide antimicrobial therapy. **Figure 1** shows the risk of CIED infection during bacteremia.

Figure 1: **Risk of CIED infection during bacteremia. S. Aureus: Staphylococci aureus; CoNS: Coagulase-negative Staphylococci; VGS: Viridians group streptococci; GNB: other Gram-negative bacteria.**



Recommendation 2: In a retrospective series of 95 patients with CIED pocket infection, patients without evidence of bloodstream infection who did not receive pre-extraction antibiotics were found to have a trend of higher frequency of positive intraoperative pocket and device cultures compared with patients treated with antibiotics prior to extraction (79.4% vs. 58.6%; p = 0.06).[7] Importantly, evidence of a systemic inflammatory response (tachycardia, tachypnea, fever, hypothermia, or hypotension) was an independent predictor of bloodstream infection, allowing identification of patients requiring immediate antibiotic therapy. In clinically stable patients with pocket infection without systemic signs of infection, deferring antibiotics until the time of CIED removal may improve diagnostic yield of pocket and hardware culture and facilitate pathogen identification, essential for targeted antimicrobial therapy post extraction.

Recommendation 3: Although transthoracic echocardiogram (TTE) has limited sensitivity for detecting CIED lead infection, it is a useful imaging modality for detecting lead-related

or valvular echo densities, particularly given its wide availability and low risk. In retrospective series of patients with CIED infection, TTE identifies vegetations in 23-30%.[8,9] In the multicenter MEDIC registry, TTE detected lead-related vegetations only in 7-10% of patients with CIED-related endocarditis, mostly when the vegetation size was greater than 1 cm.[6] Transesophageal echocardiogram (TEE) not only has substantially higher sensitivity for lead involvement, TEE can also provide valuable information with respect to the presence, size and mobility of echo densities, and can guide planning of further diagnostic or management steps. Both TTE and TEE are limited by their inability to accurately discern if a given echo density is a vegetation or represents thrombotic or fibrotic material.[2]

Recommendation 4: TEE offers greater sensitivity compared with TTE for detecting CIED lead echo densities and vegetations. In patients with a CIED and *Staphylococcus aureus* bacteremia, the sensitivity of TTE was 63% and TEE was substantially better at 88%.[11] A retrospective review of 160 patients with non-*Staphylococcus aureus* bloodstream infection, TEE identified lead or valvular vegetations in 54% of patients, compared with only 5% by TTE.[10]. Similarly, in the MEDIC registry, only 8% of patients with confirmed CIED-related endocarditis had vegetations detected by TTE, while all had findings on TEE.[6] However, it is important to recognize that echo densities seen on TEE are not specific for infection and echocardiographers are unable to reliably distinguish infected from non-infected echo densities in blinded review.[2] Therefore, while TEE enhances detection and can support diagnosis in high-suspicion cases, interpretation of results must be integrated with clinical and microbiologic data.

Recommendation 5: 18F-FDG PET/CT has emerged as a valuable adjunctive imaging modality in the evaluation of suspected CIED infections, particularly when echocardiographic imaging is inconclusive. A systematic review and meta-analysis of 14 studies involving 492 patients reported an overall pooled sensitivity of 83% and specificity of 89%. Diagnostic accuracy for CIED-related endocarditis was lower than for pocket infections (76% vs. 96% sensitivity, respectively).[12] A larger systematic review and meta-analysis of subtypes of infective endocarditis, including 26 studies and 1358 patients, reported an overall sensitivity of 72% and specificity of 83% for CIED-related endocarditis. Notably, pooled sensitivity and specificities were higher for studies published since 2015, suggesting improved performance over time.[13] Although comparative data are sparse, radiolabeled white blood cells, single photon emission CT has been shown to have high sensitivity and specificity for CIED infection as an alternative to 18F-FDG PET/CT and may improve the diagnostic accuracy of the modified Duke-ISCCID Criteria.[14]

8.2. Management of CIED Pocket Infection

A CIED pocket can become infected at the time of implantation, during subsequent surgical access, or seeding from a secondary source that results in disseminated bloodstream infection, which infects the hardware. Patients with a CIED pocket infection can present with localized erythema (41%), swelling (38%), pain (28%), warmth (18%), drainage (38%), or device erosion with exposure (21%).[15] In the acute setting after device implant or reintervention, erythema, tenderness, and swelling can represent healing, hematoma, a superficial infection, or a true pocket infection. Patients with pocket infection may have bloodstream lead involvement leading to fever, chills, malaise, fatigue,

or anorexia, yet can present without systemic symptoms or signs even in the presence of lead vegetations or bacteremia. Device erosion usually occurs quite late after a CIED procedure. Once hardware is exposed through the skin, it is deemed infected because it is in direct contact with skin pathogens. Patients who present with device erosion are less likely to have associated systemic infection. [16]

Recommendations for Management of CIED Pocket Infection			
COR	**LOE**	**Recommendations**	**References**
1	**B-NR**	**6. In patients with CIED pocket infection (clinical signs of pocket purulence, abscess, dehiscence, erosion), complete device system removal with thorough debridement of infected material, fibrotic capsule, and all non-absorbable sutures, followed by pocket irrigation is recommended for effective infection management.**	17, 18, 19
2b	**C-LD**	**7. In patients with CIED pocket infection who are at a prohibitively high risk for complications from lead extraction or who decline complete system removal, a salvage strategy that includes pocket debridement and chronic suppressive antibiotic therapy may be considered.**	20,21

1	**C-LD**	**8. In patients with CIED pocket infection, gram stain and culture of pocket tissue and leads are recommended at device removal to improve identification of causative pathogens and guide antimicrobial therapy.**	22, 23
2b	**C-LD**	**9. In patients with CIED pocket infection, use of advanced diagnostic technology such as vortexing-sonication or 16S/18s rRNA polymerase chain reaction sequencing of pocket tissue or explanted device components (generator or leads) may be considered to increase identification of causative pathogens.**	24,25,26

Synopsis

Removal of all CIED hardware (generator, leads, anchoring sleeves, sutures, etc.) is consistently associated with improved outcomes in CIED pocket infection. In addition to hardware removal, thorough debridement and irrigation of the pocket is warranted. Device system removal provides the opportunity for pocket and removed hardware cultures that can guide antimicrobial therapies. Advanced microbial identification techniques can improve diagnostic accuracy, particularly in culture-negative cases or after antibiotic exposure. Many small series of operative salvage strategies have shown good clinical

success for managing patients in whom lead extraction poses a prohibitive risk, or who decline extraction, albeit with higher recurrence rates.

Recommendation-specific supportive text

Recommendation 6: Complete removal of all CIED hardware is a cornerstone of the management of CIED pocket infections. Observational studies consistently demonstrate an association between device removal with improved outcomes compared to medical therapy with antibiotics alone. Although specific surgical management strategies are not discussed in these publications, debridement, removal of all infected material, and irrigation are the standard of care in the surgical management of infections[27,28]In a single-center observational cohort study of 189 patients with CIED infection, 69% of whom had pocket infection, 98% underwent complete device removal. When combined with antibiotic therapy, this resulted in a 96% cure rate.[17] A systematic review and meta-analysis of 32 studies, including 1100 patients with a CIED infection or endocarditis with an indwelling CIED, reported an association with a lower risk of relapse and a lower risk of mortality (odds ratio 0.52, 95% CI 0.34-0.78, p = 0.002).[19] However, a Medicare cohort study of 11,304 patients with CIED infection showed that device removal rates were only 18.6% within 30 days of diagnosis. Earlier extraction was associated with an adjusted hazard ratio of 0.82 for mortality.[18]

Recommendation 7: In selected patients with CIED pocket infection who either are not candidates for complete hardware removal or who decline extraction, limited observational evidence supports salvage strategies such as pocket debridement and generator relocation[29], or negative pressure wound therapy (NPWT) combined with chronic

suppressive antibiotic therapy. In a nonrandomized observational series of 80 patients with pocket infection, continuous in situ-targeted ultrahigh concentration of antibiotics (CITA) was curative in 85% at a median follow-up of 3 years, compared with a 96% cure rate for 81 patients who underwent extraction.[20] Rates of serious complications were higher in the extraction group (15% vs. 1.5%, p = 0.005), and all-cause mortality at one year was similar in the two groups. Over 15 small series report successful outcomes with surgical salvage approaches, including the "Removal, Excision, Sterilization and Quarantine" (RESQ) method[30], NPWT[31], flap coverage[32], and varying pocket revision techniques[29,33,34]. However, long-term success rates vary, ranging from < 50% to 100% at one year, and failure is unsurprisingly more common in cases with lead vegetations or *Staphylococcus aureus* infection.[20,21,29-34] Overall, these data support salvage as a reasonable palliative or bridging option in selected patients, though recurrence rates are higher compared with extraction. Most studies included only patients with localized pocket involvement, and patient-specific risks must be carefully weighed.

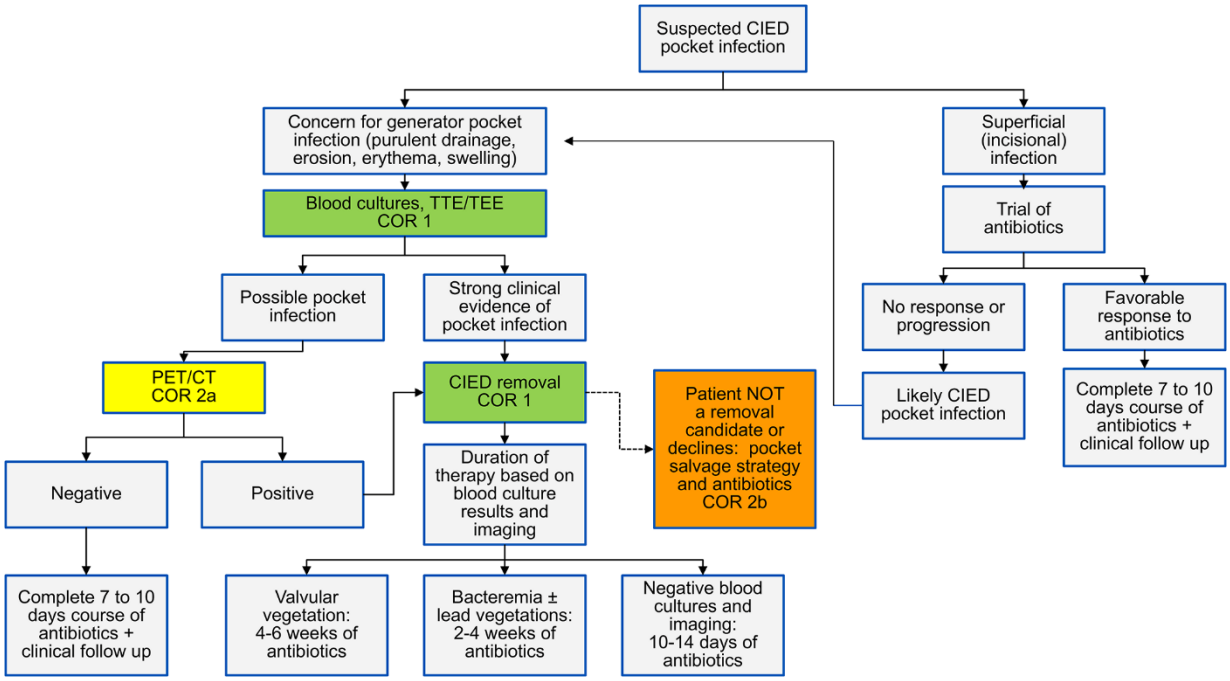
Recommendation 8: Gram stain and culture of pocket tissue and lead tips at the time of CIED removal increases detection of pathogens and guides antimicrobial therapy in patients with CIED pocket infection. In a prospective, single-center, observational study of 71 patients undergoing lead extraction for infection, pocket tissue cultures were positive in 69%, compared with a 31% positivity rate for pocket swab cultures.[22] Importantly, 28% of patients without clinically evident pocket infection had positive cultures, suggesting pocket infection may be present even when clinical abnormalities are absent. Similarly, in a multicenter observational study of 105 patients with CIED infection, cultures from the

pocket segment and tips were positive in 92% and 79% respectively, while wound swabs were positive in 38% of cases.[23] Of note, positive tissue culture does not always represent infection. In a series of 122 patients without evidence of CIED infection undergoing generator replacement or lead intervention, 33% had positive cultures from pocket tissue or leads. After a median follow-up of 203 days, device infection was diagnosed in 3 patients (7.5%) with a positive culture and 2 patients with a negative culture.[35]

Recommendation 9: Microbial detection may be improved by sonication of explanted CIED components and pocket tissue, particularly in patients with negative conventional cultures or who have had prior antibiotic exposure. Two recent systematic reviews and meta-analyses have evaluated the diagnostic utility of sonication in addition to traditional cultures. Martín-Gutiérrez et. al. included 9 studies reviewing 1838 cultures and reported an overall higher sensitivity (76% vs. 49%) and a lower specificity (77% vs. 87%) compared with non-sonicated cultures[24]. False positives were more common with sonication (24% vs. 17%), but the use of a threshold could decrease this rate. Similarly, Araújo et. al. included 8 studies with 519 patients and found sonication resulted in an overall sensitivity of 82% and specificity of 63% in sonicated cultures.[25] This study also reported a higher false-positive rate with sonication, particularly in patients without a clinical infection. In a study of 322 specimens of sonicate fluid from extracted CIEDs, 16S ribosomal RNA gene (rRNA) polymerase chain reaction (PCR)/sequencing had a higher sensitivity compared with fluid culture (64% vs. 56%, p = 0.003) and detected a pathogen in 28/118 culture-negative cases of clinical infection. [26]

Figure 2 shows an evaluation, diagnosis and management flow chart for patients with suspected CIED pocket infection.

Figure 2: Suspected CIED Pocket Infection



8.3. Management of Patients with a CIED and *Staphylococcus aureus* Bacteremia or Endocarditis

Recommendations for Management of Patients with a CIED and *Staphylococcus Aureus* Bloodstream Infection or Endocarditis			
COR	**LOE**	**Recommendations**	**References**

1	**C-LD**	**10. In patients with CIED and *Staphylococcus aureus* bacteremia with lead involvement by imaging, CIED system removal is indicated to reduce infectious complications and ensure improved outcomes.**	36, 37, 38,39
1	**B-NR**	**11. In patients with persistent Staphylococcus aureus bacteremia for more than 4 days, CIED system removal is indicated to reduce the risk of relapse.**	36,40
2a	**C-LD**	**12. In patients with CIED and *Staphylococcus aureus* bacteremia without conclusive evidence of lead infection, CIED system removal is reasonable to reduce the risk of recurrent infection.**	41,42
2a	**C-LD**	**13. In patients with Staphylococcus aureus bacteremia and no signs of pocket infection or vegetation by TEE, validated risk scores, including PREDICT-SAB, can be useful to determine the risk of associated CIED infection and guide CIED management decisions.**	36

Synopsis

Staphylococcus aureus is a notably virulent bacterium that accounts for 25% of CIED infections. Staphylococcal pathogens are resistant to antimicrobial therapy and host defenses because they form a protective biofilm of layers of extracellular polymeric matrix which limits the penetrability of antibiotics coupled with creating a protective microclimate that allows bacteria to persist in a dormant state, relatively impervious to

antibiotic's bactericidal effect and host defences.[43] When S. aureus bacteremia (SAB) occurs in patients with a CIED, there should be a high index of suspicion for infection, and evaluation should be timely and comprehensive. For patients with definite or possible CIED infection in the setting of SAB, complete CIED system removal is associated with a reduction of infectious complications and improved mortality. In cases where CIED involvement is indeterminate, empiric device removal or risk stratification using the PREDICT-SAB score is supported by observational evidence.

Recommendation-specific supportive text

Recommendation 10: In a single-center cohort of patients with SAB, the incidence of confirmed CIED infection by imaging or microbiology was 15 of 33 (45%), and no local pocket signs or symptoms were evident in 60% of those with infected CIED systems.[37] Although not randomized, treatment failure was reported in 52% of patients not undergoing extraction compared with 25% in those who underwent extraction.[37] In a more recent single-center survey of 110 patients with CIED who developed SAB and underwent TEE, 52% were diagnosed with definite and 28% possible CIED infection.[39] Of those with definite CIED infection, 80% underwent CIED extraction, and there was an association with reduced mortality in the extraction group. However, there was no overall difference in 1-year mortality between the three groups, comprising definite infection, probable, and rejected.[39] In a Swedish county hospital cohort, of 61 cases of SAB in patients with a CIED, 21% were diagnosed with CIED-related endocarditis.[38] Death occurred in the hospital in 31%, 56% were discharged with a retained CIED and 13% were discharged after CIED removal. No recurrences were seen in the removal group; in 4 cases with CIED

endocarditis, discharged with a device, one had a recurrence. Among 30 patients discharged with a retained CIED and no evidence of endocarditis, 73% had no further related events.[38] The heterogeneity within the population of SAB with a CIED suggests that a management strategy based on an individual risk-benefit analysis could be an alternative to mandatory device removal. However, in addition to antibiotic resistance, *S. aureus* is a particularly challenging pathogen to eradicate from implanted devices due to its ability to form a protective biofilm matrix that hinders antibiotic penetration and normal immune response,[44] resulting in reduced risk of recurrent infection with hardware removal.

Recommendation 11: Persistent SAB is strongly associated with CIED infection, even in the absence of overt clinical findings.[40] In a single-center retrospective review of SAB of 131 patients with CIED and no clinical signs of pocket infection, 34% were found to have CIED infection by clinical or echocardiographic criteria.[36] A duration of SAB of ^{3} 4 days was an independent predictor of CIED infection.[36]

Recommendation 12: *S. aureus* accounts for the majority of CIED endovascular infections, and underlying CIED infection should always be considered in patients with SAB.[45] [36] Limited observational data support consideration of empiric CIED removal to reduce the risk of recurrent infection. In a single-center study of 360 patients with CIED and SAB, 178 (49%) had no evidence of CIED infection, yet 10% underwent empiric CIED removal.[41] In those who did not undergo removal, SAB relapse was reported in 19% and was associated with the duration of SAB. One-year mortality for the entire cohort was 35% and empiric CIED removal was associated with a decreased risk of mortality (hazard ratio 0.28; 95% CI 0.08-0.95; p = 0.04).[41] Similarly, in a Swedish cohort of 274 patients with CIED

and SAB, endocarditis was diagnosed in 14% (50% with CIED involvement, but 92% with left heart involvement).[42] Extraction was performed in 14% of patients, half of whom had definite endocarditis, and half who did not. Recurrence was seen in 6%, 2 in the extraction group (5%) and 14 who had not undergone extraction (6%).[42]

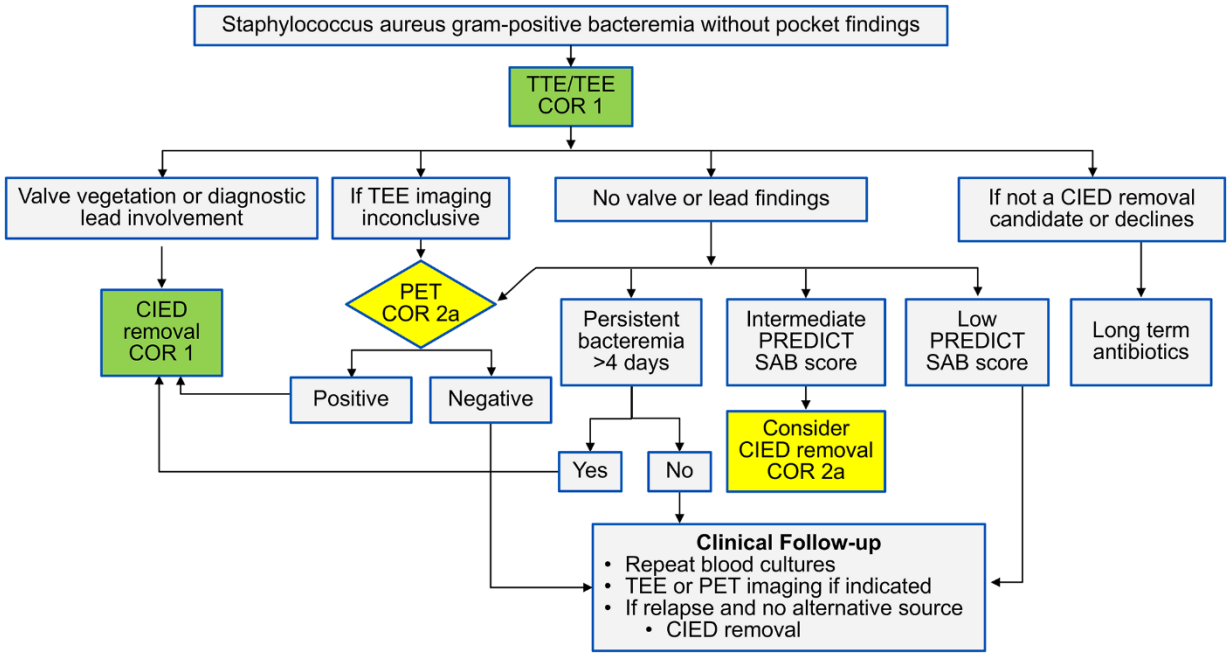
Recommendation 13: Accurately determining whether a CIED is infected in the setting of SAB can be challenging and poses a critical clinical dilemma in the clinical care of CIED patients. The PREDICT-SAB score, developed from a retrospective cohort of 131 patients with CIED and SAB without signs of pocket infection, assists in identifying patients at the highest and lowest risk of CIED infection[36]. Patients without any of the 3 high-risk features of 1) presence of a permanent pacemaker, 2) history of more than one CIED procedure, and 3) SAB persisting for ^{3} 4 days, had a low risk of CIED infection and may be managed without device extraction but with close follow-up and monitoring.[36] (**see The PREDICT-SAB risk score table**). **Figure 3** shows the suggested algorithm for evaluation and management in SAB.

Table 1: PREDICT SAB Scoring

PREDICT SAB Score	Probability of CIED Infection
0.0	0.07
3.5	0.20
4.0	0.23
5.0	0.29
7.5	0.49
8.5	0.58
9.0	0.62
12.5	0.84

Table legend: PREDICT SAB Scoring: SAB ≥ 4 days = 5 points, Pacemaker = 4 points, > 1 device procedure = 3.5 points

Figure 3: S. aureus bacteremia without pocket abnormality



8.4. Management of Patients with a CIED and Non-*Staphylococcus aureus* Bacteremia or Endocarditis

Recommendations for Management of Patients with a CIED and Non-Staphylococcus Aureus Bacteremia or Endocarditis			
COR	**LOE**	**Recommendations**	**References**
1	**C-LD**	**14. In patients with a CIED and bloodstream infection with non-S.aureus gram-positive organisms (CoNS, Enterococcus, Viridans group of streptococci), and CIED lead vegetation or involvement by advanced imaging, CIED system removal is recommended to reduce the risk of relapse.**	46,10
2a	**C-LD**	**15. In patients with CIED and high risk non-Staphylococcal (*CoNS, Enterococcus, Viridans group of streptococci, P. aeruginosia, S. marascens)* BSI and absence of alternative source of bacteremia, CIED removal can be useful to reduce the risk of recurrent infection.**	46,10
2b	**C-LD**	**16. In patients with CIED and bloodstream infection with non-S. aureus gram-positive organisms, but without signs of CIED infection or suggestive imaging, the**	46, 10

		usefulness of CIED system removal is not well established.	
2a	**C-LD**	**17. In patients with CIED and gram-negative bacteremia without pocket involvement, suggestive imaging, or known alternative source of bacteremia, conservative management with antibiotics is reasonable.**	47, 48

Synopsis

The likelihood of CIED infection in the setting of bacteremia varies substantially by the organism type and species. Therefore, understanding the pathogenicity of the specific microbe is critical to assessing the risk of infection and the benefit of hardware removal. Non-*S. aureus* bloodstream infections with Coagulase-negative *Staphylococcus* (CoNS), Enterococcus or *Viridans Group Streptococci* (VGS) demonstrate a higher risk for secondary CIED infection, and a higher level of concern is therefore warranted in the setting of bacteremia. Similarly, *Pseudomonas aeruginosa* and *Serratia marcescens* have a substantially higher likelihood of indwelling CIED infection compared to other gram-negative bacteria.

Recommendation-specific supportive text

Recommendation 14: A retrospective single-center review of 74 patients with non-S. aureus gram-positive (non-SA GPC) bacteremia and a CIED found that 30% were diagnosed with a CIED infection.[46] The most common agent was coagulase-negative

staphylococci (CoNS), and a lead vegetation was noted in 68% of those with CIED infection. Patients without evidence of CIED infection who did not undergo CIED system removal had a recurrence rate of 15%, and all relapses occurred in CoNS infections. However, none of these patients had demonstrable CIED infection at the time of relapse, and several had alternative sources of infection.[46] There was no difference in the mortality rate of those who underwent CIED removal vs. those who did not. These findings suggest routine device removal in the absence of imaging-based evidence of CIED infection is not required for patients with Gram-positive cocci (GPC) bacteremia not due to *S. aureus*. However, TEE imaging is necessary in patients with a CIED and a GPC bacteremia for the diagnosis of CIED infection. A more recent observational study from the same center of 160 patients with a CIED and non-SA GPC bacteremia reported infection in 56%.[10] The adjusted odds of CIED infection in cases due to CoNS, Enterococcus, and viridans group streptococci were 19-, 14-, and 15-fold higher than other non-SA GPC.[10] There were no differences in mortality between the group of patients who underwent CIED removal for infection and the group that did not.[10] Given the differences in CIED infection rates based on microbiology, treatment decisions should be guided by organism-specific data.

Recommendation 15: In a retrospective, observational series of 160 patients with a CIED and non-SA GPC bacteremia, CIED infection was diagnosed in 56%.[10] In cases due to CoNS (46%), Enterococcus (33%), and Viridians group streptococci (14%), the adjusted odds of CIED infection were substantially higher than in other non-SA GPC (19-, 14-, and 15-fold, respectively).[10] However, there were no differences in mortality between the group of patients who underwent CIED removal for infection and the group that did not.[10] In

some series, a higher rate of CIED infection has been described in patients with *Serratia marcescens* bacteremia compared with other GNB.[47] Notably, a prospective cohort study of 284 patients with CIED and bacteremia showed that the risk of CIED infection varied by species and that patients with Pseudomonas aeruginosa and Serratia marcescens had an elevated risk of CIED infection compared to other species of Gram-negative bacteremia.[48] These data support stratifying CIED infection risk by infecting organism.

Recommendation 16: A retrospective single-center study of 74 patients with non-*S. aureus* gram-positive (non-SA GPC) bacteremia and a CIED reported a 30% rate of CIED infection.[46] Among those patients who did not have diagnosed CIED involvement and did not undergo device removal, the relapse rate was 15% within three months, but relapses were largely attributable to alternative sources of infection rather than CIED infection.[46] Mortality rates were similar regardless of whether device extraction was performed or not.[46] In a later series of 160 patients with CIED and non-SA GPC bacteremia, mortality did not differ between patients with CIED infection and non-GPC bacteremia who underwent extraction or did not undergo extraction.[10] These findings suggest that while a risk of relapse exists, particularly with CoNS bacteremia, routine extraction in the absence of imaging or clinical evidence of CIED infection may not always be necessary. Treatment decisions should therefore be individualized, balancing the risks of extraction for that patient against the relatively low rate of proven device-related relapse.

Recommendation 17: A retrospective, single-center, observational series of 126 patients with a CIED and gram-negative bacteremia (GNB) without clinical pocket infection reported definite CIED infection in 3% and probable in 8%. CIED extraction was performed

in 4 patients, 2 with possible and 2 with rejected CIED infection.[47] None of the patients in the definite or possible CIED infection groups had relapsing GNB, despite no device extraction. There was no difference in 1-year survival between the definite/possible and the rejected CIED infection groups.[47] These findings support that routine removal of CIED hardware may not be necessary in all GNB due to low rates of relapse in the setting of device retention and that clinical decision-making must take species into account when considering risk and benefit.

Figure 4 illustrates the algorithm for evaluation and management of Non-S. aureus gram-positive bacteremia without pocket abnormality. **Figure 5** illustrates the algorithm for evaluation and management of Gram-negative bacteremia without a pocket abnormality

Figure 4: Non-S. aureus gram-positive bacteremia without pocket abnormality

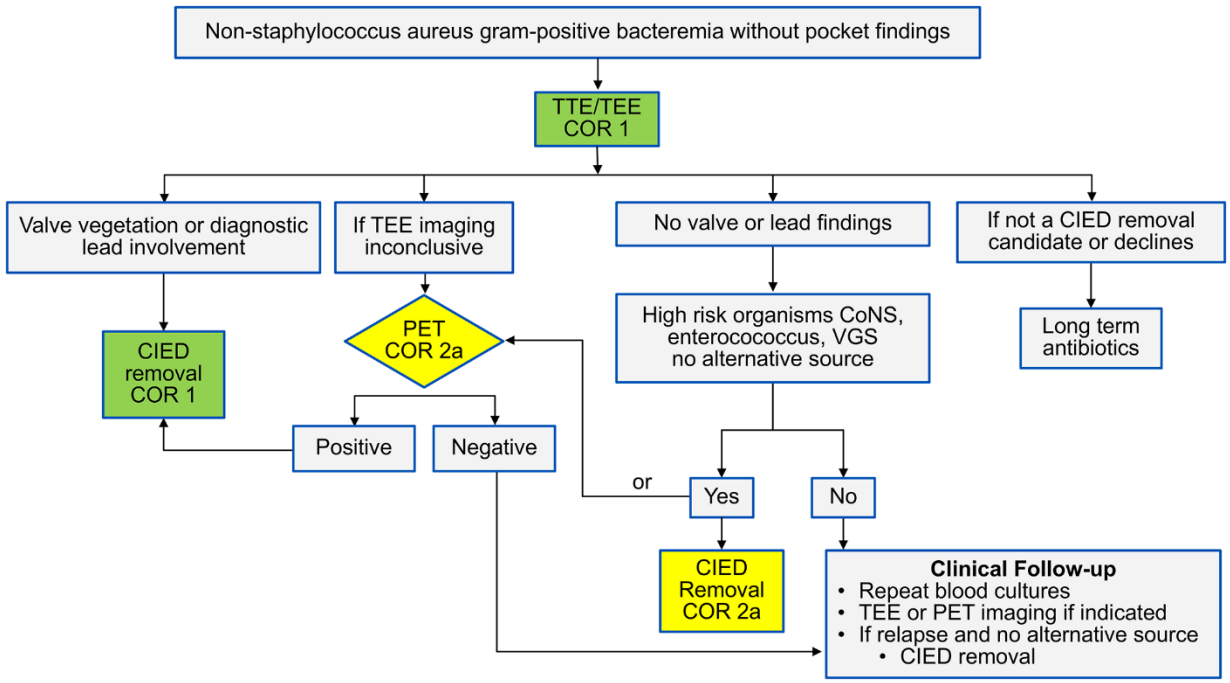
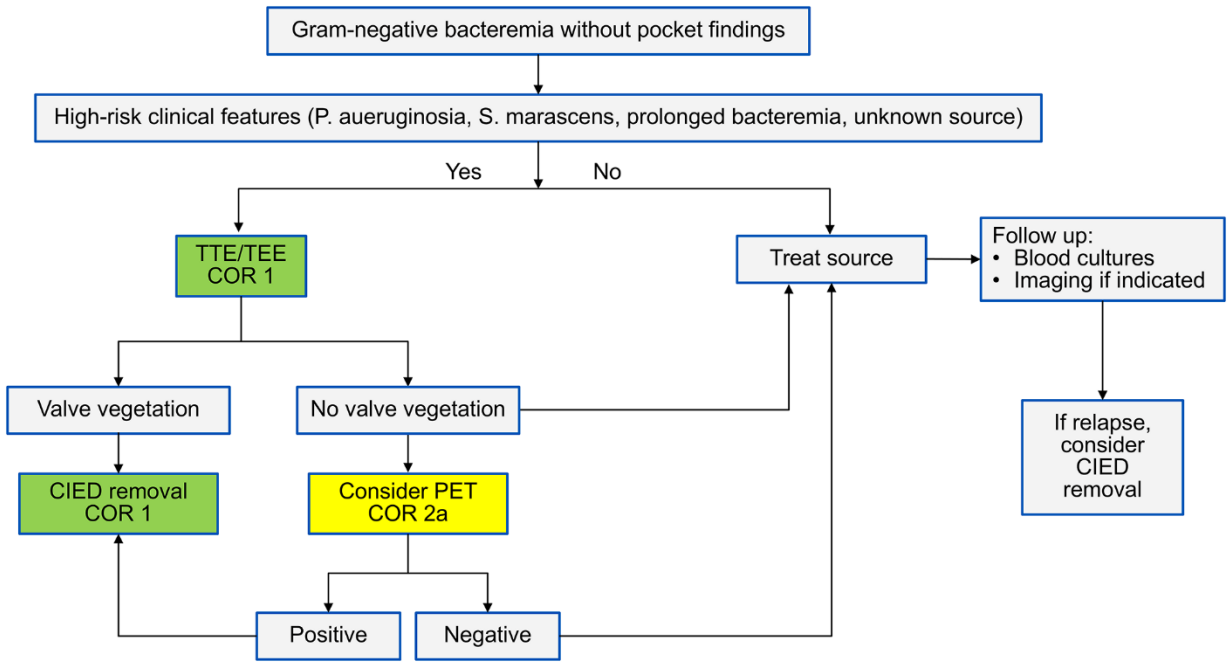


Figure 5: Gram-negative bacteremia without pocket abnormality



8.5 Management of Patients with a CIED and Fungemia

Recommendations for Management of Patients with a CIED and Fungemia			
COR	**LOE**	**Recommendations**	**References**
1	**C-LD**	**18. In patients with CIED and fungal bloodstream infection with suspected CIED involvement, CIED system removal is recommended in addition to antifungal therapy.**	49,50

Synopsis

The management of fungemia in a patient with a CIED can pose a significant clinical challenge, due to the wide variability in presentation and the limited data available to guide care. Although rare, Candida species are the most commonly described fungal pathogen in device-related infections. Published data are limited and consist of case reports, small series, and a systematic review of cases. Mortality is high regardless of selected treatment strategy; device and vegetation cultures are frequently negative when the CIED is removed, yet relapses can occur in patients managed without device removal. Higher risk findings include findings on imaging consistent with infection and persistent bloodstream infection without an alternative source. Given the lack of definitive diagnostic criteria and high mortality rate, management decisions must be individualized in weighing specific procedural risk and uncertain benefit in the context of limited data.

Recommendation-specific supportive text

Recommendation 18: A systematic review of 48 cases from 41 studies of systemic fungal infections in the setting of a CIED reported that Candida and Aspergillus species were most common [49] There was significant heterogeneity in antifungal medication selection and duration of treatment. There was an association between CIED extraction and survival to discharge (92% vs. 56%), although data were observational and limited to individual case reports and one small case series.[49] In a single-center series of 23 patients with a CIED and candidemia, 17.4% were ultimately confirmed to have CIED infection.[50] Only 2 patients with lead masses underwent extraction, but device cultures were negative. Of 6

patients managed as candidemia without CIED infection, 2 subsequently developed relapse and underwent CIED removal; device cultures were positive in both. Prognosis was poor in all groups; overall, 74% of patients died within 90 days of diagnosis of candidemia.[50]

8.6. Procedural Management for Infection Indication of CIED Removal

Recommendations for Procedural Management for Infection Indication of CIED Removal			
COR	**LOE**	**Recommendations**	**References**
1	**C-LD**	**19. In patients with CIED bloodstream infection, gram stain and culture of pocket tissue and lead tips are recommended at device removal to guide antimicrobial therapy.**	22,23
1	**B-NR**	**20. In patients with CIED infection undergoing system removal, early removal is beneficial compared with delayed extraction, particularly for virulent organisms such as *Staphylococcus aureus*.**	51,52,18
2a	**C-LD**	**21. In patients with CIED infection and lead vegetation who are undergoing CIED system removal, transvenous lead removal is reasonable, even in the presence of a larger vegetation.**	53,17

2a	**C-LD**	**22. In patients with CIED infection and vegetation > 1-2 cm, percutaneous mechanical aspiration can be effective to debulk lead and valve-associated vegetations.**	54,55
2b	**C-LD**	**23. In patients who are at very high risk of complications from transvenous lead extraction (eg, very large vegetations, > 4 leads, long duration of dwell time, high-risk leads, low body mass index, female sex, and no prior cardiac surgery), surgical lead extraction may be considered.**	56,57,58, 59
1	**B-NR**	**24. In patients with a CIED who are undergoing cardiac surgery for valvular endocarditis, particularly with high-risk organisms such as *S aureus*, complete CIED system removal is indicated to reduce the risk of recurrent infection.**	19,57,11, 37
2b	**C-LD**	**25. In patients with both a CIED and an LVAD who present with systemic or pocket infection, complete removal of the CIED system while leaving the LVAD in situ may be considered.**	Black-Maier60 Krishnamoorthy61 Riaz62

Synopsis

The timing of extraction is critical for patients with overwhelming S. aureus or infection with other virulent microbes. Earlier removal of infected hardware is associated with a substantially improved outcome in observational analyses. CIED system removal in the setting of infection affords the opportunity for enhanced diagnostic accuracy by use of tissue or lead material culture, or using advanced microbial detection techniques in pocket and hardware materials. Similarly, percutaneous mechanical aspiration at the time of CIED removal allows for debulking of large vegetations, which may improve infection outcomes, as well as allowing for culture of infected material.

Recommendation-specific supportive text

Recommendation 19: In a series of 71 patients with a CIED undergoing extraction, 49% of whom were diagnosed with infection, positive pocket tissue cultures were more frequent than swab cultures (69% vs. 31%).[22] Of note, patients without clinical infection had positive cultures at a similar rate by tissue culture (28%) and swab culture (22%). Patients who did not have a clinically diagnosed infection were not treated with additional antibiotics and did not develop subsequent infection.[22] In a series of 105 patients with CIED pocket infection undergoing extraction, the intravascular parts of the lead had positive cultures in 79%, and the extravascular parts were positive in 92%, in contrast to a 38% positivity rate in pocket swab cultures.[23] These data support the routine culture of pocket tissue and lead components at CIED removal for infection to guide antimicrobial therapy, although careful clinical interpretation of culture results is essential.[22]

Recommendation 20: In a single-center observational series of 233 patients undergoing CIED removal, the majority of whom had *S. aureus* or CoNS bloodstream or pocket infection, delayed extraction (15 days) in the setting of bloodstream infection was associated with adverse outcomes of septic shock, acute kidney injury, respiratory failure, and heart failure.[51] Delayed extraction (mean? 11 days) in patients with pocket infection was associated with acute kidney injury.[51] Although observational, delayed extraction in both groups was associated with lower survival.[51] Similarly, a Nationwide Readmissions Database observational analysis of 13,000 patients undergoing extraction for CIED infection showed an association of delayed extraction (> 7 days) and in-hospital mortality, major adverse events, and postprocedural length of stay.[52] In a large Medicare cohort study of over one million patients diagnosed with CIED infection by claims data, only 19% underwent CIED removal.[18] Undergoing extraction within 30 days of infection diagnosis, and particularly within 6 days, was associated with lower mortality compared with delayed or no extraction [18]

Recommendation 21: Transvenous lead extraction can be safely performed in patients with CIED infection and lead vegetations, including larger vegetation sizes. Observational studies have shown that while pulmonary embolization events may occur in the setting of vegetations, they are usually not clinically relevant. In a single-center observational series of 25 consecutive patients with vegetations > 10 mm undergoing extraction, pre-extraction CT showed subclinical pulmonary emboli (PE) in 72%, and subclinical PE in 78% of those post-extraction.[53] There were no patients with new PE.[53] In a series of 9 patients undergoing extraction with lead vegetations of 10-38 mm, 5 of 9 patients had evidence of PE, all of

whom had a full recovery without a longer hospitalization.[63] In a series of 189 patients with CIED infection undergoing extraction, 23% had vegetations with a size ranging from 0.3 to 7 cm in the longest dimension. None of these patients had clinical manifestations of PE at or after lead extraction.[17] In a series of 100 patients with vegetations ranging from 0.2 to 4 cm undergoing extraction, 2 patients had embolization and did not have clinical sequelae.[64] A publication from the MEDIC registry reported similar outcomes in 129 patients with vegetations < or > 1 cm, although major complications were associated with an open surgical approach for CIED removal.[6] In patients with very large vegetations (eg, > 3-4 cm), percutaneous aspiration,[65] open surgical extraction, or embolic protection strategies can be pursued when clinically indicated.

Recommendation 22: Observational series report adjunctive vegetation debulking with percutaneous mechanical aspiration in the setting of CIED infection with a high rate of procedural success (88-94%) and a low risk of complications (3%).[54] Multiple tools have been developed, and comparative studies are not available. In a multicenter observational study of 101 patients with a mean vegetation size of 30.7 +/- 13.5 mm, complete procedural success was reported in 94% and partial in 5%, with a complication rate of 3% (death from shock, iliac vein perforation, and hemodynamic collapse before aspiration)[55] A scoping review of 51 studies including 294 patients (152 of whom had debulking of CIED vegetations) noted inconsistent reporting of patient outcomes but a reasonably low risk of procedural complications of 2.7%, including worsening tricuspid regurgitation.[54] Concurrent lead extraction success rates do not appear to differ from historical series when percutaneous mechanical aspiration is used.[54] Although the available data do not

extend to improvement of clinical outcomes, these studies support percutaneous aspiration as a reasonable adjunct in select patients.

Recommendation 23: Surgical extraction offers a reasonable alternative to transvenous lead extraction when the risks are very high. A multicenter study of 2325 patients undergoing lead extraction identified clinical variables associated with perforation (no prior cardiac surgery, female sex, left ventricular ejection fraction ^{3} 40%, lead age > 8 years, ^{3} 2 leads, and diabetes).[56] Clinical variables associated with mortality included infection as an indication for extraction, anemia, and older age.[56] A single-center study of outcomes of a heart team approach reported 21 of 384 patients underwent primary open surgical extraction (for high risk of bleeding, anticipated difficult condition, or large vegetations) and 10 transvenous extraction patients required surgical intervention (5 for failed lead extraction, 5 for bleeding). There were no deaths in the planned surgical group, and one death in a patient with a superior vena cava laceration.[57] In a single-center series of 29 patients undergoing elective open surgical extraction, 41% had an infectious indication for CIED removal and 38% had an additional indication for open extraction. The rate of both major complications and procedural failure was 3%. Length of stay was longer in patients with infectious indications.[58] Another single-center observational study of 24 patients undergoing surgical extraction and 329 undergoing transvenous extraction, surgical patients were more likely to have positive blood cultures, larger vegetations, and higher Charlson comorbidity index scores.[59] One-year mortality rates were higher in the surgical group, even after adjustment for other comorbidities, but patients were not randomized.[59] Data from the Canadian registry suggest that surgical extraction can reduce

the risk of major procedural complications associated with large vegetations and other high-risk features, with no significant difference in mortality compared to transvenous lead extraction. [56]

Recommendation 24: Although there is no specific evidence to support CIED system removal at the time of cardiac surgery for infective endocarditis, data support removal of potentially infected hardware, particularly in the setting of high-risk infectious agents, since the risk associated with surgical extraction is low. A systematic review and meta-analysis of patients in 32 studies of CIED infection or infective endocarditis showed an association with a lower risk of relapse and a lower mortality risk in those who underwent hardware removal (n=905) vs. antibiotic therapy (n=195).[57] In a single-center study of patients who underwent open surgical extraction, the majority required valve surgery and outcomes were excellent.[58] *Staphylococcus aureus* bacteremia is a particularly high-risk clinical setting, and retention of CIED hardware is associated with a substantial risk of recurrent infection.[60] **Recommendation 25:** Data to support specific management strategies in patients with CIED infection and LVAD are very limited. Small observational studies from 2 high-volume extraction centers of 6-27 patients support the safety and efficacy of TLE in this patient population for either pocket or bloodstream infection.[60-62] Patients with bloodstream infection or endocarditis were usually treated with chronic suppressive antibiotic therapy after CIED removal. Recurrent or persistent infection after CIED extraction was associated with a high mortality rate. In the largest series, 21 of 27 (78%) patients were free of recurrent infection at one year, with 83% treated with oral suppressive antibiotics after extraction. Persistent infection after extraction occurred in 4

(15%) patients and was associated with a 50% mortality rate.[60] Individualized decision-making with consideration of clinical circumstances, the severity of infection, and institutional expertise is essential.

8.7. Pacing Management at CIED Removal

Recommendations for Pacing Management at CIED Removal			
COR	**LOE**	**Recommendations**	**References**
1	**C-LD**	**26. In patients who are pacing-dependent and undergoing CIED removal for infection, temporary pacing using a standard implanted pacemaker lead and externalized generator is an effective means to provide stable pacing during a course of antibiotic therapy before permanent device reimplantation.**	66, 67
2b	**C-LD**	**27. In patients who are pacing dependent and undergoing CIED removal for infection, the usefulness of implanting a permanent epicardial pacing system as an adjunct to transvenous lead removal is not well-established.**	68,69
1	**C-LD**	**28. Implantation of an epicardial pacing system is recommended for patients undergoing**	70,69,68

		cardiothoracic surgery for valvular or CIED-related endocarditis who require pacing therapy.	
1	**C-LD**	**29. In patients who are pacing dependent and undergoing CIED removal for infection, implantation of a leadless pacemaker during or after CIED removal is useful to reduce the risk of recurrent infection.**	71,72,73

Synopsis

Effective management of pacing needs in dependent patients after CIED removal for infection requires balancing the needs for safe and reliable pacing with controlling infection, a particular challenge in the setting of endocarditis or bloodstream infection. Temporary-permanent pacing systems using an externalized standard permanent pacing lead and generator offer a bridge to reimplant of a permanent device with a low rate of complications, even with hospital discharge. A permanent epicardial CIED system, particularly in patients already undergoing cardiac surgery, also offers stable long-term pacing. Increasingly, a leadless pacemaker system has become a preferred option due to the low risk of reinfection.

Recommendation-specific supportive text

Recommendation 26: Temporary transvenous pacing using a standard active fixation lead and an external pacemaker generator can provide a stable option for pacemaker-dependent patients that allows for hospital discharge while completing a course of

antibiotics for CIED infection. In one of the larger of several single-center series, 334 patients underwent temporary-permanent pacing system placement after CIED removal for infection.[66] The most common access site was the ipsilateral subclavian or axillary vein.[66] Complications occurred in 1.5%, including lead dislodgement in 0.6% and infection in 0.3%.[66] In a nationwide cohort study not restricted to CIED infection, 2,952 patients were treated with a temporary-permanent pacing system.[67] There was an increased rate of infection of the subsequent device, which was no longer significant after adjustment for clinical risk factors.[67] The temporary permanent pacemaker also allows patients to ambulate, reducing the length of their CCU stay and complications related to immobility.

Recommendation 27: In a single-center observational study of pacemaker-dependent patients who underwent lead extraction, either epicardial reimplantation (n=59) or active fixation temporary pacing (n=52) was performed.[68] In-hospital complication rates were similar (37% vs. 33%). In the active fixation temporary pacing cohort, 25% required an epicardial implant for infection.[68] No difference was seen in mortality by reimplantation strategy, but use of temporary pacing was associated with a reduced risk of late endocarditis and device reintervention compared with an epicardial device.[68] In a series of 66 patients who underwent CIED extraction, 42 patients underwent epicardial pacemaker placement and 24 active fixation temporary systems.[69] The patients who received an epicardial device were discharged earlier, and complication rates were similar in the two groups.[69]

Recommendation 28: Implantation of a surgical epicardial pacemaker system in the setting of CIED infection and transvenous extraction is supported by several small,

observational case series.[68-70] The largest study, which comprised 160 pacemaker-dependent patients undergoing CIED extraction for infection at two centers, showed equivalent outcomes at both the center using a strategy of delayed transvenous pacemaker implant and a second center that performed a concurrent surgical epicardial pacemaker implant at the time of extraction.[70] In this observational study, epicardial pacemaker implantation was associated with a shorter hospital length of stay. Limited data have been published regarding the outcomes of surgical epicardial devices implanted after valve surgery for endocarditis[74] although concurrent epicardial device placement is suggested by current surgical guidelines due to a lower risk of infection.[75] Collectively, these findings support an epicardial pacing strategy in patients undergoing cardiac surgery for valvular endocarditis.

Recommendation 29: In patients who undergo CIED removal for infection, implantation of a leadless pacemaker system can provide stable pacing, with a low risk of recurrent infection. Multiple observational studies and several systematic reviews have reported a low rate of infection following leadless pacemaker implantation in this setting. In the Micra Post-approval Registry, 105 patients with prior CIED infection underwent leadless pacemaker placement 30 days after removal of a prior system.[71] During follow-up, 2 patients died of sepsis, and no Micra devices were explanted for infection.[71] A systematic review of 22 studies, including 657 patients, reported that 45% of patients underwent concurrent leadless pacemaker implantation.[72] A total of 194 patients (30%) had systemic CIED infections, and 153 (23%) had pocket infections. Only 3 patients (0.46%) experienced persistent or recurrent infection.[72] Although studies differ in their assessment of the best

timing of leadless pacemaker implantation, and include implantation at the time of extraction or later, overall rates of complications and recurrent infections are low.[72,73,76]

8.8. Management of Reimplant Timing after CIED Removal for Infection

Recommendations for Reimplant Timing after CIED Removal for Infection			
COR	**LOE**	**Recommendations**	**References**
1	**C-LD**	**30. In pacemaker-dependent patients undergoing CIED removal for infection, the timing of reimplantation and device selection should be individualized based on clinical status and risk of reinfection.**	77,78,72,79

Synopsis

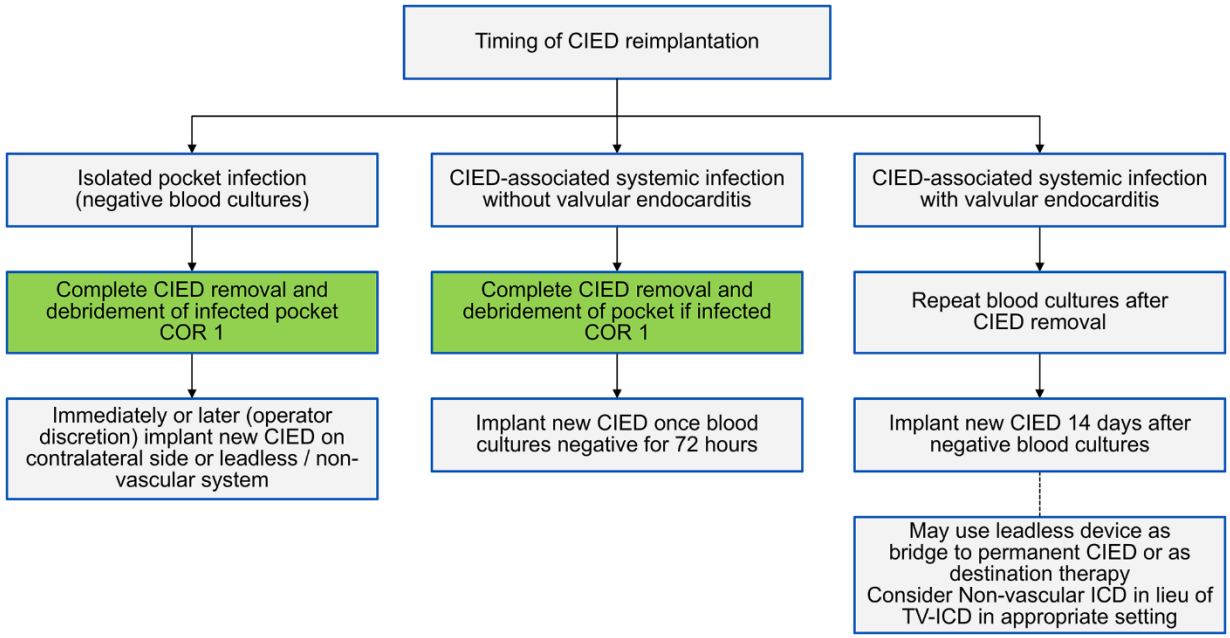
After CIED system extraction, a significant number of patients no longer require CIED reimplant. In a study of 300 patients who underwent extraction for infection, 41% continued to have an indication for the same device, 23% received a different kind of CIED, and 37% were discharged without need for CIED.[80]. Timing of reimplantation varies depending on the clinical circumstance, including the virulence of the infecting microbe, and the extent of infection.

Recommendation-specific supportive text

Recommendation 30: In a retrospective single-center observational review of 109 patients treated for CIED-related infective endocarditis requiring reimplantation, patients with valve vegetation and reimplant in < 14 days had an association with reduced survival.[81] A MEDIC registry report of 220 patients who underwent extraction for infection and later implant

showed a repeat infection rate of 1.8% with a broad range of reimplant strategies.[77] A systematic review and meta-analysis of 8 studies, including 96 patients with CIED infection, reported a pooled incidence rate of device reinfection of 0.45%. There was no difference in reinfection rates when time to reimplantation was stratified at 1 week, but significant heterogeneity in the studies limited interpretation.[78] A systematic review of 22 studies, including 657 patients who underwent leadless pacemaker implantation after CIED removal for infection, reported a 0.46% rate of recurrent or persistent infections.[72] In a multicenter observational study of 229 patients who underwent ICD extraction and subsequent S-ICD or TV-ICD implantation, no lead failures, systemic infection, or system-related deaths occurred in the S-ICD group. In the TV-ICD group, one lead fracture and 2 infections occurred, one of which resulted in death.[79] **Figure 6** shows a flow chart on the timing of CIED reimplantation following the CIED system removal.

Figure 6: Timing of CIED reimplantation



8.9. CIED infection antimicrobial therapy

Recommendations for Antimicrobial Therapy			
COR	**LOE**	**Recommendations**	**References**
1	**C-LD**	**31. In patients with CIED presenting with systemic infection, initiation of empiric broad-spectrum antimicrobial therapy targeting both Gram-positive and Gram-negative organisms is recommended until pathogen identification and susceptibility results are available**	82,83
1	**B-NR**	**32. In patients with CIED infection, a complete course of antimicrobial therapy (typically 4 to 6 weeks for bloodstream**	84

		infection and 7 to 14 days for pocket infection) guided by pathogen identification and in vitro susceptibility testing is recommended following complete device removal.	
2a	**B-NR**	**33. In selected patients with CIED infection who are at prohibitively high risk for, or who decline device removal, long-term suppressive antibiotic therapy and local wound management may be reasonable as palliative treatment.**	84 85
2b	**C-LD**	**34. In stable patients who undergo CIED removal for device infection, transitioning to oral antibiotic therapy after an initial course of intravenous treatment may be reasonable.**	86 87

Synopsis

Antimicrobial choice and duration for CIED infections vary based on the causative pathogen and clinical presentation. Once the infected CIED is removed, most pocket infections can be treated with 1 to 2 weeks of antibiotic therapy, often transitioning to an oral agent at discharge. For systemic infections, most patients with uncomplicated bacteremia can be managed with 2 weeks of antibiotic therapy. Switching to an oral agent at discharge may be appropriate in select patients—particularly when bacteremia clears quickly, the infection is caused by an organism susceptible to a highly bioavailable oral antibiotic, and outpatient adherence is reliable. Complicated CIED infections with lead or valvular vegetations are typically treated with 4 to 6 weeks of antibiotics. Long-term suppressive therapy is reserved as a palliative option for patients in whom the infected CIED cannot be removed, though it carries a high risk of relapse.

Recommendation-specific supportive text

Recommendation 31: 429 cases of CIED infection. 68 cases (71.6%) were categorized as non-BSI and 27 (28.4%) as BSI. Patients with CIED pocket infection who meet systemic inflammatory response syndrome criteria and/or are hypotensive at admission are more likely to have underlying BSI and should be started on empiric antibiotics after blood cultures are obtained. (7) The aim of this study was to compare empirical treatment with antistaphylococcal penicillin (ASP) or cefazolin vs. other treatments in methicillin-susceptible Staph aureus endocarditis. 208 patients were included. Empirical treatment with ASP or cefalozin is more effective than other treatments.(88)

After blood cultures are collected, vancomycin is usually recommended for the empiric treatment of a pocket infection. Empiric antimicrobial coverage for patients with possible CIED infection and a suspected bacteremic presentation should consider clinical findings, epidemiologic factors, and the need for inclusion of coverage for gram-negative bacilli pending blood culture results. Vancomycin (or an equivalent agent) should be administered as initial therapy until the microbiological etiology is identified to ensure robust gram-positive coverage. Antibiotic therapy is the first pillar in CIED infection management. It should be started promptly following blood culture sampling and follow the principles of treatment of infectious endocarditis. (89,90)

Recommendation 32: There are no comparative trials to guide the selection of an optimal antimicrobial treatment for infection. For pocket site erosion without purulence, a 7-day treatment course after extraction is reasonable. For pocket site infection with purulence, a 10-day duration of antibiotics after extraction is reasonable. A longer duration of

antimicrobial therapy is suggested in patients with bloodstream infection; patients with valvular IE may need up to 4 to 6 weeks of parenteral treatment, depending on the causative pathogen and whether there is native or prosthetic valve IE. (82)

Recommendation 33: Suppressive antimicrobial therapy indication relies to date on local expert opinion rather than clinical evidence (42 patients). The choice of antimicrobial therapy should be guided by in vitro susceptibility testing of the causative organism. However, dosing and duration are based on wound, tissue blood cultures, but may be empirical, given the limited available study results. The long-term outcome of this approach is unknown.(84,91)

Recommendation 34: The randomized multicenter POET trial examining the efficacy and safety of partial oral versus intravenous antibiotic therapy in patients with IE, including patients with CIEDs, found that step-down oral therapy was non-inferior to continued intravenous antibiotic treatment. This study examined changes in the length of hospital stay (mortality and relapse of bacteremia) before and after the POET publication. 3008 patients before POET and 1740 after POET. There is a reduction in the median length of hospital stay of 8 days with no changes in mortality and associated lower rate of relapse of bacteremia.(7,83)

8.10. Prevention

Recommendations for Prevention			
COR	**LOE**	**Recommendations**	**References**

1	**A**	**35. In patients undergoing a CIED procedure with incision, administration of preoperative systemic antibiotics prior to incision is recommended to reduce the risk of infection.**	92-95
2a	**B-R**	**36. In high-risk patients with a CIED, such as those undergoing generator replacement or system upgrade, or with prior device infection, immunosuppression, or renal dysfunction, use of an antibacterial envelope can be useful to reduce the risk of pocket infection.**	96-98

Synopsis

Systemic antibiotic prophylaxis is the key strategy for preventing CIED infection. Administering antibiotics within an hour before the procedure, typically cefazolin, significantly lowers infection risk by 40–95%. For patients allergic to cephalosporins, vancomycin or clindamycin are suitable alternatives. Most CIED infections are pocket-related. Antibacterial envelopes are effective in reducing pocket infection and should be considered in higher-risk patients, such as those undergoing generator replacement, revision, or cardiac resynchronization therapy. Risk stratification tools, like the PADIT Score, can help identify high-risk patients. Despite its frequent use in surgery, wound irrigation has no demonstrated benefit in lowering infection rates. Evidence supports focused, perioperative prophylaxis rather than extended or topical antibiotic use.

Recommendation-specific supportive text

Recommendation 35: Administering systemic antibiotics one hour before the procedure has been shown to significantly reduce the risk of device infection, with a relative risk

reduction ranging from 40% to 95%; a first-generation cephalosporin like cefazolin (given within 1 hour before incision) or vancomycin (given within 2 hours before incision) is administered. For patients truly allergic to cephalosporins, vancomycin or clindamycin are considered suitable alternatives. The PADIT trial confirmed that using a dual antibiotic preoperative approach, including vancomycin, did not provide a significant benefit. Compared to the standard prophylaxis with periprocedural cefazolin in patients undergoing CIED implantation, a more aggressive multicomponent antibiotic regimen did not show a notable advantage in preventing device-related infections. Postoperative antibiotics are not recommended, as there is no supporting data for their use. The use of povidone iodine ointment, neomycin ointment, and antiseptic pads did not demonstrate any benefit in preventing CIED infections compared to placebo. (92-95)

Recommendation 36: The majority of CIED infections are pocket related. The WRAP-IT randomized study was conducted in a population deemed at higher risk of pocket infection (CIED generator replacement, device upgrade/revision, or cardiac resynchronization therapy implantation). Use of an antibacterial envelope as an adjunctive measure decreased the occurrence of major CIED infections in this higher-risk population compared to standard infection prevention strategies alone, although absolute infection rates were low and statistical significance was modest (0.7% vs 1.2% respectively, 40% relative risk reduction, P=0.04). Staphylococcus species were the most common pathogens, and envelope use resulted in a significant decrease in Staphylococcus-related pocket infections, although there were more cases of Staph. bacteremia in the envelope group. (98) Several risk calculators, including online tools like the PADIT Score, help identify high-risk patients.

Although wound irrigation during surgery is common across various surgical fields, there is no evidence that it reduces infection risk. Similarly, postoperative antibiotics have not demonstrated any benefit in preventing infections. Povidone iodine ointment, neomycin ointment, and antiseptic pads did not provide any advantage over placebo in preventing CIED infections.(96,97)

References

1. Baddour LM, Esquer Garrigos Z, Rizwan Sohail M et al. Update on Cardiovascular Implantable Electronic Device Infections and Their Prevention, Diagnosis, and Management: A Scientific Statement From the American Heart Association: Endorsed by the International Society for Cardiovascular Infectious Diseases. Circulation 2024;149:e201-e216.
2. George MP, Esquer Garrigos Z, Vijayvargiya P et al. Discriminative Ability and Reliability of Transesophageal Echocardiography in Characterizing Cases of Cardiac Device Lead Vegetations Versus Noninfectious Echodensities. Clin Infect Dis 2021;72:1938-1943.
3. Chesdachai S, Esquer Garrigos Z, DeSimone CV, DeSimone DC, Baddour LM. Infective Endocarditis Involving Implanted Cardiac Electronic Devices: JACC Focus Seminar 1/4. J Am Coll Cardiol 2024;83:1326-1337.
4. Cheng MP, Stenstrom R, Paquette K et al. Blood Culture Results Before and After Antimicrobial Administration in Patients With Severe Manifestations of Sepsis: A Diagnostic Study. Ann Intern Med 2019;171:547-554.
5. Margey R, McCann H, Blake G et al. Contemporary management of and outcomes from cardiac device related infections. EP Europace 2009;12:64-70.
6. Greenspon AJ, Le KY, Prutkin JM et al. Influence of vegetation size on the clinical presentation and outcome of lead-associated endocarditis: results from the MEDIC registry. JACC Cardiovasc Imaging 2014;7:541-9.

7. Esquer Garrigos Z, George MP, Khalil S et al. Predictors of Bloodstream Infection in Patients Presenting With Cardiovascular Implantable Electronic Device Pocket Infection. Open Forum Infect Dis 2019;6:ofz084.

8. Klug D, Lacroix D, Savoye C et al. Systemic infection related to endocarditis on pacemaker leads: clinical presentation and management. Circulation 1997;95:2098-107.

9. Victor F, De Place C, Camus C et al. Pacemaker lead infection: echocardiographic features, management, and outcome. Heart 1999;81:82-7.

10. Chesdachai S, Baddour LM, Sohail MR et al. Bacteremia due to non-Staphylococcus aureus gram-positive cocci and risk of cardiovascular implantable electronic device infection. Heart Rhythm O2 2023;4:207-214.

11. Khan UA, Zaidi SH, Majeed H et al. Clinical Risk Factors for Infective Endocarditis Patients With Staphylococcus Aureus Bacteremia and the Diagnostic Utility of Transesophageal Echocardiogram. Current Problems in Cardiology 2022;47:101331.

12. Mahmood M, Kendi AT, Farid S et al. Role of (18)F-FDG PET/CT in the diagnosis of cardiovascular implantable electronic device infections: A meta-analysis. J Nucl Cardiol 2019;26:958-970.

13. Wang TKM, Sánchez-Nadales A, Igbinomwanhia E, Cremer P, Griffin B, Xu B. Diagnosis of Infective Endocarditis by Subtype Using (18)F-Fluorodeoxyglucose Positron Emission Tomography/Computed Tomography: A Contemporary Meta-Analysis. Circ Cardiovasc Imaging 2020;13:e010600.

14. Calais J, Touati A, Grall N et al. Diagnostic Impact of ¹⁸F-Fluorodeoxyglucose Positron Emission Tomography/Computed Tomography and White Blood Cell SPECT/Computed Tomography in Patients With Suspected Cardiac Implantable Electronic Device Chronic Infection. Circulation: Cardiovascular Imaging 2019;12:e007188.
15. Kusumoto FM, Schoenfeld MH, Wilkoff BL et al. 2017 HRS expert consensus statement on cardiovascular implantable electronic device lead management and extraction. Heart Rhythm 2017;14:e503-e551.
16. Tsai V, Chen H, Hsia H, Zei P, Wang P, Al-Ahmad A. Cardiac device infections complicated by erosion. J Interv Card Electrophysiol 2007;19:133-7.
17. Sohail MR, Uslan DZ, Khan AH et al. Management and outcome of permanent pacemaker and implantable cardioverter-defibrillator infections. J Am Coll Cardiol 2007;49:1851-9.
18. Pokorney SD, Zepel L, Greiner MA et al. Lead Extraction and Mortality Among Patients With Cardiac Implanted Electronic Device Infection. JAMA Cardiology 2023;8:1165-1173.
19. Caldonazo T, Fischer J, Spagnolo A et al. Outcomes of complete removal versus conservative therapy in cardiac implantable electronic device infections - A systematic review and Meta-analysis. Int J Cardiol 2024;411:132264.
20. Topaz M, Chorin E, Schwartz AL et al. Regional Antibiotic Delivery for Implanted Cardiovascular Electronic Device Infections. JACC 2023;81:119-133.

21. Peacock JE, Jr., Stafford JM, Le K et al. Attempted salvage of infected cardiovascular implantable electronic devices: Are there clinical factors that predict success? Pacing Clin Electrophysiol 2018;41:524-531.

22. Dy Chua J, Abdul-Karim A, Mawhorter S et al. The role of swab and tissue culture in the diagnosis of implantable cardiac device infection. Pacing Clin Electrophysiol 2005;28:1276-81.

23. Klug D, Wallet F, Lacroix D et al. Local symptoms at the site of pacemaker implantation indicate latent systemic infection. Heart 2004;90:882-6.

24. Martín-Gutiérrez G, Martín-Pérez C, Ortiz-de la Rosa JM, Gutiérrez-Carretero E, de Alarcón A, Lepe JA. Usefulness of sonication in the microbiological diagnosis of cardiovascular implantable electronic device infections: systematic review, meta-analysis and meta-regression. Ann Clin Microbiol Antimicrob 2024;23:96.

25. Araújo D, Martins JP, Ferreira SL, Mota S, Ferreira PL, Pimenta R. A meta-analysis on the role of sonication in the diagnosis of cardiac implantable electronic device-related infections. Front Microbiol 2024;15:1361626.

26. Esquer Garrigos Z, Sohail MR, Greenwood-Quaintance KE et al. Molecular Approach to Diagnosis of Cardiovascular Implantable Electronic Device Infection. Clin Infect Dis 2020;70:898-906.

27. Stevens DL, Bisno AL, Chambers HF et al. Practice Guidelines for the Diagnosis and Management of Skin and Soft Tissue Infections: 2014 Update by the Infectious Diseases Society of America. Clinical Infectious Diseases 2014;59:e10-e52.

28. Pettersson GB, Hussain ST. Current AATS guidelines on surgical treatment of infective endocarditis. Ann Cardiothorac Surg 2019;8:630-644.

29. Chatterjee P, Sharma AK, Pratap P, Dabas A, Mishra B, Mehare S. Salvage of Infected Cardiac Implantable Electrical Devices with Subpectoral Plane Pocket Revision. Indian J Plast Surg 2021;54:344-349.

30. Liao FC, Chien CY, Lin SI et al. The Removal, Excision, Sterilization, and Quarantine (RESQ) Method is a Feasible Alternative Treatment for Cardiac Implantable Electronic Device Infections. Acta Cardiol Sin 2023;39:109-115.

31. Zheng S, Huang X, Lin Y, Chen X, Lin G, Zhuang J. Negative-pressure wound therapy (NPWT) for the treatment of pacemaker pocket infection in patients unable or unwilling to undergo CIED extraction. J Interv Card Electrophysiol 2021;61:245-251.

32. Dağdelen D, Aksoy A. Salvage of Exposed Cardiac Implants Using Fasciocutaneous Rotation Flaps. Ann Plast Surg 2020;84:85-89.

33. Roshdy H, Seaoud E, Elbelbesy R. Low-budget, single-session elimination of CIED pocket infection. Pacing Clin Electrophysiol 2021;44:129-134.

34. Bisignani A, De Bonis S, Mancuso L, Ceravolo G, Bisignani G. Pacemaker pocket infection: Innovative conservative treatment in elderly patients with no signs of systemic infection. Pacing Clin Electrophysiol 2019;42:1340-1346.

35. Kleemann T, Becker T, Strauss M et al. Prevalence of bacterial colonization of generator pockets in implantable cardioverter defibrillator patients without signs of infection undergoing generator replacement or lead revision. EP Europace 2009;12:58-63.

36. Sohail MR, Palraj BR, Khalid S et al. Predicting Risk of Endovascular Device Infection in Patients With Staphylococcus aureus Bacteremia (PREDICT-SAB). Circulation: Arrhythmia and Electrophysiology 2015;8:137-144.

37. Chamis AL, Peterson GE, Cabell CH et al. Staphylococcus aureus Bacteremia in Patients With Permanent Pacemakers or Implantable Cardioverter-Defibrillators. Circulation 2001;104:1029-1033.

38. Pichtchoulin S, Selmeryd I, Freyhult E, Hedberg P, Selmeryd J. Staphylococcus aureus bacteremia and cardiac implantable electronic devices in a county hospital setting: a population-based retrospective cohort study. Ups J Med Sci 2021;126.

39. Chesdachai S, Baddour LM, Sohail MR et al. Evaluation of European Heart Rhythm Association consensus in patients with cardiovascular implantable electronic devices and Staphylococcus aureus bacteremia. Heart Rhythm 2022;19:570-577.

40. Uslan DZ, Dowsley TF, Sohail MR et al. Cardiovascular implantable electronic device infection in patients with Staphylococcus aureus bacteremia. Pacing Clin Electrophysiol 2010;33:407-13.

41. Nakajima I, Narui R, Tokutake K et al. Staphylococcus bacteremia without evidence of cardiac implantable electronic device infection. Heart Rhythm 2021;18:752-759.

42. Berge A, Carlsén C, Petropoulos A, Gadler F, Rasmussen M. Staphylococcus aureus bacteraemia, cardiac implantable electronic device, and the risk of endocarditis: a retrospective population-based cohort study. Eur J Clin Microbiol Infect Dis 2023;42:583-591.

43. Zhao A, Sun J, Liu Y. Understanding bacterial biofilms: From definition to treatment strategies. Front Cell Infect Microbiol 2023;13:1137947.

44. Rasmussen RV, Fowler VG, Jr., Skov R, Bruun NE. Future challenges and treatment of Staphylococcus aureus bacteremia with emphasis on MRSA. Future Microbiol 2011;6:43-56.

45. Hussein AA, Baghdy Y, Wazni OM et al. Microbiology of Cardiac Implantable Electronic Device Infections. JACC: Clinical Electrophysiology 2016;2:498-505.

46. Madhavan M, Sohail MR, Friedman PA et al. Outcomes in Patients With Cardiovascular Implantable Electronic Devices and Bacteremia Caused by Gram-Positive Cocci Other Than Staphylococcus Aureus. Circulation: Arrhythmia and Electrophysiology 2010;3:639-645.

47. Chesdachai S, Baddour LM, Sohail MR et al. Risk of Cardiovascular Implantable Electronic Device Infection in Patients Presenting With Gram-Negative Bacteremia. Open Forum Infect Dis 2022;9:ofac444.

48. Maskarinec SA, Thaden JT, Cyr DD, Ruffin F, Souli M, Fowler VG. The Risk of Cardiac Device-Related Infection in Bacteremic Patients Is Species Specific: Results of a 12-Year Prospective Cohort. Open Forum Infectious Diseases 2017;4.

49. Baman JR, Medhekar AN, Jain SK et al. Management of systemic fungal infections in the presence of a cardiac implantable electronic device: A systematic review. Pacing Clin Electrophysiol 2021;44:159-166.

50. Chesdachai S, Baddour LM, Sohail MR et al. Candidemia in Patients With Cardiovascular Implantable Electronic Devices: Uncertainty in Management Based on Current International Guidelines. Open Forum Infect Dis 2023;10:ofad318.
51. Lin AY, Saul T, Aldaas OM et al. Early Versus Delayed Lead Extraction in Patients With Infected Cardiovascular Implantable Electronic Devices. JACC Clin Electrophysiol 2021;7:755-763.
52. Lee JZ, Majmundar M, Kumar A et al. Impact of timing of transvenous lead removal on outcomes in infected cardiac implantable electronic devices. Heart Rhythm 2022;19:768-775.
53. Bontempi L, Arabia G, Salghetti F et al. Lead-related infective endocarditis with vegetations: Prevalence and impact of pulmonary embolism in patients undergoing transvenous lead extraction. J Cardiovasc Electrophysiol 2022;33:2195-2201.
54. Mourad A, Hillenbrand M, Skalla LA et al. Scoping review of percutaneous mechanical aspiration for valvular and cardiac implantable electronic device infective endocarditis. Clin Microbiol Infect 2023;29:1508-1515.
55. Starck CT, Schaerf RHM, Breitenstein A et al. Transcatheter aspiration of large pacemaker and implantable cardioverter-defibrillator lead vegetations facilitating safe transvenous lead extraction. Europace 2020;22:133-138.
56. Bashir J, Lee AJ, Philippon F et al. Predictors of perforation during lead extraction: Results of the Canadian Lead ExtrAction Risk (CLEAR) study. Heart Rhythm 2022;19:1097-1103.

57. Mizuno T, Goya M, Fujiwara T et al. Surgical extraction of cardiac implantable electronic device leads based on a heart team approach. J Cardiol 2023;81:111-116.
58. Gupta AR, Power JR, Yang Y et al. Indications and outcomes of elective open chest lead extractions. J Cardiovasc Electrophysiol 2024;35:2128-2133.
59. Patel D, Khan F, Shah H, Bhattacharya S, Adelstein E, Saba S. Cardiac implantable electronic device lead extraction in patients with underlying infection using open thoracotomy or percutaneous techniques. Cardiol J 2015;22:68-74.
60. Black-Maier E, Piccini JP, Bishawi M et al. Lead Extraction for Cardiovascular Implantable Electronic Device Infection in Patients With Left Ventricular Assist Devices. JACC: Clinical Electrophysiology 2020;6:672-680.
61. KRISHNAMOORTHY A, POKORNEY SD, LEWIS RK et al. Cardiac Implantable Electronic Device Removal in Patients with Left Ventricular Assist Device Associated Infections. Journal of Cardiovascular Electrophysiology 2014;25:1199-1205.
62. Riaz T, Nienaber JJ, Baddour LM, Walker RC, Park SJ, Sohail MR. Cardiovascular implantable electronic device infections in left ventricular assist device recipients. Pacing Clin Electrophysiol 2014;37:225-30.
63. Meier-Ewert HK, Gray ME, John RM. Endocardial pacemaker or defibrillator leads with infected vegetations: a single-center experience and consequences of transvenous extraction. Am Heart J 2003;146:339-44.
64. Grammes JA, Schulze CM, Al-Bataineh M et al. Percutaneous Pacemaker and Implantable Cardioverter-Defibrillator Lead Extraction in 100 Patients With

Intracardiac Vegetations Defined by Transesophageal Echocardiogram. Journal of the American College of Cardiology 2010;55:886-894.

65. Marinacci LX, Sethi SS, Paras ML et al. Percutaneous Mechanical Aspiration for Infective Endocarditis: Proceedings From an Inaugural Multidisciplinary Summit and Comprehensive Review. J Soc Cardiovasc Angiogr Interv 2024;3:102283.

66. Zhou X, Ze F, Li D, Li X, Wang B. Outcomes of temporary pacing using active fixation leads and externalized permanent pacemakers in patients with cardiovascular implantable electronic device infection and pacemaker dependency. J Cardiovasc Electrophysiol 2021;32:3051-3056.

67. Frausing MHJP, Nielsen JC, Johansen JB et al. Rate of permanent cardiac implantable electronic device infections after active fixation temporary transvenous pacing: A nationwide Danish cohort study. Heart Rhythm O2 2022;3:50-56.

68. Perrin T, Maille B, Lemoine C et al. Comparison of epicardial vs. endocardial reimplantation in pacemaker-dependent patients with device infection. Europace 2018;20:e42-e50.

69. Al-Maisary SSA, Romano G, Karck M, De Simone R. Epicardial pacemaker as a bridge for pacemaker-dependent patients undergoing explantation of infected cardiac implantable electronic devices. J Card Surg 2019;34:424-427.

70. Amraoui S, Sohal M, Li A et al. Comparison of delayed transvenous reimplantation and immediate surgical epicardial approach in pacing-dependent patients undergoing extraction of infected permanent pacemakers. Heart Rhythm 2015;12:1209-15.

71. El-Chami MF, Johansen JB, Zaidi A et al. Leadless pacemaker implant in patients with pre-existing infections: Results from the Micra postapproval registry. J Cardiovasc Electrophysiol 2019;30:569-574.

72. Nadeem B, Sedrakyan S, Fatima A et al. Outcomes of concurrent and delayed leadless pacemaker implantation following extraction of infected cardiovascular implantable electronic device. J Interv Card Electrophysiol 2024.

73. Inoue N, Ito Y, Imaizumi T, Morikawa S, Murohara T. Assessment of adverse events stratified by timing of leadless pacemaker implantation with cardiac implantable electronic devices extraction due to infection: A systematic review and meta-analysis. Journal of Arrhythmia 2025;41:e13208.

74. Waddingham PH, Behar JM, Roberts N et al. Post-operative cardiac implantable electronic devices in patients undergoing cardiac surgery: a contemporary experience. Europace 2021;23:104-112.

75. Pettersson GB, Coselli JS, Pettersson GB et al. 2016 The American Association for Thoracic Surgery (AATS) consensus guidelines: Surgical treatment of infective endocarditis: Executive summary. The Journal of Thoracic and Cardiovascular Surgery 2017;153:1241-1258.e29.

76. Tan MC, Tan JL, Tay ST et al. A Systematic Review of Short-Term Outcomes of Leadless Pacemaker Implantation After Transvenous Lead Removal of Infected Cardiac Implantable Electronic Device. Am J Cardiol 2023;203:444-450.

77. Boyle TA, Uslan DZ, Prutkin JM et al. Reimplantation and Repeat Infection After Cardiac-Implantable Electronic Device Infections: Experience From the MEDIC

(Multicenter Electrophysiologic Device Infection Cohort) Database. Circ Arrhythm Electrophysiol 2017;10.

78. Chew D, Somayaji R, Conly J, Exner D, Rennert-May E. Timing of device reimplantation and reinfection rates following cardiac implantable electronic device infection: a systematic review and meta-analysis. BMJ Open 2019;9:e029537.

79. Viani S, Migliore F, Tola G et al. Use and outcomes of subcutaneous implantable cardioverter-defibrillator (ICD) after transvenous ICD extraction: An analysis of current clinical practice and a comparison with transvenous ICD reimplantation. Heart Rhythm 2019;16:564-571.

80. Döring M, Hienzsch L, Ebert M et al. Extraction of infected cardiac implantable electronic devices and the need for subsequent re-implantation. Int J Cardiol 2020;309:84-91.

81. Arshad V, Baddour LM, Lahr BD et al. Impact of delayed device re-implantation on outcomes of patients with cardiovascular implantable electronic device related infective endocarditis. Pacing Clin Electrophysiol 2021;44:1303-1311.

82. Phillips P, Krahn AD, Andrade JG et al. Treatment and Prevention of Cardiovascular Implantable Electronic Device (CIED) Infections. CJC Open 2022;4:946-958.

83. Perrin T, Deharo JC. Therapy and outcomes of cardiac implantable electronic devices infections. Europace 2021;23:iv20-iv27.

84. Baddour LM, Esquer Garrigos Z, Rizwan Sohail M et al. Update on Cardiovascular Implantable Electronic Device Infections and Their Prevention, Diagnosis, and Management: A Scientific Statement From the American Heart Association:

Endorsed by the International Society for Cardiovascular Infectious Diseases. Circulation 2024;149:e201-e216.

85. Love CJ. Palliation and Nonextraction Approaches. Card Electrophysiol Clin 2018;10:681-687.

86. Iversen K, Ihlemann N, Gill SU et al. Partial Oral versus Intravenous Antibiotic Treatment of Endocarditis. N Engl J Med 2019;380:415-424.

87. Ostergaard L, Pries-Heje MM, Voldstedlund M et al. Length of Hospital Stay for Endocarditis Before and After the Partial Oral Treatment of Endocarditis Trial. J Am Coll Cardiol 2024;84:2293-2304.

88. Lecomte R, Deschanvres C, Bourreau A et al. Comparative effectiveness of empirical antibiotic treatments in methicillin-susceptible Staphylococcus aureus infective endocarditis: A post hoc analysis of a prospective French cohort study. Int J Infect Dis 2024;142:106989.

89. Daneman N, Homenauth E, Saskin R, Ng R, Ha A, Wijeysundera HC. The predictors and economic burden of early-, mid- and late-onset cardiac implantable electronic device infections: a retrospective cohort study in Ontario, Canada. Clin Microbiol Infect 2020;26:255.e1-255.e6.

90. Tarakji KG, Chan EJ, Cantillon DJ et al. Cardiac implantable electronic device infections: presentation, management, and patient outcomes. Heart Rhythm 2010;7:1043-7.

91. Russo A, Serraino R, Serapide F, Trecarichi EM, Torti C. New advances in management and treatment of cardiac implantable electronic devices infections. Infection 2024;52:323-336.

92. Baddour LM, Wilson WR, Bayer AS et al. Infective Endocarditis in Adults: Diagnosis, Antimicrobial Therapy, and Management of Complications: A Scientific Statement for Healthcare Professionals From the American Heart Association. Circulation 2015;132:1435-86.

93. Darouiche R, Mosier M, Voigt J. Antibiotics and antiseptics to prevent infection in cardiac rhythm management device implantation surgery. Pacing Clin Electrophysiol 2012;35:1348-60.

94. Polyzos KA, Konstantelias AA, Falagas ME. Risk factors for cardiac implantable electronic device infection: a systematic review and meta-analysis. Europace 2015;17:767-77.

95. Krahn AD, Longtin Y, Philippon F et al. Prevention of Arrhythmia Device Infection Trial: The PADIT Trial. J Am Coll Cardiol 2018;72:3098-3109.

96. Khalighi K, Aung TT, Elmi F. The role of prophylaxis topical antibiotics in cardiac device implantation. Pacing Clin Electrophysiol 2014;37:304-11.

97. Callahan TD, Tarakji KG, Wilkoff BL. Antibiotic eluting envelopes: evidence, technology, and defining high-risk populations. Europace 2021;23:iv28-iv32.

98. Tarakji KG, Mittal S, Kennergren C et al. Antibacterial Envelope to Prevent Cardiac Implantable Device Infection. N Engl J Med 2019;380:1895-1905.

Section 9 Indications for Lead Extractions (Noninfectious)

9.1. Chronic Pocket Pain

Chronic pain at the device site or the lead insertion site is an infrequent indication for lead extraction, and the scope of this problem has not been well defined. The incidence of chronic pain following a CIED implantation has not been fully established, but generally represents about 1%–3% of lead extraction cases.[1,2]

Pain and tenderness at the device site represent a wide range of clinical scenarios, from subclinical infection to possible CIED allergies, poorly formed device pocket, fibromyalgia or musculoskeletal problems. The presentation of a device infection is often variable. It is conceivable that chronic pain at the device site might be a manifestation of an indolent, chronic infection by a slow-growing organism. Still, the direct relationship between subclinical device infections and chronic pain remains to be elucidated. CIED contact dermatitis, though rare, has been well established, with many case reports illustrating a broad spectrum of possible symptoms, ranging from pain and tenderness to dermatological manifestations.[3,4] The diagnosis of CIED contact dermatitis is confirmed with positive skin patch testing of any of the components of the CIED system, together with an absence of proof of infection.

Implantable cardiac defibrillators have been associated with postoperative discomfort and pain.[5] Chronic shoulder pain and disability were described in 131 (54%) patients more than 3 years after ICD implantation.[6] The only predictor of shoulder pain was the number of implanted leads. Another possible cause for musculoskeletal pain at the device site and shoulder region is thoracic outlet syndrome, which can cause pain, numbness, and fatigue

of the shoulder and arm due to compression of the brachial plexus and subclavian vessels. Placement of the device in or very close to the deltopectoral groove may cause pain due to compression of the tissue and structures in the area during ipsilateral arm adduction.

Recommendations for Chronic Pocket Pain			
COR	**LOE**	**Recommendations**	**References**
2a	**C-LD**	**1. In patients with severe, chronic pain at the CIED site, believed to be secondary to the CIED system, and that is not manageable by medical therapies or surgical revision, device and lead removal can be beneficial.**	1-10

Synopsis

Chronic pain at the device implant site or lead insertion site is an infrequent indication for lead extraction.[1,2] The scope of this problem is likely multifactorial, ranging from indolent infection to musculoskeletal conditions.[3-9] An individualized treatment plan is necessary, and removal of the device and lead extraction in patients with severe chronic pain may relieve symptoms when other strategies have failed.

Recommendation-specific supportive text

Recommendation 1. Chronic pain at the CIED generator site is variable and can present as persistent or movement-triggered and be due to dermatitis, subclinical infection, thoracic outlet syndrome, fibromyalgia or a poorly formed device pocket. In a 27-patient, multi-center, retrospective observational study, extraction relieved constant and intermittent pain in two-thirds of patients.[8] Although there are various causes of chronic

pain at the device site and/or lead insertion site, it is important to keep in mind that this clinical scenario can be multifactorial, and a careful and individualized treatment plan is necessary. Medical therapy with antinociceptive medications such as amitriptyline, pregabalin, and gabapentin has proved useful in some patients. When alternative management strategies are not available or have failed to resolve chronic pain, removal of the device and leads is reasonable after shared decision-making with the patient.

9.2 Thrombosis, Vascular Obstruction/Occlusion

CIED lead-related vascular stenosis or occlusion is a relatively common finding and is often asymptomatic.[10] Symptomatic patients may have debilitating symptoms requiring treatment. A comprehensive plan including anticoagulation, endovascular treatment with venoplasty and possible stent placement, and/or transvenous lead extraction should be considered.[11,12] Placement of the device in or very close to the deltopectoral groove may cause pain due to compression of the tissue and structures in the area during ipsilateral arm adduction.

Recommendations for Thrombosis, Vascular Obstruction/Occlusion

COR	LOE	Recommendations	References
1	C-LD	**2. Lead removal as part of a comprehensive plan for maintaining vascular patency is recommended for patients with symptomatic vascular stenosis or occlusion.**	10-12

1	**C-EO**	**3. Lead removal is recommended for patients with clinically significant thromboembolic events attributable to thrombus on a lead or a lead fragment that cannot be treated by other means.**	13-15
1	**C-EO**	**4. Lead removal is recommended for patients with planned stent deployment in a vein already containing a transvenous lead, to avoid entrapment of the lead.**	16,17

Synopsis

CIED lead-related venous occlusion is common and, fortunately, most often asymptomatic due to the development of collateral blood vessels. Venous occlusion/thrombosis after pacemaker or ICD system implantation can make system revision and device upgrades challenging, contribute to the development of symptomatic venous occlusion, including SVC syndrome, and, rarely, lead to thromboembolic complications.[13]

Endovascular treatment with subclavian percutaneous balloon venoplasty offers symptom relief with a high rate of technical success; however, restenosis is common. When employed in the setting of failed leads with venous occlusion, venoplasty adds to the overall lead burden by leaving redundant lead(s) behind. Furthermore, this approach is not applicable in cases of a complete occlusion that cannot be crossed. Alternatively,

transvenous lead extraction to regain venous access of an occluded vein preserves the contralateral side for potential future use, minimizes overall lead burden and the long-term risks of abandoned leads.

Asymptomatic SVC occlusion in the setting of well-developed collaterals might preclude the placement of additional leads in a patient with existing leads. Under these circumstances, the extraction of an existing lead is one approach to regain access. In patients with symptomatic SVC syndrome, venoplasty alone often only resolves symptoms; however, the benefit is frequently short-lived due to near inevitable re-occlusion. In experienced extraction centers, lead extraction offers a safe and effective method for symptom resolution and long-term maintenance of SVC patency.12 When a stenting strategy is employed, all existing transvenous leads should be extracted prior to the stent placement to avoid entrapment of leads behind the stent.[16,17]

Recommendation-specific supportive text

Recommendation 2: Combining transvenous lead extraction (TLE) with percutaneous treatment of symptomatic vascular stenosis is a safe and effective treatment strategy.[11,12]

A number of observational studies of TLE in patients with SVC syndrome support this management approach. Gabriels et al. described their experience with patients undergoing TLE for symptomatic SVC syndrome at a single high-volume center. 37 leads were extracted from 16 patients. Periprocedural management included SVC stenting post-TLE in 6 patients with antecedent balloon angioplasty in 5 of the 6 cases; 11 patients underwent CIED reimplant. There was 1 major complication due to an SVC tear that was managed surgically. Importantly, the majority of patients (75%) remained free of SVC

restenosis and symptoms over long-term follow-up (median 5.5-year follow-up).[12] Arora and Carrillo reported similar outcomes in their experience of CIED-related SVC syndrome. Among 17 patients, management included TLE and venoplasty in 13 patients, venoplasty alone in 3 patients, and surgical SVC reconstruction in one patient. Ten patients underwent CIED reimplantation. Symptom resolution was achieved and maintained in all patients at both six and twelve-month follow-ups. When compared with controls, there was no significant difference in the rate of complications associated with TLE for SVC syndrome.[11]

Recommendation 3: Clinically significant thromboembolic events related to transvenous leads occur infrequently but have been reported and are of particular concern in patients with intracardiac shunts.[13-15] In a multicenter, retrospective study of 202 patients with intracardiac shunts: Sixty-four had transvenous leads (group 1), 56 had epicardial leads (group 2), and 82 had right-to-left shunts but no pacemaker or implantable cardioverter defibrillator leads (group 3). Multivariate, stepwise regression analyses indicated that transvenous leads were an independent predictor of systemic thromboembolic events (HR, 2.6; P=0.0265).

Recommendation 4: Endovascular treatment with stent placement is often employed for the treatment of lead-induced symptomatic venous occlusion (eg, SVC, subclavian, brachiocephalic). Existing leads should be removed prior to stent placement to prevent entrapment of leads behind the stent (potentially causing lead malfunction as well as completely precluding future lead removal for any indication, including infection).[16,17]

9.3 Lead Malfunction/Recalled Leads, Extract vs Abandonment

Recommendations for Lead Malfunction/Recalled Leads, Extract vs Abandonment			
COR	**LOE**	**Recommendations**	**References**
2a	**B-NR**	**5. It is reasonable to choose lead removal over lead abandonment for patients with malfunctioning lead(s) when the benefits outweigh the risks.**	18-23
2b	**C-EO**	**6. Lead and leadless device removal may be considered in the setting of normally functioning advisory leads and/or devices that, due to a design failure, pose a potential future threat to the patient if left in place.**	18,19,24

Synopsis

Transvenous leads are the weak link in the CIED system. Leads are engineered to withstand various unique and complex forces including implantation manipulation, twisting and torquing with upper body movement, and bending with myocardial contraction with each cardiac cycle all while enduring the harsh in vitro environment.[25,26] Failure of a transvenous lead whether on advisory or not can result in serious clinical events, including premature battery depletion, failure to capture or defibrillate, and oversensing leading to inappropriate shocks or pacing inhibition. Reported failure rates vary widely, with estimates as high as 17% at 12 years,[27] but more recent observations of lead survivability at 8 years are 94% for contemporary non-advisory leads and 81% for

advisory leads.[28] However, specific lead advisories have demonstrated significantly higher failure rates of nearly 4% per year.[29] Additionally, lead electrical parameters may not always predict physical lead integrity.[30]

Recommendation-specific supportive text

Recommendation 5: There are no randomized studies comparing TLE to abandonment for failed leads. Multiple observational studies have suggested the safety of lead abandonment, but they are limited by selection bias and a lack of long-term follow-up.3[1-34] Conversely, other observational studies have demonstrated an increased incidence of venous occlusion and infection;[35] and, if TLE is required, abandoned leads are associated with an increased risk of incomplete extraction and major complications.[35-37] In fact, abandoned leads are frequently cited as a risk factor for lead extraction complications.[38,39] TLE has become safer with growing experience, newer technology and the rescue balloon. Each patient must be considered as an individual, weighing the risks and benefits of each approach. When the benefits of TLE outweigh the risks and TLE is considered, it should be performed at an experienced center with appropriate safety protocols.

Recommendation 6: Management of CIED advisories needs to be individualized to the advisory and the patient. When the lead failure incidence is low with a low risk of patient harm, regular and close surveillance via a remote monitoring system is advised. In certain cases, lead extraction may be considered for functional advisory leads to prevent patient harm, such as inappropriate shocks, symptomatic device failure (eg, symptomatic bradycardia and/or syncope), and mechanical complications. In addition,

the difficulty of transvenous lead extraction increases with increasing implant duration and removal of a relatively young advisory lead with a significant failure risk will be technically easier when performed earlier rather than at some time in the future if the lead fails.[40] Extraction registries have reported higher complication rates or clinical failure when there are large numbers of leads requiring removal.[38,39,41,42] Therefore, abandoning leads could complicate future TLE and potentially lead to increased risk of major complications.[22,23] In a large registry study of 2962 procedures, patients with multiple abandoned leads had an increased risk of infection and all-cause mortality vs controls without abandoned leads matched by age, sex, device type, and device revision/removal date.[22] For advisory leads that have failed, the decision regarding abandonment versus extraction should follow the same guiding principles as for non-advisory leads. The risk/benefit ratio of lead(s) or leadless device removal on a normally functioning lead or device must be considered in a shared decision-making process with the patient when the lead management plan is discussed [18,24]

9.4 CIED Upgrade/Downgrade

Recommendations for CIED Upgrade/Downgrade			
COR	**LOE**	**Recommendations**	**References**
2a	**C-EO**	**7. Lead removal is reasonable for patients with vascular stenosis or occlusion that prevents implantation of a necessary lead.**	21,23,43,44

2a	**B-NR**	**8. It is reasonable to choose removal of superfluous leads over abandonment when upgrading, downgrading or revising a CIED system when the benefit outweighs the risk.**	21,23,41,42
2a	**C-LD**	**9. Lead removal can be useful if inserting additional lead(s) would result in an excessive number of leads that exceed the capacity of the vasculature.**	6,22,45

Synopsis

Procedural options for device system upgrade necessitate knowledge of ipsilateral venous patency. Thus, assessment of vascular patency prior to the procedure is preferable, as this knowledge may impact the procedural strategy. In case of an obstruction/occlusion, options include a contralateral lead implantation with tunneling across the chest, attempted venoplasty or extraction of a superfluous or functional lead to gain vascular access. An individualized approach should be taken based on operator and center expertise and an assessment of the risk and benefit of each option.

In patients with ipsilateral venous patency and leads that are no longer required (eg, upgrading a pacemaker to an ICD), there are the options of abandoning the lead and placing a new lead versus extraction and reimplantation. In each individual patient, the upfront risk of extraction must be weighed against the long-term risk of lead abandonment. When this indication is considered, it is crucial to balance the risk of the intervention (including the age, number and model of the lead(s) and the lead extraction center's

experience) with the patient factors such as age and life expectancy. TLE has become safer with growing experience, newer technology and the rescue balloon and lead abandonment is not without risk. Studies have demonstrated an increased incidence of venous occlusion and infection. In addition, if TLE is ultimately required, abandoned leads are associated with an increased risk of incomplete extraction and major complications.

When upgrading or downgrading a CIED system will result in a superfluous lead (eg, PPM to ICD or CRTD to CRTP), the same decision process for TLE versus abandonment as described for nonfunctional and advisory leads should be undertaken.

Recommendation-specific supportive text

Recommendation 7: Venous access can become an issue during a device upgrade or requirement for an additional lead due to venous occlusion at the desired venous access point. Based on operator and center expertise and the patient's condition, an individualized approach should be taken. For example, tunneling may be the only option for operators not skilled in venoplasty or TLE, however, with the associated limitations of utilization of the only remaining superior access site as well as the potential discomfort of the tunneled lead. Additionally, not all clinical cases may be amenable to all management options. In the setting of complete occlusion, venoplasty might not be possible. TLE as an approach to device upgrade for patients with vascular stenosis or occlusion is well described and has been shown to be a safe and effective strategy.[21,23,43-45] One post hoc study of a large, multi-center registry showed a clinical success rate of TLE to facilitate CIED upgrade was comparable to those who underwent TLE for other reasons (97.6% vs. 93.0%, $p = 0.569$).[21] However, in an older patient with long-dwelling lead(s) and other

comorbidities, contralateral lead implantation with tunneling across the chest is, perhaps, a more appropriate option.

Recommendation 8: In patients undergoing a CIED upgrade that would result in a superfluous lead (ie, PPM to ICD), the same decision process for TLE versus abandonment as described above should be undertaken taking into account the risk of removing the lead versus potential future complications of abandoning the lead. Superfluous leads have been associated with more technically challenging TLE, lower success rates and higher complication rates.[41-42] Additionally, the presence of abandoned leads conferred an increased risk of infection and all-cause mortality as compared with matched controls in a large registry series. [22] In fact, infection rates as high as 5.5% have been observed among patients with superfluous leads. [45]

Recommendation 9: Decisions regarding lead abandonment versus extraction of superfluous leads need to be individualized to the patient and the operator, taking into account the overall lead burden relative to the vessel size. Data regarding extraction versus abandonment are limited to retrospective, observational studies and often with limited follow-up. Regardless, increasing transvenous lead burden is not without potential complications, including symptomatic vascular occlusion and infection. While the accepted number of implanted leads within one vessel varies among operators, there is a clear association between the number of leads and the sum of their diameters in contributing toward venous stenosis and an increased incidence of pacemaker-related infection with three or more abandoned leads or four or more total leads.[29] Increased shoulder pain and other complications have also been reported in patients with a larger

number of leads on the ipsilateral side.[6] As always, lead management decisions are an individualized risk versus risk assessment, weighing the upfront risk of extraction against the long-term risk of lead abandonment.

9.5. Magnetic Resonance Imaging

Recommendations for managing CIEDs in the MRI setting were addressed in the 2017 HRS consensus document.[46] The safety of MRI in conditional and non-conditional CIED systems has previously been well established. The definition of "MRI non-conditional" comprises all CIED systems that have not been FDA-labeled as "MR-conditional." This also includes CIED systems with leads from differing manufacturers, whether or not the leads have been approved as part of another MRI-conditional system, as well as CIED systems with abandoned or epicardial leads.[46]

Substantial evidence has accumulated to demonstrate that MRI can be safely accomplished in most MRI non-conditional CIED systems, including those with abandoned or epicardial leads.[46-50] Not all patients with MRI non-conditional CIED systems have reasonable imaging alternatives. Therefore, for the individual patient, shared decision-making regarding the risks of undergoing MRI with a non-conditional CIED vs the risks of lead extraction to achieve an MRI-compatible system in this setting is paramount [51-55]

Recommendations for MRI			
COR	**LOE**	**Recommendations**	**References**

1	**B-NR**	**10. It is recommended that facilities develop and have protocols for performing MRI in patients with non-conditional CIED systems.**	
2b	**C-EO**	**11. Lead removal may be considered for selected patients to facilitate access to MRI after considering other imaging modalities including off-label MRI.**	47-55

Synopsis

Many FDA-approved MRI-conditional CIED systems are widely implanted today and are safe for use in the MRI environment when managed according to specific labeling requirements, including reprogramming. Substantial evidence has been accumulated to demonstrate that MRI can be safely performed in most MRI non-conditional CIED systems, including those with abandoned or epicardial leads.[46-50] It must be noted that the use of a multidisciplinary collaborative protocol is advisable. However, currently there is limited availability for MRI non-conditional CIED system scans. Therefore, removal of malfunctioning or abandoned leads to allow implantation of an MR-conditional system may be considered to facilitate MRI imaging, especially those for whom no other optimal imaging modality is readily available.

Recommendation-specific supportive text

Recommendation 10: It is recommended that a standardized, multidisciplinary protocol for MRI scanning be developed and implemented in any CIED. However, in patients with an MRI non-conditional system, additional steps are advisable to ensure safety and minimize hazards to the patient. These should include a risk vs. benefit discussion and consideration of alternative imaging modalities. Substantial evidence has been accumulated to demonstrate that MRI can be safely performed in most MRI non-conditional CIED systems. There is a growing body of literature that has shown MRI in nonconditional epicardially implanted leads or abandoned leads in both the pediatric and adult populations does not represent a greater risk than MRI performed on transvenous CIEDs. [46-50]

Recommendation 11: Although the large body of evidence shows a low risk when using MRI in patients who have MRI non-conditional CIEDs despite the manufacturer's labeling, access to MRI for these patients remains limited. Therefore, the class 2b indication for consideration of lead extraction to facilitate obtaining an MRI-conditional CIED status has been maintained. As lead extraction can be associated with serious complications, albeit at a very low rate, we advocate improving access to MRI for CIED patients and ultimately lifting the restriction for MRI with non-conditional CIEDs.

9.6. CIED Management in Tricuspid Valve Disease

CIEDs and tricuspid valve disease frequently coexist either in an independent or causal relationship. Tricuspid valve dysfunction can occur as a result of CIED implant from mechanical interference of the lead(s) with the valve leaflet function because of

lead adhesion or direct trauma to the valve itself, or due to altered right ventricular geometry as a consequence of long-term pacing.[56-59] The reported prevalence of tricuspid regurgitation (TR) following CIED implantation varies widely from 7-45%; [57,58,60-66] and, 10-38% when classified as a >= 2 grade increase in TR severity.[62,64,66-68] Various risk factors have been associated with CIED-related TR; however, none have proven consistent, highlighting the multitude of variables at play.[69]

Recommendations for Tricuspid Valve Disease			
COR	**LOE**	**Recommendations**	**References**
1	**C-EO**	**12. Lead removal is recommended in patients with transvenous leads crossing the tricuspid valve and planned transvenous tricuspid valve replacement to avoid entrapment of the lead, and to facilitate the TTVR procedure.**	56 70 71
2a	**B-NR**	**13. Lead removal can be beneficial in selected patients with severe tricuspid regurgitation where the mechanism of tricuspid regurgitation is thought to be secondary to the existing transvenous lead(s).**	57 61

Synopsis

Reported outcomes of tricuspid valve function with transvenous lead extraction are inconsistent,[61,72-81] likely reflecting variability in the TR mechanism. Among 2678

patients undergoing TLE, Polewczyk et al.[61,72] identified 119 patients with lead-related TR and observed a 35% reduction in TR in this group, emphasizing the importance of accurately evaluating TR etiology. In a smaller series, Nazmul et al.[82] observed a relationship between tricuspid valve annular dilation and irreversible lead-related TR, highlighting the significance of appropriate patient selection for valvular intervention. Lastly, severe TV injury is a potential yet uncommon complication of TLE. Large series at high-volume centers have reported an incidence of TLE associated TV injury of 0.8-2.5% [6, 23] while smaller series have described incidences of worsening TR (defined as >=1 grade increase) as high as 11.5-15%.[78,81] Importantly, injuries resulting in tricuspid valve flail leaflets were not observed in leads less than or equal to 7 years old.

The management of severe TR is undergoing an evolution with the advent of transcatheter tricuspid valve replacement (TTVR). In recent studies, patients with preexisting transvenous leads represent more than one-third of the TTVR population.[83] While each case should be individualized, the jailing of transvenous leads by TTVR should be avoided for two principal reasons. First, the potential for reduction in TR severity with lead removal, especially with younger leads, may obviate the need for TTVR. Second, there are tangible risks associated with jailing leads.

While studies of TTVR-jailed transvenous leads have limited follow-up to date, the early results are concerning. In just 15 months of follow-up, Anderson et al.[70] observed an 11% risk of lead failure among 28 TTVR patients with entrapment of the right ventricular lead from the Valve-in-Valve International Database. More recently, Mekary et al.[71] described their experience with TTVR entrapped leads in a real-world experience.

Among 14 TTVR patients with entrapped RV leads, they observed a 21% failure rate with 14% mortality after only 10.5 months of follow-up. Causes of mortality included local CIED infection progressing to endocarditis and, ultimately, death and sudden cardiac death in a pacemaker-dependent patient. The rates of lead failure and death with RV lead entrapment by TTVR are alarming. The TRIPLACE TTVR registry for a 5.9% failure rate of jailed leads at only 6 months, as well as an increased risk of TV reintervention and perivalvular leak.[84]

Recommendation-specific supportive text

Recommendation 12: TTVR is a rapidly evolving technology for the percutaneous management of tricuspid valve disease, whose popularity and implementation are growing rapidly. The management of CIEDs in tricuspid valve disease is complex and warrants involvement of a multidisciplinary team, including electrophysiologists specifically skilled in CIED management and lead extraction. Existing transvenous leads should be removed prior to valve placement, thus avoiding entrapment of these leads behind the valve. The adverse events associated with jailed leads include lead dislodgement, lead malfunction, infection, sepsis, and death. In the event of future infection, complete removal of the infected jailed lead may not be possible, certainly without jeopardizing the overlying valve apparatus. The management of leads crossing the tricuspid valve, analogous to the recommendations for venous stenting and endovascular leads, seems both logical and prudent. Additionally, pacing requirements after TV intervention should ideally employ TV-sparing approaches such as leadless pacemakers or coronary sinus lead placement if possible. Finally, any

decisions regarding CIED management in this patient population require the involvement of a multidisciplinary team with electrophysiologists specializing in CIED management and shared decision-making.

Recommendation 13: Tricuspid regurgitation can occur as a result of concomitant disease processes that require CIED therapy or as a result of the CIED therapy itself. Consideration of lead removal among patients with severe tricuspid regurgitation, mechanistically related to the existing transvenous lead(s), should be entertained to mitigate the valvular regurgitation. Yet, early intervention (right ventricular lead removal or reposition) within 1-2 years of lead implant is advised, as late intervention may not restore the tricuspid valve function despite removing the lead.

9.7. Radiation therapy

Recommendations for [subsection title]			
COR	**LOE**	**Recommendations**	**References**
2b	**C-EO**	**14. Lead removal may, in rare instances, be considered as part of the management strategy for patients with a CIED generator location that interferes with the treatment of a malignancy after considering other options.**	85,86 87 88 89-91

Synopsis

It is estimated that 1.25 million pacemakers and 410,000 implantable cardioverter-defibrillators (ICDs) are implanted worldwide annually. [92] In 2025, it is projected that there

will be more than 2 million new cancer cases that will occur in the United States alone, with approximately half requiring radiotherapy as part of their treatment plan.[93] The exponential increase in the intersection of these events is unavoidable.

Fortunately, radiation therapy-induced CIED malfunction is uncommon, and the clinical consequences are tempered.[85-91,94-101] In fact, the majority of cases can be managed with device reprogramming and careful monitoring. Thus, the need for preventive complete device system removal is exceedingly rare and only indicated when the CIED is situated in the path of a planned radiation beam, resulting in interference with adequate tumor treatment.

The reported rate of radiation-related CIED malfunction is highly variable, with incidences described between 1% and 20%.[86,88,89,91] However, clinically significant adverse events are infrequent. The most commonly observed CIED malfunctions are software-related issues, either transient effects during the radiation therapy itself or device reset recoverable after reprogramming, while permanent device damage occurs less frequently [102] Risk factors for radiotherapy-induced CIED malfunction include pacemaker dependency, the presence of ICD and CRT devices, photon beam energy >10 MV, electron energy >20 MeV or proton therapy and cumulative generator absorbed dose > 5 Gy. Despite this, there is substantial evidence documenting the tolerance of the CIED generator to radiation exposure even among those at highest risk for device malfunction. Risk stratification and enhanced monitoring programs without invasive measures are the preferred management strategy for CIED patients undergoing radiation therapy.

Recommendation-specific supportive text

Recommendation 14: CIED system revision can be considered if the CIED is located directly in the path of the planned radiation therapy beam and its very position would interfere with adequate radiation delivery. In these infrequent situations, device generator relocation often suffices. Even amongst patients at high risk for CIED malfunction (pacemaker dependency; ICD and CRT devices; photon beam energy >10 MV, electron energy >20 MeV or proton therapy; and cumulative generator absorbed dose > 5 Gy), patients are often best managed conservatively.

9.8. Other

Recommendations for Other Issues			
COR	**LOE**	**Recommendations**	**References**
1	**C-EO**	**15. Lead or leadless device removal is recommended for patients with symptomatic arrhythmias secondary to the device, leads and/or lead fragment(s).**	103
1	**C-EO**	**16. Lead removal is recommended for patients with an abandoned lead that interferes with the operation of a CIED system.**	104,105
1	**B-NR**	**17. Lead removal is recommended for patients with complications (eg, pain, bleeding) as a result of lead perforation.**	106,107 108,109 110

1	**C-LD**	**18. Lead extraction is recommended to ensure complete hardware removal when partial lead removal is performed as part of a concomitant open surgical procedure, such as cardiac transplantation or tricuspid valve surgery.**	111

Synopsis

Other noninfectious indications for TLE include refractory lead-induced arrhythmias, abandoned lead-related CIED interference, lead perforation, and as part of a strategy to ensure complete hardware removal.

Recommendation-specific supportive text

Recommendation 15: Reports of lead-induced refractory ventricular arrhythmias with resolution following TLE exist in the literature but are uncommon. Mechanical proarrhythmia from transvenous endocardial leads or leadless devices is a rare but clinically important event.[103] The mechanism is unknown but is believed to be multifactorial. Identification of this form of lead or device proarrhythmia requires a high index of suspicion, particularly in cases where electrophysiological mapping localizes the origin of the arrhythmia to the region of the device or lead tip. As TLE is curative, prompt recognition is important. When frequent premature ventricular contractions or ventricular tachycardia are clearly associated with the lead or leadless device and are unable to resolve, removing or repositioning the lead/device should be considered.

Recommendation 16: Adverse lead-lead interactions requiring removal of an abandoned lead may occur. Both electrical and mechanical lead-lead interactions have been reported in the literature.[104,105] While the standard of care is to avoid contact between an abandoned and newly implanted lead, electrode contact can and does occur. Lead removal or repositioning to eliminate lead-to-lead interaction is the definitive treatment of choice.

Recommendation 17: While lead perforation frequently presents as an acute problem necessitating immediate intervention, cases of delayed perforation do occur.[106,108,109,112-115] When complications such as bleeding and pain develop as a consequence of perforation, lead removal is an integral part of the treatment strategy.

Lead removal can often be performed with simple traction,[116] but advanced transvenous extraction techniques may be required.[106,108,109,115] Several studies have demonstrated the safety and efficacy of both transvenous and surgical lead removal.[106,108,109,115-118] Conversely, conservative management of lead perforation, versus early lead revision, has been associated with increased complications.[110] Lead removal should be performed for complications related to lead perforation when lead function is compromised, and unresolved chest pain related to the lead perforation. Transvenous or surgical lead removal can be performed safely in the majority of patients.

Recommendation 18: Transvenous lead removal is frequently attempted at the time of planned surgical procedures such as cardiac transplant or tricuspid valve surgery. However, lead removal can be incomplete or not attempted at all, with leads transected and only intracardiac portions removed[119,120], with up to 39% of patients with remaining lead remnants.[119] Lead remnants are associated with complications such as infection,

lead embolization and migration, erosion[111,119,120], and loss of venous access.[121]. When lead remnants remain after cardiac surgery, transvenous lead extraction can be performed successfully and safely but may often require specialized tools and various vascular approaches.[111,121]

At the time of transplant, for devices older than a few years, cutting the leads in the superior vena cava (SVC), removing the device and pulling the lead from the pocket often results in lead remnants in the subclavian/brachiocephalic veins that are difficult to remove. It is recommended that the lead(s) be cut as high as possible in the SVC, and the device and proximal leads left in place. Prior to discharge, the device and lead remnants can be safely removed using a standard TLE approach to minimize complications of retained lead fragments.

References

1. Gomes S, Cranney G, Bennett M, Li A, Giles R. Twenty-year experience of transvenous lead extraction at a single centre. *Europace*. 2014;16:1350–1355. doi: 10.1093/europace/eut424

2. Jones SOt, Eckart RE, Albert CM, Epstein LM. Large, single-center, single-operator experience with transvenous lead extraction: outcomes and changing indications. *Heart Rhythm*. 2008;5:520–525. doi: 10.1016/j.hrthm.2008.01.009

3. Citerne O, Gomes S, Scanu P, Milliez P. Painful Eczema mimicking pocket infection in a patient with an ICD: a rare cause of skin allergy to nickel/cobalt alloy. *Circulation*. 2011;123:1241–1242. doi: 10.1161/CIRCULATIONAHA.110.000547

4. Kang J, Simpson CS, Campbell D, Borici-Mazi R, Redfearn DP, Michael KA, Abdollah H, Baranchuk A. Cardiac rhythm device contact dermatitis. *Ann Noninvasive Electrocardiol*. 2013;18:79–83. doi: 10.1111/j.1542-474X.2012.00509.x

5. Bode K, Breithardt OA, Kreuzhuber M, Mende M, Sommer P, Richter S, Doering M, Dinov B, Rolf S, Arya A, et al. Patient discomfort following catheter ablation and rhythm device surgery. *Europace*. 2015;17:1129–1135. doi: 10.1093/europace/euu325

6. Celikyurt U, Agacdiken A, Bozyel S, Argan O, Sade I, Vural A, Ural D. Assessment of shoulder pain and shoulder disability in patients with implantable cardioverter-defibrillator. *J Interv Card Electrophysiol*. 2013;36:91–94. doi: 10.1007/s10840-012-9753-7

7. Dy Chua J, Abdul-Karim A, Mawhorter S, Procop GW, Tchou P, Niebauer M, Saliba W, Schweikert R, Wilkoff BL. The role of swab and tissue culture in the diagnosis of implantable cardiac device infection. *Pacing Clin Electrophysiol*. 2005;28:1276–1281. doi: 10.1111/j.1540-8159.2005.00268.x

8. Lewis K, Dai M, Patton KK, Cha YM, Pollema T, Feld GK, Birgersdotter-Green U, Pretorius V. Lead extraction for reduction of chronic pain related to cardiovascular implantable electronic device. *Europace*. 2019;21:781–786. doi: 10.1093/europace/euy320

9. Rohacek M, Weisser M, Kobza R, Schoenenberger AW, Pfyffer GE, Frei R, Erne P, Trampuz A. Bacterial colonization and infection of electrophysiological cardiac devices detected with sonication and swab culture. *Circulation*. 2010;121:1691–1697. doi: 10.1161/CIRCULATIONAHA.109.906461

10. Morani G, Bolzan B, Valsecchi S, Morosato M, Ribichini FL. Chronic venous obstruction during cardiac device revision: Incidence, predictors, and efficacy of percutaneous techniques to overcome the stenosis. *Heart Rhythm*. 2020;17:258–264. doi: 10.1016/j.hrthm.2019.08.012

11. Arora Y, Carrillo RG. Lead-related superior vena cava syndrome: Management and outcomes. *Heart Rhythm*. 2021;18:207–214. doi: 10.1016/j.hrthm.2020.09.006

12. Gabriels J, Chang D, Maytin M, Tadros T, John RM, Sobieszczyk P, Eisenhauer A, Epstein LM. Percutaneous management of superior vena cava syndrome in patients with cardiovascular implantable electronic devices. *Heart Rhythm*. 2021;18:392–398. doi: 10.1016/j.hrthm.2020.11.012

13. Noheria A, Ponamgi SP, Desimone CV, Vaidya VR, Aakre CA, Ebrille E, Hu T, Hodge DO, Slusser JP, Ammash NM, et al. Pulmonary embolism in patients with transvenous cardiac implantable electronic device leads. *Europace*. 2016;18:246–252. doi: 10.1093/europace/euv038

14. Khairy P, Landzberg MJ, Gatzoulis MA, Mercier LA, Fernandes SM, Cote JM, Lavoie JP, Fournier A, Guerra PG, Frogoudaki A, et al. Transvenous pacing leads and systemic thromboemboli in patients with intracardiac shunts: a multicenter study. *Circulation*. 2006;113:2391–2397. doi: 10.1161/CIRCULATIONAHA.106.622076

15. Larsen JM, Theuns DA, Thogersen AM. Paradoxical thromboembolic stroke during extraction of a recalled St Jude Medical Riata defibrillator lead with conductor externalization. *Europace*. 2014;16:240. doi: 10.1093/europace/eut164

16. Fu HX, Huang XM, Zhong L, Osborn MJ, Bjarnason H, Mulpuru S, Zhao XX, Friedman PA, Cha YM. Outcome and management of pacemaker-induced superior vena cava syndrome. *Pacing Clin Electrophysiol*. 2014;37:1470–1476. doi: 10.1111/pace.12455

17. Riley RF, Petersen SE, Ferguson JD, Bashir Y. Managing superior vena cava syndrome as a complication of pacemaker implantation: a pooled analysis of clinical practice. *Pacing Clin Electrophysiol*. 2010;33:420–425. doi: 10.1111/j.1540-8159.2009.02613.x

18. Gasperetti A, Schiavone M, Ziacchi M, Vogler J, Breitenstein A, Laredo M, Palmisano P, Ricciardi D, Mitacchione G, Compagnucci P, et al. Long-term complications in patients implanted with subcutaneous implantable cardioverter-defibrillators:

Real-world data from the extended ELISIR experience. *Heart Rhythm*. 2021;18:2050–2058. doi: 10.1016/j.hrthm.2021.07.008

19. Zeitler EP, Wang Y, Pokorney SD, Curtis J, Prutkin JM. Comparative outcomes of Riata and Fidelis lead management strategies: Results from the NCDR-ICD Registry. *Pacing Clin Electrophysiol*. 2021;44:1897–1906. doi: 10.1111/pace.14361

20. Mar PL, John A, Kumar S, Barry N, Chen G, Longserre S, Kabra R, Atkins D, Koerber S, Hussein A, et al. Management and long-term outcomes associated with recalled implantable cardioverter-defibrillator leads: A multicenter experience. *Heart Rhythm*. 2020;17:1909–1916. doi: 10.1016/j.hrthm.2020.06.004

21. Haeberlin A, Noti F, Breitenstein A, Auricchio A, Reichlin T, Conte G, Klersy C, Curti M, Pruvot E, Domenichini G, et al. Transvenous Lead Extraction during Cardiac Implantable Device Upgrade: Results from the Multicenter Swiss Lead Extraction Registry. *J Clin Med*. 2023;12. doi: 10.3390/jcm12165175

22. Kwon S, Lee E, Choi EK, Lee SR, Oh S, Choi YS. Long-term outcomes of abandoned leads of cardiac implantable electronic devices. *Heart Rhythm*. 2023;20:1639–1646. doi: 10.1016/j.hrthm.2023.07.068

23. Stefanczyk P, Nowosielecka D, Polewczyk A, Jachec W, Glowniak A, Kosior J, Kutarski A. Efficacy and Safety of Transvenous Lead Extraction at the Time of Upgrade from Pacemakers to Cardioverter-Defibrillators and Cardiac Resynchronization Therapy. *Int J Environ Res Public Health*. 2022;20. doi: 10.3390/ijerph20010291

24. Alqarawi W, Coppens J, Aldawood W, Ramirez FD, Redpath CJ, Nair GM, Nery PB, Davis DR, Abu Shama R, Aydin A, et al. A Strategy of Lead Abandonment in a Large Cohort of Patients With Sprint Fidelis Leads. *JACC Clin Electrophysiol*. 2019;5:1059–1067. doi: 10.1016/j.jacep.2019.07.006

25. Maisel WH. Transvenous implantable cardioverter-defibrillator leads: the weakest link. *Circulation*. 2007;115:2461–2463. doi: 10.1161/CIRCULATIONAHA.107.698597

26. Maytin M, Epstein LM. Lead Design for Safer Lead Extraction. *Cardiac Electrophysiology Clinics*. 2014;6:345–354. doi: 10.1016/j.ccep.2014.03.004

27. van der Heijden AC, Borleffs CJ, Buiten MS, Thijssen J, van Rees JB, Cannegieter SC, Schalij MJ, van Erven L. The clinical course of patients with implantable cardioverter-defibrillators: Extended experience on clinical outcome, device replacements, and device-related complications. *Heart Rhythm*. 2015;12:1169–1176. doi: 10.1016/j.hrthm.2015.02.035

28. Giacopelli D, Azzolina D, Comoretto RI, Quartieri F, Rovaris G, Schillaci V, Gargaro A, Gregori D. Implantable cardioverter defibrillator lead performance: A systematic review and individual patient data Meta-analysis. *Int J Cardiol*. 2023;373:57–63. doi: 10.1016/j.ijcard.2022.11.048

29. Hauser RG, Hayes DL. Increasing hazard of Sprint Fidelis implantable cardioverter-defibrillator lead failure. *Heart Rhythm*. 2009;6:605–610. doi: 10.1016/j.hrthm.2009.02.024

30. Maytin M, Epstein LM. Lead electrical parameters may not predict integrity of the Sprint Fidelis ICD lead. *Heart Rhythm*. 2012;9:1446–1451. doi: 10.1016/j.hrthm.2012.04.033

31. Zeitler EP, Wang Y, Dharmarajan K, Anstrom KJ, Peterson ED, Daubert JP, Curtis JP, Al-Khatib SM. Outcomes 1 Year After Implantable Cardioverter-Defibrillator Lead Abandonment Versus Explantation for Unused or Malfunctioning Leads: A Report from the National Cardiovascular Data Registry. *Circ Arrhythm Electrophysiol*. 2016;9. doi: 10.1161/CIRCEP.116.003953

32. Pokorney SD, Mi X, Lewis RK, Greiner M, Epstein LM, Carrillo RG, Zeitler EP, Al-Khatib SM, Hegland DD, Piccini JP. Outcomes Associated With Extraction Versus Capping and Abandoning Pacing and Defibrillator Leads. *Circulation*. 2017;136:1387–1395. doi: 10.1161/CIRCULATIONAHA.117.027636

33. Amelot M, Foucault A, Scanu P, Gomes S, Champ-Rigot L, Pellissier A, Milliez P. Comparison of outcomes in patients with abandoned versus extracted implantable cardioverter defibrillator leads. *Arch Cardiovasc Dis*. 2011;104:572–577. doi: 10.1016/j.acvd.2011.08.004

34. Rijal S, Shah RU, Saba S. Extracting versus abandoning sterile pacemaker and defibrillator leads. *Am J Cardiol*. 2015;115:1107–1110. doi: 10.1016/j.amjcard.2015.01.537

35. Boyle TA, Uslan DZ, Prutkin JM, Greenspon AJ, Baddour LM, Danik SB, Tolosana JM, Le K, Miro JM, Peacock JE, et al. Impact of Abandoned Leads on Cardiovascular Implantable Electronic Device Infections: A Propensity Matched Analysis of MEDIC

(Multicenter Electrophysiologic Device Infection Cohort). *JACC Clin Electrophysiol*. 2018;4:201–208. doi: 10.1016/j.jacep.2017.09.178

36. Hussein AA, Tarakji KG, Martin DO, Gadre A, Fraser T, Kim A, Brunner MP, Barakat AF, Saliba WI, Kanj M, et al. Cardiac Implantable Electronic Device Infections: Added Complexity and Suboptimal Outcomes With Previously Abandoned Leads. *JACC Clin Electrophysiol*. 2017;3:1–9. doi: 10.1016/j.jacep.2016.06.009

37. Wollmann CG, Bocker D, Loher A, Paul M, Scheld HH, Breithardt G, Gradaus R. Two different therapeutic strategies in ICD lead defects: additional combined lead versus replacement of the lead. *J Cardiovasc Electrophysiol*. 2007;18:1172–1177. doi: 10.1111/j.1540-8167.2007.00940.x

38. Jachec W, Polewczyk A, Polewczyk M, Tomasik A, Janion M, Kutarski A. Risk Factors Predicting Complications of Transvenous Lead Extraction. *Biomed Res Int*. 2018;2018:8796704. doi: 10.1155/2018/8796704

39. Brunner MP, Cronin EM, Duarte VE, Yu C, Tarakji KG, Martin DO, Callahan T, Cantillon DJ, Niebauer MJ, Saliba WI, et al. Clinical predictors of adverse patient outcomes in an experience of more than 5000 chronic endovascular pacemaker and defibrillator lead extractions. *Heart Rhythm*. 2014;11:799–805. doi: 10.1016/j.hrthm.2014.01.016

40. Zabek A, Boczar K, Debski M, Matusik PT, Pfitzner R, Ulman M, Musial R, Lelakowski J, Malecka B. Transvenous extraction of very old (over 20-year-old) pacemaker leads using mechanical systems: Effectiveness and safety. *Pacing Clin Electrophysiol*. 2019;42:998–1005. doi: 10.1111/pace.13714

41. Bongiorni MG, Kennergren C, Butter C, Deharo JC, Kutarski A, Rinaldi CA, Romano SL, Maggioni AP, Andarala M, Auricchio A, et al. The European Lead Extraction ConTRolled (ELECTRa) study: a European Heart Rhythm Association (EHRA) Registry of Transvenous Lead Extraction Outcomes. *Eur Heart J*. 2017;38:2995–3005. doi: 10.1093/eurheartj/ehx080

42. Sood N, Martin DT, Lampert R, Curtis JP, Parzynski C, Clancy J. Incidence and Predictors of Perioperative Complications With Transvenous Lead Extractions: Real-World Experience With National Cardiovascular Data Registry. *Circ Arrhythm Electrophysiol*. 2018;11:e004768. doi: 10.1161/CIRCEP.116.004768

43. Gula LJ, Ames A, Woodburn A, Matkins J, McCormick M, Bell J, Sink D, McConville J, Epstein LM. Central venous occlusion is not an obstacle to device upgrade with the assistance of laser extraction. *Pacing Clin Electrophysiol*. 2005;28:661–666. doi: 10.1111/j.1540-8159.2005.00163.x

44. Sohal M, Williams S, Akhtar M, Shah A, Chen Z, Wright M, O'Neill M, Patel N, Hamid S, Cooklin M, et al. Laser lead extraction to facilitate cardiac implantable electronic device upgrade and revision in the presence of central venous obstruction. *Europace*. 2014;16:81–87. doi: 10.1093/europace/eut163

45. Suga C, Hayes DL, Hyberger LK, Lloyd MA. Is there an adverse outcome from abandoned pacing leads? *J Interv Card Electrophysiol*. 2000;4:493–499. doi: 10.1023/a:1009860514724

46. Indik JH, Gimbel JR, Abe H, Alkmim-Teixeira R, Birgersdotter-Green U, Clarke GD, Dickfeld TL, Froelich JW, Grant J, Hayes DL, et al. 2017 HRS expert consensus

statement on magnetic resonance imaging and radiation exposure in patients with cardiovascular implantable electronic devices. *Heart Rhythm*. 2017;14:e97–e153. doi: 10.1016/j.hrthm.2017.04.025

47. Gakenheimer-Smith L, Etheridge SP, Niu MC, Ou Z, Presson AP, Whitaker P, Su J, Puchalski MD, Asaki SY, Pilcher T. MRI in pediatric and congenital heart disease patients with CIEDs and epicardial or abandoned leads. *Pacing Clin Electrophysiol*. 2020;43:797–804. doi: 10.1111/pace.13984

48. Gakenheimer-Smith L, Ou Z, Kuang J, Moore JP, Burrows A, Kovach J, Dechert B, Beach CM, Ayers M, Tan RB, et al. Multicenter retrospective evaluation of magnetic resonance imaging in pediatric and congenital heart disease patients with cardiac implantable electronic devices. *Heart Rhythm*. 2023;20:1752–1758. doi: 10.1016/j.hrthm.2023.08.034

49. Ma YD, Watson RE, Jr., Olson NE, Birgersdotter-Green U, Patel K, Mulpuru SK, Madhavan M, Deshmukh AJ, Killu AM, Friedman PA, et al. Safety of magnetic resonance imaging in patients with surgically implanted permanent epicardial leads. *Heart Rhythm*. 2023;20:1111–1118. doi: 10.1016/j.hrthm.2023.04.003

50. Schaller RD, Brunker T, Riley MP, Marchlinski FE, Nazarian S, Litt H. Magnetic Resonance Imaging in Patients With Cardiac Implantable Electronic Devices With Abandoned Leads. *JAMA Cardiol*. 2021;6:549–556. doi: 10.1001/jamacardio.2020.7572

51. Austin CO, Landolfo K, Parikh PP, Patel PC, Venkatachalam KL, Kusumoto FM. Retained cardiac implantable electronic device fragments are not associated with

magnetic resonance imaging safety issues, morbidity, or mortality after orthotopic heart transplant. *Am Heart J*. 2017;190:46–53. doi: 10.1016/j.ahj.2017.04.011

52. Higgins JV, Gard JJ, Sheldon SH, Espinosa RE, Wood CP, Felmlee JP, Cha YM, Asirvatham SJ, Dalzell C, Acker N, et al. Safety and outcomes of magnetic resonance imaging in patients with abandoned pacemaker and defibrillator leads. *Pacing Clin Electrophysiol*. 2014;37:1284–1290. doi: 10.1111/pace.12419

53. Langman DA, Goldberg IB, Finn JP, Ennis DB. Pacemaker lead tip heating in abandoned and pacemaker-attached leads at 1.5 Tesla MRI. *J Magn Reson Imaging*. 2011;33:426–431. doi: 10.1002/jmri.22463

54. Naehle CP, Meyer C, Thomas D, Remerie S, Krautmacher C, Litt H, Luechinger R, Fimmers R, Schild H, Sommer T. Safety of brain 3-T MR imaging with transmit-receive head coil in patients with cardiac pacemakers: pilot prospective study with 51 examinations. *Radiology*. 2008;249:991–1001. doi: 10.1148/radiol.2493072195

55. Padmanabhan D, Kella DK, Mehta R, Kapa S, Deshmukh A, Mulpuru S, Jaffe AS, Felmlee JP, Jondal ML, Dalzell CM, et al. Safety of magnetic resonance imaging in patients with legacy pacemakers and defibrillators and abandoned leads. *Heart Rhythm*. 2018;15:228–233. doi: 10.1016/j.hrthm.2017.10.022

56. Hahn RT, Wilkoff BL, Kodali S, Birgersdotter-Green UM, Ailawadi G, Addetia K, Andreas M, Auricchio A, Ehlert F, George I, et al. Managing Implanted Cardiac Electronic Devices in Patients With Severe Tricuspid Regurgitation: JACC State-of-the-Art Review. *J Am Coll Cardiol*. 2024;83:2002–2014. doi: 10.1016/j.jacc.2024.02.045

57. Leong DP, Dokainish H, Mondesert B, Cavalli G, Khetan A, Cirne F, Baro Vila R, Klimis H, De Jesus TA, AlGhasab NS, et al. Effects of Implantable Cardioverter-Defibrillator Leads on the Tricuspid Valve and Right Ventricle: A Randomized Trial. *JACC Clin Electrophysiol*. 2024;10:2088–2096. doi: 10.1016/j.jacep.2024.04.034

58. Alnaimat S, Doyle M, Krishnan K, Biederman RWW. Worsening tricuspid regurgitation associated with permanent pacemaker and implantable cardioverter-defibrillator implantation: A systematic review and meta-analysis of more than 66,000 subjects. *Heart Rhythm*. 2023;20:1491–1501. doi: 10.1016/j.hrthm.2023.07.064

59. Gabriels JK, Schaller RD, Koss E, Rutkin BJ, Carrillo RG, Epstein LM. Lead management in patients undergoing percutaneous tricuspid valve replacement or repair: a 'heart team' approach. *Europace*. 2023;25. doi: 10.1093/europace/euad300

60. Breeman KTN, Peijster AJL, De Bruin-Bon H, Pepplinkhuizen S, Van der Stuijt W, De Veld JA, Beurskens NEG, Stuiver MM, Wilde AAM, Tjong FVY, et al. Worsening tricuspid regurgitation after ICD implantation is rather due to transvenous lead than natural progression. *Int J Cardiol*. 2023;376:76–80. doi: 10.1016/j.ijcard.2023.02.007

61. Polewczyk A, Jachec W, Nowosielecka D, Tomaszewski A, Brzozowski W, Szczesniak-Stanczyk D, Duda K, Kutarski A. Lead Dependent Tricuspid Valve Dysfunction-Risk Factors, Improvement after Transvenous Lead Extraction and Long-Term Prognosis. *J Clin Med*. 2021;11. doi: 10.3390/jcm11010089

62. Seo J, Kim DY, Cho I, Hong GR, Ha JW, Shim CY. Prevalence, predictors, and prognosis of tricuspid regurgitation following permanent pacemaker implantation. *PLoS One*. 2020;15:e0235230. doi: 10.1371/journal.pone.0235230

63. Trankle CR, Gertz ZM, Koneru JN, Kasirajan V, Nicolato P, Bhardwaj HL, Ellenbogen KA, Kalahasty G. Severe tricuspid regurgitation due to interactions with right ventricular permanent pacemaker or defibrillator leads. *Pacing Clin Electrophysiol*. 2018;41:845–853. doi: 10.1111/pace.13369

64. Riesenhuber M, Spannbauer A, Gwechenberger M, Pezawas T, Schukro C, Stix G, Schneider M, Goliasch G, Anvari A, Wrba T, et al. Pacemaker lead-associated tricuspid regurgitation in patients with or without pre-existing right ventricular dilatation. *Clin Res Cardiol*. 2021;110:884–894. doi: 10.1007/s00392-021-01812-3

65. Vij A, Kavinsky CJ. The Clinical Impact of Device Lead-Associated Tricuspid Regurgitation: Need for a Multidisciplinary Approach. *Circulation*. 2022;145:239–241. doi: 10.1161/CIRCULATIONAHA.121.055019

66. Chodor-Rozwadowska KE, Sawicka M, Morawski S, Lenarczyk R, Kalarus Z, Kukulski T. Lead-related tricuspid regurgitation and ventricle dysfunction: Current management and future perspectives. *Adv Clin Exp Med*. 2023;32:1049–1061. doi: 10.17219/acem/159531

67. Klutstein M, Balkin J, Butnaru A, Ilan M, Lahad A, Rosenmann D. Tricuspid incompetence following permanent pacemaker implantation. *Pacing Clin Electrophysiol*. 2009;32 Suppl 1:S135–137. doi: 10.1111/j.1540-8159.2008.02269.x

68. Hoke U, Auger D, Thijssen J, Wolterbeek R, van der Velde ET, Holman ER, Schalij MJ, Bax JJ, Delgado V, Marsan NA. Significant lead-induced tricuspid regurgitation is associated with poor prognosis at long-term follow-up. *Heart*. 2014;100:960–968. doi: 10.1136/heartjnl-2013-304673

69. Murphy SP, Lew J, Yucel E, Singh J, Mela T. Cardiac implantable electronic device-induced tricuspid regurgitation: Implications and management. *J Cardiovasc Electrophysiol*. 2024;35:1017–1025. doi: 10.1111/jce.16251

70. Anderson JH, McElhinney DB, Aboulhosn J, Zhang Y, Ribichini F, Eicken A, Whisenant B, Jones T, Kornowski R, Dvir D, et al. Management and Outcomes of Transvenous Pacing Leads in Patients Undergoing Transcatheter Tricuspid Valve Replacement. *JACC Cardiovasc Interv*. 2020;13:2012–2020. doi: 10.1016/j.jcin.2020.04.054

71. Mekary W, Ibrahim R, Lloyd MS, Bhatia NK, Westerman SB, Shah AD, Byku I, Gleason P, Greenbaum A, Babaliaros V, et al. Pacing considerations in patients undergoing transcatheter tricuspid valve replacement: Insights from a tertiary care center. *Heart Rhythm*. 2025. doi: 10.1016/j.hrthm.2025.02.004

72. Polewczyk A, Jachec W, Nowosielecka D, Tomaszewski A, Brzozowski W, Szczesniak-Stanczyk D, Duda K, Kutarski A. Tricuspid Valve Damage Related to Transvenous Lead Extraction. *Int J Environ Res Public Health*. 2022;19. doi: 10.3390/ijerph191912279

73. Migliore F, Pittorru R, De Lazzari M, Dall'Aglio PB, Cecchetto A, Previtero M, Pergola V, Thiene G, Masiero G, Tarantini G, et al. Evaluation of tricuspid valve regurgitation

following transvenous rotational mechanical lead extraction. *Europace*. 2024;26. doi: 10.1093/europace/euae191

74. Kutarski A, Glowniak A, Kosior J, Jachec W, Nowosielecka D, Czajkowski M, Polewczyk A. Outcomes of Transvenous Extraction of Leads Older Than 20 and 30 Years-A Large Cohort Study. *Int J Environ Res Public Health*. 2022;19. doi: 10.3390/ijerph192114184

75. Jachec W, Polewczyk A, Nowosielecka D, Tomaszewski A, Brzozowski W, Szczesniak-Stanczyk D, Duda K, Nowosielecka A, Kutarski A. Change in Tricuspid Valve Function after Transvenous Lead Extraction, Predisposing Factors and Prognostic Roles. *Rev Cardiovasc Med*. 2024;25:198. doi: 10.31083/j.rcm2506198

76. Tulecki L, Polewczyk A, Jachec W, Nowosielecka D, Tomkow K, Stefanczyk P, Kosior J, Duda K, Polewczyk M, Kutarski A. Analysis of Risk Factors for Major Complications of 1500 Transvenous Lead Extraction Procedures with Especial Attention to Tricuspid Valve Damage. *Int J Environ Res Public Health*. 2021;18. doi: 10.3390/ijerph18179100

77. Pecha S, Castro L, Gosau N, Linder M, Vogler J, Willems S, Reichenspurner H, Hakmi S. Evaluation of tricuspid valve regurgitation following laser lead extractiondagger. *Eur J Cardiothorac Surg*. 2017;51:1108–1111. doi: 10.1093/ejcts/ezx011

78. Givon A, Vedernikova N, Luria D, Vatury O, Kuperstein R, Feinberg MS, Eldar M, Glikson M, Nof E. Tricuspid Regurgitation following Lead Extraction: Risk Factors and Clinical Course. *Isr Med Assoc J*. 2016;18:18–22.

79. Coffey JO, Sager SJ, Gangireddy S, Levine A, Viles-Gonzalez JF, Fischer A. The impact of transvenous lead extraction on tricuspid valve function. *Pacing Clin Electrophysiol*. 2014;37:19–24. doi: 10.1111/pace.12236

80. Rodriguez Y, Mesa J, Arguelles E, Carrillo RG. Tricuspid insufficiency after laser lead extraction. *Pacing Clin Electrophysiol*. 2013;36:939–944. doi: 10.1111/pace.12160

81. Park SJ, Gentry JL, 3rd, Varma N, Wazni O, Tarakji KG, Mehta A, Mick S, Grimm R, Wilkoff BL. Transvenous Extraction of Pacemaker and Defibrillator Leads and the Risk of Tricuspid Valve Regurgitation. *JACC Clin Electrophysiol*. 2018;4:1421–1428. doi: 10.1016/j.jacep.2018.07.011

82. Nazmul MN, Cha YM, Lin G, Asirvatham SJ, Powell BD. Percutaneous pacemaker or implantable cardioverter-defibrillator lead removal in an attempt to improve symptomatic tricuspid regurgitation. *Europace*. 2013;15:409–413. doi: 10.1093/europace/eus342

83. Kodali S, Hahn RT, George I, Davidson CJ, Narang A, Zahr F, Chadderdon S, Smith R, Grayburn PA, O'Neill WW, et al. Transfemoral Tricuspid Valve Replacement in Patients With Tricuspid Regurgitation: TRISCEND Study 30-Day Results. *JACC Cardiovasc Interv*. 2022;15:471–480. doi: 10.1016/j.jcin.2022.01.016

84. Scotti A, Puri R, Sturla M, Zahr F, Boone R, Kodali S, Tchetche D, De Backer O, Coisne A, Ludwig S, et al. Incidence, Predictors, and Management of Conduction Disturbances After Transcatheter Tricuspid Valve Replacement: The TRIPLACE Registry. *JACC Cardiovasc Interv*. 2025. doi: 10.1016/j.jcin.2025.05.029

85. Gauter-Fleckenstein B, Barthel C, Buttner S, Wenz F, Borggrefe M, Tulumen E. Effectivity and applicability of the German DEGRO/DGK-guideline for radiotherapy in CIED-bearing patients. *Radiother Oncol*. 2020;152:208–215. doi: 10.1016/j.radonc.2020.01.006

86. Zagzoog A, Wronski M, Birnie DH, Yeung C, Baranchuk A, Healey JS, Golian M, Boles U, Carrizo AG, Turner S, et al. Assessment of Radiation-Induced Malfunction in Cardiac Implantable Electronic Devices. *CJC Open*. 2021;3:1438–1443. doi: 10.1016/j.cjco.2021.07.005

87. Mirzaei M, Rowshanfarzad P, Gill S, Ebert MA, Dass J. Risk of cardiac implantable device malfunction in cancer patients receiving proton therapy: an overview. *Front Oncol*. 2023;13:1181450. doi: 10.3389/fonc.2023.1181450

88. Hamza M, Rice S, Lamichhane N, Chen S, Mohindra P. Conformal Radiation Therapy in Patients With Cardiovascular Implantable Electronic Devices: Proposed Practical Implementation of the 2019 American Association of Physicists in Medicine Task Group No. 203 Risk-Stratified Interrogation Schedule. *Pract Radiat Oncol*. 2021;11:e402–e414. doi: 10.1016/j.prro.2021.03.004

89. Gulletta S, Falasconi G, Cianfanelli L, Centola A, Paglino G, Cireddu M, Radinovic A, D'Angelo G, Marzi A, Sala S, et al. Patients with Cardiac Implantable Electronic Device Undergoing Radiation Therapy: Insights from a Ten-Year Tertiary Center Experience. *J Clin Med*. 2022;11. doi: 10.3390/jcm11174990

90. Xu B, Wang Y, Tse G, Chen J, Li G, Korantzopoulos P, Liu T. Radiotherapy-induced malfunctions of cardiac implantable electronic devices: A meta-analysis. *Heart Rhythm*. 2023;20:689–698. doi: 10.1016/j.hrthm.2023.01.024

91. Malavasi VL, Imberti JF, Tosetti A, Romiti GF, Vitolo M, Zecchin M, Mazzeo E, Giuseppina M, Lohr F, Lopez-Fernandez T, et al. A systematic review and meta-analysis on oncological radiotherapy in patients with a cardiac implantable electronic device: Prevalence and predictors of device malfunction in 3121 patients. *Eur J Clin Invest*. 2023;53:e13862. doi: 10.1111/eci.13862

92. Mond HG, Proclemer A. The 11th world survey of cardiac pacing and implantable cardioverter-defibrillators: calendar year 2009--a World Society of Arrhythmia's project. *Pacing Clin Electrophysiol*. 2011;34:1013–1027. doi: 10.1111/j.1540-8159.2011.03150.x

93. Siegel RL, Kratzer TB, Giaquinto AN, Sung H, Jemal A. Cancer statistics, 2025. *CA Cancer J Clin*. 2025;75:10–45. doi: 10.3322/caac.21871

94. Zaremba T, Jakobsen AR, Sogaard M, Thogersen AM, Riahi S. Radiotherapy in patients with pacemakers and implantable cardioverter defibrillators: a literature review. *Europace*. 2016;18:479–491. doi: 10.1093/europace/euv135

95. Stuhlinger M, Burri H, Vernooy K, Garcia R, Lenarczyk R, Sultan A, Brunner M, Sabbag A, Ozcan EE, Ramos JT, et al. EHRA consensus on prevention and management of interference due to medical procedures in patients with cardiac implantable electronic devices. *Europace*. 2022;24:1512–1537. doi: 10.1093/europace/euac040

96. Fradley MG, Lefebvre B, Carver J, Cheung JW, Feigenberg SJ, Lampert R, Liu J, Rajagopalan B, Lenihan DJ. How to Manage Patients With Cardiac Implantable Electronic Devices Undergoing Radiation Therapy. *JACC CardioOncol*. 2021;3:447–451. doi: 10.1016/j.jaccao.2021.08.005

97. Bravo-Jaimes K, Samala V, Fernandez G, Moravan MJ, Dhakal S, Shah AH, Messing S, Singh K, Aktas MK. CIED malfunction in patients receiving radiation is a rare event that could be detected by remote monitoring. *J Cardiovasc Electrophysiol*. 2018;29:1268–1275. doi: 10.1111/jce.13659

98. Falco MD, Genovesi D, Caravatta L, Di Carlo C, Bliakharskaia E, Appignani M, Faustino M, Furia N, Di Girolamo E. A randomized in vitro evaluation of transient and permanent cardiac implantable electronic device malfunctions following direct exposure up to 10 Gy. *Strahlenther Onkol*. 2021;197:198–208. doi: 10.1007/s00066-020-01651-7

99. Mircea AA, Donisan T, Feigenberg S, Fradley MG. What do national radiotherapy guidelines for patients with cardiac devices teach us? *Heart Rhythm O2*. 2024;5:189–193. doi: 10.1016/j.hroo.2024.01.008

100. Aslian H, Kron T, Longo F, Rad R, Severgnini M. A review and analysis of stereotactic body radiotherapy and radiosurgery of patients with cardiac implantable electronic devices. *Australas Phys Eng Sci Med*. 2019;42:415–425. doi: 10.1007/s13246-019-00751-8

101. Larsen MB, Jakobsen AR, Lundbye-Christensen S, Riahi S, Thogersen AM, Zaremba T. Evaluation of cardiac implantable electronic device lead parameters before and

after radiotherapy. *Pacing Clin Electrophysiol*. 2024;47:1176–1184. doi: 10.1111/pace.15048

102. Souliman SK, Christie J. Pacemaker failure induced by radiotherapy. *Pacing Clin Electrophysiol*. 1994;17:270–273. doi: 10.1111/j.1540-8159.1994.tb01387.x

103. Lee JC, Epstein LM, Huffer LL, Stevenson WG, Koplan BA, Tedrow UB. ICD lead proarrhythmia cured by lead extraction. *Heart Rhythm*. 2009;6:613–618. doi: 10.1016/j.hrthm.2009.01.039

104. Pfitzner P, Trappe HJ. Oversensing in a cardioverter defibrillator system caused by interaction between two endocardial defibrillation leads in the right ventricle. *Pacing Clin Electrophysiol*. 1998;21:764–768. doi: 10.1111/j.1540-8159.1998.tb00136.x

105. Valentino V, Greenberg YJ, Saunders P, Yang F. An unusual interaction between an abandoned pacing lead and an ICD lead. *Heart Rhythm*. 2015;12:1400–1401. doi: 10.1016/j.hrthm.2015.02.021

106. Issa ZF, Issa TZ. Feasibility and Safety of Percutaneous Lead Revision for Subacute and Delayed Cardiac Device Lead Perforation. *JACC Clin Electrophysiol*. 2021;7:26–35. doi: 10.1016/j.jacep.2020.07.024

107. Archontakis S, Sideris K, Aggeli K, Gatzoulis K, Demosthenous M, Tolios P, Lozos V, Koumallos N, Limperiadis D, Tousoulis D, et al. Percutaneous lead extraction and repositioning: An effective and safe therapeutic strategy for early ventricular lead perforation with dislocation both inside and outside the pericardial sac following a

cardiac device implantation. *J Cardiovasc Electrophysiol*. 2019;30:299–307. doi: 10.1111/jce.13804

108. Waddingham PH, Elliott J, Bates A, Bilham J, Muthumala A, Honarbakhsh S, Ullah W, Hunter RJ, Lambiase PD, Lane RE, et al. Iatrogenic cardiac perforation due to pacemaker and defibrillator leads: a contemporary multicentre experience. *Europace*. 2022;24:1824–1833. doi: 10.1093/europace/euac105

109. Jessel PM, Yadava M, Nazer B, Dewland TA, Miller J, Stecker EC, Bhamidipati CM, Song HK, Henrikson CA. Transvenous management of cardiac implantable electronic device late lead perforation. *J Cardiovasc Electrophysiol*. 2020;31:521–528. doi: 10.1111/jce.14331

110. Rav Acha M, Rafael A, Keaney JJ, Elitzur Y, Danon A, Shauer A, Taha L, Shechter Y, Bogot NR, Luria D, et al. The management of cardiac implantable electronic device lead perforations: a multicentre study. *Europace*. 2019;21:937–943. doi: 10.1093/europace/euz120

111. Kusmierski K, Przybylski A, Oreziak A, Sobieszczanska-Malek M, Kolsut P, Rozanski J. Post heart transplant extraction of the abandoned fragments of pacing and defibrillation leads: proposed management algorithm. *Kardiol Pol*. 2013;71:159–163. doi: 10.5603/KP.2013.0009

112. Zabek A, Boczar K, Krupinski M, Debski M, Lelakowski J, Malecka B. Delayed perforation of the right ventricle by cardioverter-defibrillator lead - safe transvenous lead extraction by mechanical systems. *Postepy Kardiol Interwencyjnej*. 2023;19:192–194. doi: 10.5114/aic.2023.126180

113. Yamamoto A, Takahashi S. Delayed right ventricular lead perforation by a pacemaker lead 2-year post-implantation. *Clin Case Rep*. 2022;10:e05760. doi: 10.1002/ccr3.5760

114. Waechter C, Koenig AM, Chatzis G, Mueller J, Schieffer B, Luesebrink U. Delayed perforation of an atrial pacemaker electrode: Lifelong risk for a rare but serious complication. *Clin Case Rep*. 2023;11:e7525. doi: 10.1002/ccr3.7525

115. Rajkumar CA, Claridge S, Jackson T, Behar J, Johnson J, Sohal M, Amraoui S, Nair A, Preston R, Gill J, et al. Diagnosis and management of iatrogenic cardiac perforation caused by pacemaker and defibrillator leads. *Europace*. 2017;19:1031–1037. doi: 10.1093/europace/euw074

116. Mori H, Kato R, Ikeda Y, Tsutsui K, Hasegawa S, Tanaka S, Iwanaga S, Nakano S, Muramatsu T, Sumitomo N, et al. Percutaneous Simple Lead Traction Is a Feasible and Effective Method for Right Ventricular Lead Perforations. *Int Heart J*. 2020;61:54–59. doi: 10.1536/ihj.19-326

117. Zhou X, Ze F, Li D, Wang L, Guo J, Li X. Outcomes of transvenous lead extraction in patients with lead perforation: A single-center experience. *Clin Cardiol*. 2020;43:386–393. doi: 10.1002/clc.23327

118. Elbatran AI, Akhtar Z, Bajpai A, Leung LWM, Li A, Pearse S, Zuberi Z, Kaba R, Saba MM, Norman M, et al. Percutaneous management of lead-related cardiac perforation with limited use of computed tomography and cardiac surgery. *Pacing Clin Electrophysiol*. 2021;44:614–624. doi: 10.1111/pace.14204

119. Martin A, Voss J, Shannon D, Ruygrok P, Lever N. Frequency and sequelae of retained implanted cardiac device material post heart transplantation. *Pacing Clin Electrophysiol*. 2014;37:242–248. doi: 10.1111/pace.12274

120. Pettit SJ, Orzalkiewicz M, Nawaz MA, Lewis C, Parameshwar J, Tsui S. Retained pacemaker and implantable cardioverter-defibrillator components after heart transplantation are common and may lead to adverse events. *Europace*. 2018;20:1312–1317. doi: 10.1093/europace/eux213

121. Schillaci V, Mascia G, Shopova G, Chiariello P, Ciardiello C, Solimene F. Highly complicated lead extraction procedure in patient with previous early orthotopic heart transplantation: A first case report. *Clin Case Rep*. 2018;6:2319–2321. doi: 10.1002/ccr3.1823

Section 10: Management of Patients Undergoing Lead Extraction

Lead management has become an increasingly important clinical discipline, given the higher prevalence of CIED patients and the increasing complexity of these devices. Lead extraction procedures are now commonly performed and typically result in successful outcomes without major complications. When the risks and benefits of the procedure have been carefully adjudicated and the patient elects to proceed, a careful preoperative assessment is required. In addition to performing a comprehensive history and physical examination, numerous factors need to be addressed to allow for the procedure to have the highest success rate and lowest risk of complications.

Leads in the vascular system induce a fibrotic reaction that encapsulates the leads and the cardiac and vascular structures in contact with them. Adhesions also frequently develop between leads that are adjacent to each other. Extraction of leads necessitates overcoming these adhesions. Adhesions can develop along any part of the lead or the entire course of the lead. Particularly common sites for adhesions include areas with minimal lead motions, such as the sub-clavicular region, the innominate-SVC junction, the SVC, the tricuspid valve, and the lead tip-myocardial interface. Additionally, these fibrotic adhesions can calcify over time, posing even greater challenges to extraction.

A host of factors have been identified that indicate a higher risk of unfavorable outcomes. These factors have been associated with either higher procedural complication rates or higher long-term mortality. Most of these factors are associative, rather than causal. Every patient has several clinical variables that may impact clinical outcome, and all should be considered when offering specific recommendations. Factors that predict a higher

periprocedural complication rate include the number of leads extracted, lead dwell time, low body mass index, thrombocytopenia, coagulopathy, and operator inexperience. [1] Some investigators have noted a higher risk for complications in patients with dual coil ICDs and passive fixation leads, while others have detected little additional risk. Factors that predict longer-term mortality include an infection indication for extraction, end-stage renal disease, anemia, and previous CVA. Data on gender risk is somewhat inconsistent, but it appears that women have a higher risk of periprocedural complications without an increase in 30-day mortality. [2, 3] Conversely, elderly patients appear to have very reasonable procedural outcomes but have higher long-term mortality due to the prevalence of an infection indication for extraction and comorbidities, as noted above. Reports vary as to the impact of LV dysfunction on peri-procedural outcomes. Previous open-heart surgery will almost certainly complicate any emergency rescue effort, but it also predicts a lower likelihood of procedural complications. A few investigators have developed extraction risk models to aid in risk-stratifying individual patients.

10.1 Pre-procedural Evaluation and Considerations

Recommendations for Pre-Procedural Considerations			
COR	**LOE**	**Recommendations**	**References**
1	**C-LD**	1. **It is recommended to involve a multidisciplinary team consisting of an electrophysiologist, cardiac surgeon, cardiac anesthesiologist, and other team members, such as imaging specialists, infectious disease physicians or intensive care teams.**	**4, 5, 6**

1	**C-EO**	2. **It is recommended to consider, prior to extraction, the need for device reimplantation for either continued pacing needs or sudden cardiac death prevention.**	**7, 8, 9**
1	**C-EO**	3. **It is recommended to interrupt anticoagulation, if possible, for elective TLE.**	**10**
2a	**C-LD**	4. **It is reasonable to perform TLE in selected patients requiring uninterrupted therapeutic INR (eg, mechanical valve).**	**11, 12**
1	**C-LD**	5. **It is recommended to review pre-operative radiologic imaging to determine the number and location of leads to be extracted for pre-procedural planning.**	**4**
2b	**B-NR**	6. **Preoperative contrast chest CT may be helpful to visualize lead findings that may alter extraction planning.**	**13, 14, 15, 16**
2b	**C-LD**	7. **It may be reasonable to obtain preoperative TEE for assessing lead(s) in relation to cardiac structures and vegetation(s).**	**17, 18**

4009

Synopsis

Preoperative planning is instrumental in the success of complicated procedures. This includes discussion between experienced clinicians about procedural timing in regard to patient optimization and infection risks, if applicable, as well as the need for another device and when it should be reimplanted.

Preoperative Planning Steps. 1) The extraction plan should be tailored to the procedure indication. An aggressive approach to removing infected hardware is typically required, while abandoned hardware removal alone may call for a more measured attempt. 2) Device interrogation should be performed to assess the degree of pacemaker dependence, presence and history of atrial and ventricular arrhythmias, and lead integrity. 3) Preoperative imaging should be performed to determine the number and type of leads. This and dwell time will affect both the strategy for lead removal and help predict the risks of the procedure. 4) It is important to identify specific lead models that engender unique challenges and require modified extraction approaches. Specific tools and approaches can enhance outcomes if the goal is to preserve the function of non-targeted leads. 5) The patient should be optimized medically and hemodynamically prior to the lead extraction procedure.

Recommendation-specific Supportive Text

Recommendation 1: It is recommended to involve a multidisciplinary team consisting of an electrophysiologist, cardiac surgeon, cardiac anesthesiologist, and other team members, such as imaging specialists, infectious disease physicians or intensive care

teams, as appropriate. A multi-disciplinary team should be brought together to discuss and plan the timing, procedural approach, and potential complications for complex cases. The outcomes are improved with a collaborative approach. [4,5,6] Procedural approach and techniques may be discussed to ensure the proper equipment is available. Planning also allows for alignment of scheduling for the availability of multiple clinicians, especially in the event of an acute complication. Depending on the circumstances, other team members, such as imaging specialists, infectious disease physicians, cardiac anesthesiologists, cardiothoracic surgeons, plastic surgeons, or intensive care teams, may also serve important roles.

Recommendation 2: Prior to extraction, it is recommended to consider the need for device reimplantation for either continued pacing needs or sudden cardiac death prevention. The need for device reimplantation should be determined prior to the procedure. Information that may be beneficial includes device dependence, LV function, Ventricular arrhythmia history and recurrent infection risk. In a retrospective analysis of over 3500 patients undergoing TLE, only 4.6% did not have device reimplantation at the time of TLE.[8] Studies have shown that immediate device reimplantation may not be necessary.[7,9]

Recommendation 3: Bleeding risk is higher when procedures are performed in patients who are anticoagulated. However, the risk of bleeding should be weighed against the risk of thromboembolism from anticoagulation discontinuation. Anticoagulation may be discontinued safely in some patients with low risk of thromboembolic events. A study of over 700 patients with 51% interrupting their chronic anticoagulation therapy for the TLE

procedure showed that TLE may be performed safely when anticoagulation has been temporarily discontinued.[10] There was no significant difference in major adverse events; however, minor events such as blood transfusion and pocket hematoma were greater in the group that bridged the anticoagulation therapy.

Recommendation 4: It is reasonable to perform TLE in selected patients requiring uninterrupted therapeutic INR, such as mechanical valve(s). In some patients who have mechanical valves, discontinuation of anticoagulation may lead to disastrous consequences. In cases where discontinuation is not an option (eg, mechanical mitral valve), the lowest acceptable INR should be targeted. Some small studies have shown that it is feasible to perform TLE with continuation of anticoagulation without an increased incidence of major complications.[11,12] "Bridging" may allow for full cessation of anticoagulation during the procedure, but is associated with a higher rate of bleeding complications post-procedure. Similar considerations should be made regarding patients who are receiving antiplatelet therapy.

Recommendation 5: It is recommended to review pre-operative PA and lateral chest X-rays to determine the number and location of leads to be extracted for pre-procedural planning. PA and lateral chest X-ray views should be obtained to identify the leads present, their type, and location. The number of leads, lead type, and dwell time of these leads will impact the duration and risk of the procedure and extraction planning.

Recommendation 6: The gated CT modality offers more precise information regarding vessel patency, lead binding sites, presence of calcifications and lead perforation.[13, 14] Several investigators have reported how it altered their approach or allowed them to

predict more complex procedures.[15, 16] Nonetheless, additional information that is obtained does not seem to have a major impact on the course outcome or rate of complications. In particular, lead perforations by CT criteria are often identified, yet extractions appear to be done effectively and safely in this cohort of patients. Venous patency offers the option of new lead insertions without the need for lead extraction. Even a vein that appears occluded may be amenable to venoplasty. Venography also helps identify potential binding sites. Venous stenosis has been reported in 61% of patients with previously implanted leads, and up to 25% manifest total occlusion. The presence of venous occlusion predicts a more complex procedure and the need for more advanced tools.

Recommendation 7: It may be reasonable to obtain preoperative TEE for assessing lead(s) in relation to cardiac structures and vegetation(s). Assessment of ventricular and valvular function with echocardiography, as well as the detection of cardiac shunts, aids in the planning of the procedure. In patients with active infection, preoperative transesophageal echocardiography can identify vegetations that raise consideration for percutaneous aspiration of the vegetation or conversion to an open procedure. Additionally, echocardiography can aid in the detection of lead-associated scar tissue, which may add to the complexity of the TLE procedure.[17, 18]

10.2 Intraoperative Considerations

Recommendations for Location of Procedure and Multi-Disciplinary Team Approach			
COR	**LOE**	**Recommendations**	**References**

1	**C-EO**	8. **It is recommended that a well-established, written institution-specific protocol be in place for the safe conduct of the TLE procedure and management of any complications.**	19
1	**B-NR**	9. **It is recommended that TLE be performed in appropriate procedural rooms with the necessary equipment & optimal imaging, which allows for immediate surgical rescue if required.**	6, 20, 21
1	**C-EO**	10. **It is recommended that a multi-disciplinary team be readily available during TLE.**	4, 20

Synopsis

There is a consensus that lead-extraction procedures should be performed in a manner and in an environment that delivers a high rate of success while attenuating risks. All extraction procedures carry a degree of potentially serious complications, and case planning should reflect that reality. Extractions should be performed by experienced operators with the appropriate support team and necessary equipment available.

Recommendation-specific Supportive Text

Recommendation 8: It is critical to have a well-established, written institution-specific protocol be in place for the safe conduct of the TLE procedure and management of any

complications. A standardized protocol can aid in the identification of complex procedures and patient risks for the TLE procedure, outline the proper steps of operation, potential complications, and provide pathways to activate the collaborating team if a complication does occur. This protocol can help to identify who to contact for emergency backup and ensure that the appropriate equipment is available prior to the start of the procedure.[19]

Recommendation 9: It is recommended that TLE be performed in appropriate procedural rooms with the necessary equipment and optimal imaging, which allows for immediate surgical rescue if required. TLE should be performed in a setting where experienced operators are present, high-quality fluoroscopic imaging, transesophageal echocardiography, or intracardiac echocardiography are readily available, and a full array of TLE tools that may be needed to achieve successful extraction. Also, immediate availability of tools for urgent rescue in case of a catastrophic complication, such as a temporary venous occlusion balloon in case of an SVC tear [6, 20, 21], access to and experience in performing urgent pericardiocentesis and the ability to undergo cardiopulmonary bypass in a timely manner when rescue cardiac surgery is needed.

Recommendation 10: The multi-disciplinary team must work together to care for the patient in a safe environment and monitor and manage any potential complications. Collaboration with anesthesiologists who are knowledgeable about the procedure and prepared to help manage related complications greatly enhances the safety and efficacy of the procedure. The cardiovascular surgical backup team should be ready to respond emergently to complications. Depending on the circumstances, other team members,

such as imaging specialists, infectious disease physicians or intensive care teams, may also serve important roles in the perioperative setting.

Recommendations for Anesthetic & Intraoperative Management			
COR	**LOE**	**Recommendations**	**References**
1	**B-NR**	11. **General anesthesia with endotracheal intubation is recommended for most patients undergoing lead extraction.**	22
1	**C-EO**	12. **Invasive arterial pressure monitoring is recommended for most patients undergoing TLE.**	21
1	**C-EO**	13. **Placement of femoral venous sheaths prior to TLE is recommended for use as volume lines, temporary pacemakers, femoral TLE tools, or emergency use.**	21, 23
2a	**B-NR**	14. **A rescue balloon kit can be useful with the appropriate support wire placed beyond the SVC prior to extraction when there is significant concern for possible vascular injury.**	24, 25, 26
2a	**B-NR**	15. **Continuous echocardiographic monitoring is reasonable in patients when there is**	27,28, 29, 30, 31

		significant concern for possible cardiac and vascular injury.	

Synopsis

As the removal of intravascular leads has become more prevalent, the implementation of a thoughtful plan has become necessary. A suitable anesthetic should provide the necessary means to safely perform the lead extractions. One of the anesthetic goals is the avoidance of sudden patient movement and appropriate monitoring for complications. In addition to administering the anesthetic, the anesthesiologist will also monitor for hemodynamic instability. Some complications can result in a sudden hemodynamic change. Invasive blood pressure monitoring, continuous imaging, and a method to rapidly and temporarily tamponade bleeding from an SVC tear are advisable to have a timely diagnosis and subsequent management of vascular tear and cardiac perforation. Communication between the anesthesiologist and the proceduralist is critical when there is any change in patient blood pressure or status, so that the cause of the change can be investigated promptly.

Recommendation-Specific Supportive Text

Recommendation 11: General anesthesia with endotracheal intubation is recommended for most patients undergoing lead extraction. While patient co-morbidities and extraction difficulty may vary, general anesthesia with endotracheal intubation is recommended for most patients undergoing lead extraction. A retrospective study showed that in 2021, throughout the US, 92% of lead extractions were performed using general anesthesia. [22]

The general trend over the past decade showed that general anesthesia was being utilized more compared to monitored anesthesia care or sedation.[22] Even though it is possible to do some extractions using sedation, it may be advisable to use general anesthesia and a protected airway with endotracheal intubation to facilitate the use of transesophageal echocardiography, and to have immobility of the patient throughout the procedure when using the laser and mechanical extraction tools. Many of these patients can be critically ill and have a reduced ventricular ejection fraction. High levels of anesthetic could decrease patient movement but may also increase hemodynamic instability.

Recommendation 12: Invasive arterial blood pressure monitoring is recommended during lead extraction procedures to monitor for potential rapid decreases in systemic blood pressure or even slowly decreasing blood pressure over time due to insidious blood loss. [21] Beat-to-beat monitoring could promptly detect changes in hemodynamics compared to non-invasive blood pressure. The instant hemodynamic changes allow immediate action to assess and manage potential complications. Invasive arterial access can also allow for obtaining blood gases for monitoring changes in hematocrit.

Recommendation 13: Placement of femoral venous sheaths prior to TLE is recommended for use as volume lines, temporary pacemakers, femoral TLE tools, or emergency use. Femoral venous access should be obtained to allow for infusion of fluid or blood products in an emergency, insertion of a temporary pacemaker lead when indicated, and insertion of an SVC occlusion balloon. [21, 23] Having femoral venous access may also be necessary to allow a femoral approach to TLE in addition to a superior approach. Finally, in higher-risk cases, both femoral venous and arterial access will offer a more rapid approach for

emergent Extracorporeal Membrane Oxygenation (ECMO) support. This may be especially useful for patients with a prior sternotomy as access to the heart may be delayed due to the presence of sternal wires, adhesions or the need for more careful dissection to avoid damage to bypass grafts.

Recommendation 14: A rescue balloon kit can be useful with the appropriate support wire placed beyond the SVC prior to extraction when there is significant concern for possible vascular injury. When there is significant concern for SVC injury, a wire can be placed from the femoral venous access and passed into the SVC prior to the extraction. [24, 26] This can facilitate passing an occlusion balloon if an injury occurs, to reduce blood loss until definitive surgical repair. [25]

Recommendation 15: Continuous echocardiographic monitoring is reasonable in patients undergoing TLE. In addition to standard ASA monitoring, which includes pulse oximetry, capnography, electrocardiogram, and intra-arterial blood pressure monitoring, continuous monitoring with echocardiography is beneficial. Continuous imaging can aid in the detection of an accumulating pericardial effusion, volume status, ventricular contractility, tricuspid valve regurgitation, lead location, and lead associated masses. Echocardiography can assist in the preoperative planning, throughout the procedure to detect complications, and monitor the resolution. The use of transesophageal echocardiography (TEE) or intracardiac echocardiography (ICE) can assist with procedural planning by identifying looped leads or leads adherent to cardiac structures.[27-29] Echocardiography also allows for the rapid identification of acute complications and permits the continuation of procedures where transient hypotension is seen but serious complications are excluded. [29] Possible

complications visualized with echocardiography include pericardial effusion, worsening tricuspid regurgitation, and pleural effusions.[30, 31] Echocardiography is also essential to detect leads with adherent masses for concomitant mass aspiration. Masses seen to be adherent to leads can be aspirated prior to extraction maneuvers to decrease the risk of embolization.

Recommendations for Approach, Technique, & Equipment Necessary for Lead Extraction			
COR	**LOE**	**Recommendations**	**References**
1	**C-EO**	**16. Extraction programs should be familiar with multiple vascular approaches (ie, superior, femoral, etc) for TLE and have appropriate tools available.**	32, 33, 34)
1	**C-LD**	**17. Extraction programs should have all the necessary equipment and expertise required to manage all potential complications.**	33, 35, 36, 37
1	**C-EO**	**18. When powered sheaths are employed from a superior approach, continuous traction must be maintained on the lead to provide a rail.**	

1	**C-EO**	**19. For patients in whom re-implantation is planned, it is recommended that vascular access be obtained during the procedure, prior to extraction or by retained access via the extraction sheath.**	

Synopsis

TLE lead extraction requires the ability to adapt an approach relevant to the clinical scenario and to the progress of the procedure. While the predominant approach is from the implant vascular access site (using a locking stylet and outer sheath), circumstances may require use of dedicated and non-dedicated tools from other sites (femoral and or jugular). Familiarity with access to alternate sites [34] and use of tools from these sites should form part of the training for TLE operators. Routine use of combined approaches[32] or transfer of skills from other cardiology or interventional radiology tools may aid with familiarity and success of non-implant access site adjunct approaches when required.

Recommendation-Specific Supportive Text

Recommendation 16: Extraction programs should be familiar with multiple vascular approaches (ie, superior, femoral, etc.) for TLE and have appropriate tools available. Complexities with extraction (multiple intravascular leads, lead fragments, lack of lead rail or particular lead types) require the ability to adapt the approach and use of alternate tools

either as an adjunct or the primary method for lead extraction. [33, 35, 36] Familiarity with such tools and access to them is encouraged.

Recommendation 17: Extraction programs should have all the necessary equipment and expertise required to manage all potential complications. Complications that occur during TLE fall into categories relating to vascular or cardiac injury, lead fragmentation or inability to extract. Superior vena cava injuries are a particular complication that requires emergency cardiac surgery. These injuries are the main reason for programs to have immediate access to a surgical team. Use of a rescue balloon to tamponade the vessel as a temporary measure can be helpful. The preferred technique is to place the support wire prior to the extraction, as placement attempt after SVC injury will delay rescue and may result in the wire entering the pleural or pericardial space through the tear. Placement of the rescue balloon can be safely undertaken in the emergency setting if a suitable stiff wire has been previously positioned beyond the SVC. This approach avoids unnecessary use of the balloon and the potential for thrombus formation on the balloon and subsequent embolization. However, in cases felt to be very high risk, pre-staging of the balloon with marking of the appropriate position on the shaft followed by withdrawal of the balloon to the IVC just before applying the sheath to the lead is a reasonable strategy. Where severe damage to the tricuspid valve has occurred during extraction, the multi-disciplinary team should discuss whether surgery is required during that index procedure or not. A decision regarding re-implantation strategy and other factors will be an important part of the decision-making process. The central tenet of TLE is to provide a stable lead platform to

permit the use of appropriate outer sheaths to release binding points along the vascular tree and cardiac structures.

Recommendation 18: When sheaths are employed from a superior approach, continuous traction must be maintained on the lead to provide a rail. For leads with a lumen, a locking stylet should be placed in all targeted leads prior to an attempt to extract. This prevents the inability to place the stylet should damage occur to the inner lumen of the lead during the removal of other leads. For lumenless leads, extension to the lead may be required to allow sufficient length to pass the extraction sheath into the vascular access. With a suitable rail, optimum control can be gained to allow the outer sheath to maintain a coaxial relationship to the lead, minimising potential vascular or cardiac injury and maximising a controlled extraction of the lead. Maintaining an appropriate amount of tension on the rail is a key factor and requires extensive training and experience.[37] In situations where a locking stylet cannot be passed into the central lumen of the lead or fails to pass sufficiently distal, early consideration of the use of adjunctive tools should occur. Using a femoral approach at an early stage may increase the successful extraction by reducing the force on the vascular structures and on the lead while using a sheath from the superior access. The tandem approach used by centres as the initial mode reports a better ability to maintain a coaxial relationship that aids dissection of the binding sites, increasing success rates and minimising SVC injury. [32]

Recommendation 19: For patients in whom re-implantation is planned, it is recommended that vascular access be obtained during the procedure, prior to extraction or by retained access via the extraction sheath. In cases where failed or redundant leads

are being removed and replaced, reimplantation from the same operative site is highly preferred. This approach allows for the utilization of the remaining functional hardware and avoids the need for a totally new implant via the contralateral site. Nonetheless, obtaining venous access via the ipsilateral side after extraction can prove to be complex. If the vein is patent, obtaining access prior to extraction is advised, as placement of a guidewire may be complicated by venous occlusions or tears, resulting in the inability to reach the heart. If this cannot be achieved, delivering and retaining guide wires via the extraction sheath will ensure continued access for new lead insertions.

Recommendations for Management of Complications			
COR	**LOE**	**Recommendations**	**References**
1	**C-LD**	**20. If a vascular injury occurs, deploying a rescue balloon catheter is recommended until surgical evaluation and repair.**	24, 25
1	**B-NR**	**21. Pericardiocentesis is recommended to relieve tamponade, provided it does not delay definitive surgical intervention when needed.**	38
1	**B-NR**	**22. Emergent sternotomy and initiation of Cardiopulmonary Bypass (CPB) are**	38

		recommended to repair cardiac and vascular bleeding unable to be managed by alternatives.	
2a	**B-NR**	**23. It is reasonable to evaluate and manage the development of new or worsening significant tricuspid regurgitation after TLE.**	39

Synopsis

During lead extraction, operators should carefully monitor hemodynamic changes with arterial line monitoring, ideally with the assistance of intraoperative transesophageal echocardiography, especially in higher-risk cases. Operators should be familiar with the insertion of rescue balloons. In the event of hemodynamic compromise, operators should be vigilant for signs of cardiac tamponade, including clinical signs such as respiratory variation and narrow pulse pressure and radiographic signs such as enlargement of the cardiac silhouette or transesophageal echocardiographic evidence of an enlarging pericardial effusion. Emergent sternotomy with or without the use of cardiopulmonary bypass at the discretion of the surgeon allows for definitive repair of vascular injury.[38] A fluoroscopic evaluation of the right hemithorax should be evaluated for evidence of opacification that would suggest hemothorax.

Recommendation-specific supportive text

Recommendation 20: The superior vena cava is at particular risk for injury during lead extraction, especially in patients with chronic leads. A large-bore lower extremity (femoral access) should be placed in all patients for immediate resuscitation. Lead extractors should be familiar with rescue balloons that can be placed across the superior vena cava to occlude the site of injury until surgical repair can be performed. [24, 25]

Recommendation 21: When pericardial tamponade develops, pericardiocentesis can be attempted as a temporizing measure to relieve tamponade until definitive surgical rescue can be performed.[38] Emergent sternotomy with or without the use of cardiopulmonary bypass would be at the discretion of the surgeon. If a myocardial or vascular injury does occur during lead extraction, pericardiocentesis may be performed to relieve tamponade to improve hemodynamics until surgical repair can be performed, but should not delay surgical consultation or rescue.[38]

Recommendation 22: Emergent sternotomy and initiation of cardiopulmonary bypass are recommended to repair cardiac and vascular bleeding unable to be managed by alternatives. Patients with a major myocardial or vascular injury during lead extraction require surgical intervention at the discretion of the surgeon. For patients without prior cardiac surgery, sternotomy is the most common and effective approach to provide exposure to the heart and superior vena cava. At the discretion of the surgeon, initiation of cardiopulmonary bypass can provide hemodynamic support during repair.[38]

Recommendation 23: It is reasonable to evaluate for and manage the development of new or worsening significant tricuspid regurgitation after TLE. Patients with chronic

indwelling ventricular leads traversing the tricuspid valve are at risk for tricuspid valve injury. Intra-operative transesophageal echocardiography baseline and after lead extraction provides real-time feedback on tricuspid valve function, and severe tricuspid valve injury may require repair. [39] Efforts should be made to deliver extraction sheaths down to the ventricular lead tip to protect the tricuspid valve, if possible. In some cases, tricuspid valve injury due to significant lead adhesion to the valvular structure can be significant enough to warrant repair.[39] It is a good practice to compare and document the function of the tricuspid valve before and after a ventricular lead extraction is performed.

10.3 Post-procedural Considerations

Recommendations for Post-operative Disposition			
COR	**LOE**	**Recommendations**	**References**
2a	**B-NR**	**24. In selected patients who undergo uncomplicated TLE, same-day discharge is reasonable**	40, 41

Synopsis

Patients undergoing lead extraction for infection indications may typically require extensive surgical debridement, requiring inpatient wound and pain management, ongoing administration of intravenous antibiotics and the use of bridging systems for managing their rhythm problems. For these patients, ongoing inpatient management may be required for periods of time, depending on local institutional facilities and needs. Patients who have required the extraction of their heart failure devices may also require additional hospital care to optimise their care while awaiting definitive re-implantation.

For other patients requiring lead extraction who are clinically stable and who do not have an ongoing need for inpatient care, a same-day case protocol is considered reasonable. Such patients typically have undergone extraction for vascular access or lead failure indications. If the extraction was uncomplicated and the re-implantation procedure was straightforward, discharge on the same day is a safe option. An institutional protocol for post-general anaesthetic same-day discharge can be applied, similar to the process for a new device implant.[41] This may help reduce hospital-acquired infections, minimize length of stay and associated costs, and be preferred by patients.

Recommendation Specific Supportive Text

Recommendation 24: Same-day discharge is reasonable in select patients with an uncomplicated TLE. Care should be taken to develop pre-specified requirements for successful day stay admissions that consider the pacemaker dependency, post-discharge environment and local follow-up protocols.[40, 41] Where patients do not meet these criteria, admission will be required, and institutions must provide for this.

References

1. Xiao Z, He J, Du A, Yang D, An Y, Li X. Predictors for adverse events during cardiac lead extraction - Experience from a large single centre. Int J Cardiol. 2023;371:167-74.

2. Mehta VS, Wijesuriya N, DeVere F, Howell S, Elliott MK, Mannakarra N, et al. Long-term survival following transvenous lead extraction: unpicking differences according to sex. Europace. 2023;25(9).

3. Khalil M, Maqsood MH, Maraey A, Elzanaty A, Saeyeldin A, Ong K, et al. Sex differences in outcomes of transvenous lead extraction: insights from National Readmission Database. J Interv Card Electrophysiol. 2023;66(6):1375-82.

4. Migliore F, Tarzia V, Dall'Aglio PB, Falzone PV, De Lazzari M, Bottio T, et al. The valuable interaction among cardiac surgeon and electrophysiologist for transvenous rotational mechanical lead extraction. Pacing Clin Electrophysiol. 2022;45(1):92-102.

5. Roberto M, Sicuso R, Manganiello S, Catto V, Salvi L, Nafi M, et al. Cardiac surgeon and electrophysiologist shoulder-to-shoulder approach: Hybrid room, a kingdom for two. A zero mortality transvenous lead extraction single center experience. Int J Cardiol. 2019;279:35-9.

6. Williams IE, Sharaf OM, Azarrafiy R, Demos D, Jeng EI, Freeman KA, et al. Zero superior vena cava injury lead extraction with rotational system: A contemporary experience. JTCVS Open. 2025;23:171-5.

7. Zsigmond EJ, Miklos M, Vida A, Benak A, Makai A, Schvartz N, et al. Reimplantation and long-term mortality after transvenous lead extraction in a high-risk, single-center cohort. J Interv Card Electrophysiol. 2023;66(4):847-55.

8. Kutarski A, Jachec W, Kosior J, Stec S, Nowosielecka D, Polewczyk A. Discontinuation of cardiac implantable electronic device therapy after transvenous lead extraction. Kardiol Pol. 2023;81(11):1113-21.

9. Dardari M, Iorgulescu C, Cinteza E, Deaconu A, Nastasa A, Vasile CM, et al. Transvenous Lead Extraction of Cardiac Implantable Electronic Devices: Reimplant Strategy and Outcomes in a Single-Center Experience. Maedica (Bucur). 2023;18(3):389-94.

10. Regoli F, Auricchio A, Di Cori A, Segreti L, Blomstrom-Lunqvist C, Butter C, et al. Impact of anticoagulation therapy on outcomes in patients with cardiac implantable resynchronization devices undergoing transvenous lead extraction: A substudy of the ESC-EHRA EORP ELECTRa (European Lead Extraction ConTRolled) Registry. J Cardiovasc Electrophysiol. 2019;30(7):1086-95.

11. Zheng Q, Maytin M, John RM, Killu AM, Epstein LM. Transvenous lead extraction during uninterrupted warfarin therapy: Feasibility and outcomes. Heart Rhythm. 2018;15(12):1777-81.

12. Vinit S, Vanessa C, Alexander B, Luisa B, Sarah WA, Jan S, et al. Transvenous lead extraction on uninterrupted anticoagulation: A safe approach? Indian Pacing Electrophysiol J. 2021;21(4):201-6.

13. Bhatia P, Chiou T, Svennberg E, Khoche S, Jacobs K, Pollema T, et al. Clinical significance of incidentally detected lead perforations by computed tomography. Pacing Clin Electrophysiol. 2021;44(5):936-42.

14. Asada S, Nishii N, Shinya T, Miyoshi A, Morimoto Y, Miyamoto M, et al. Usefulness of right ventriculography compared with computed tomography for ruling out the possibility of lead perforation before lead extraction. PLoS One. 2021;16(3):e0245502.

15. Patel D, Sripariwuth A, Abozeed M, Hussein AA, Tarakji KG, Wazni OM, et al. Lead Location as Assessed on Cardiac Computed Tomography and Difficulty of Percutaneous Transvenous Extraction. JACC Clin Electrophysiol. 2019;5(12):1432-8.

16. Patel D, Vatterott P, Piccini J, Epstein LM, Hakmi S, Syed I, et al. Prospective Evaluation of the Correlation Between Gated Cardiac Computed Tomography Detected Vascular Fibrosis and Ease of Transvenous Lead Extraction. Circ Arrhythm Electrophysiol. 2022;15(11):e010779.

17. Nowosielecka D, Jachec W, Stefanczyk Dzida M, Polewczyk A, Moscicka D, Nowosielecka A, Kutarski A. What Important Information Does Transesophageal Echocardiography Provide When Performed before Transvenous Lead Extraction? J Clin Med. 2024;13(17).

18. Nowosielecka D, Jachec W, Polewczyk A, Tulecki L, Kleinrok A, Kutarski A. The role of transesophageal echocardiography in predicting technical problems and complications of transvenous lead extractions procedures. Clin Cardiol. 2021;44(9):1233-42.

19. Kancharla K, Acker NG, Li Z, Samineni S, Cai C, Espinosa RE, et al. Efficacy and Safety of Transvenous Lead Extraction in the Device Laboratory and Operating Room Guided by a Novel Risk Stratification Scheme. JACC Clin Electrophysiol. 2019;5(2):174-82.

20. Starck CT, Gonzalez E, Al-Razzo O, Mazzone P, Delnoy PP, Breitenstein A, et al. Results of the Patient-Related Outcomes of Mechanical lead Extraction Techniques

(PROMET) study: a multicentre retrospective study on advanced mechanical lead extraction techniques. Europace. 2020;22(7):1103-10.

21. Martin A, De Bie B, O'Loughlin J. Anaesthesia for extraction of long-term cardiac device leads. BJA Educ. 2022;22(8):290-4.

22. McGuire JA, Hayanga JWA, Thibault D, Zukowski A, Grose B, Woods K, et al. Anesthetic Choice for Cardiovascular Implantable Electronic Device Placement and Lead Removal: A National Anesthesia Clinical Outcomes Registry Analysis. J Cardiothorac Vasc Anesth. 2023;37(12):2461-9.

23. Chung DU, Muller L, Ubben T, Yildirim Y, Petersen J, Sinning C, et al. Benefits of routine prophylactic femoral access during transvenous lead extraction. Heart Rhythm. 2021;18(6):970-6.

24. Tsang DC, Azarrafiy R, Pecha S, Reichenspurner H, Carrillo RG, Hakmi S. Long-term outcomes of prophylactic placement of an endovascular balloon in the vena cava for high-risk transvenous lead extractions. Heart Rhythm. 2017;14(12):1833-8.

25. Azarrafiy R, Tsang DC, Wilkoff BL, Carrillo RG. Endovascular Occlusion Balloon for Treatment of Superior Vena Cava Tears During Transvenous Lead Extraction: A Multiyear Analysis and an Update to Best Practice Protocol. Circ Arrhythm Electrophysiol. 2019;12(8):e007266.

26. Contractor T, Bhardwaj R, Mandapati R, Kotak K, Garg J. Adverse events associated with the bridge occlusion balloon for lead extraction: A MAUDE database study. Heart Rhythm. 2023;20(1):142-3.

27. Sadek MM, Cooper JM, Frankel DS, Santangeli P, Epstein AE, Marchlinski FE, Schaller RD. Utility of intracardiac echocardiography during transvenous lead extraction. Heart Rhythm. 2017;14(12):1779-85.

28. Beaser AD, Aziz Z, Besser SA, Jones CI, Jameria Z, Kannan A, et al. Characterization of Lead Adherence Using Intravascular Ultrasound to Assess Difficulty of Transvenous Lead Extraction. Circ Arrhythm Electrophysiol. 2020;13(8):e007726.

29. Nowosielecka D, Polewczyk A, Jachec W, Tulecki L, Tomkow K, Stefanczyk P, et al. A new approach to the continuous monitoring of transvenous lead extraction using transesophageal echocardiography-Analysis of 936 procedures. Echocardiography. 2020;37(4):601-11.

30. Strachinaru M, Kievit CM, Yap SC, Hirsch A, Geleijnse ML, Szili-Torok T. Multiplane/3D transesophageal echocardiography monitoring to improve the safety and outcome of complex transvenous lead extractions. Echocardiography. 2019;36(5):980-6.

31. Nowosielecka D, Jachec W, Polewczyk A, Kleinrok A, Tulecki L, Kutarski A. The prognostic value of transesophageal echocardiography after transvenous lead extraction: landscape after battle. Cardiovasc Diagn Ther. 2021;11(2):394-410.

32. Yap SC, Bhagwandien RE, Theuns D, Yasar YE, de Heide J, Hoogendijk MG, et al. Efficacy and safety of transvenous lead extraction using a liberal combined superior and femoral approach. J Interv Card Electrophysiol. 2021;62(2):239-48.

33. Migliore F, Pittorru R, Dall'Aglio PB, De Lazzari M, Rovaris G, Piazzi E, et al. Outcomes of transvenous lead extraction of very old leads using bidirectional rotational mechanical sheaths: Results of a multicentre study. J Cardiovasc Electrophysiol. 2023;34(3):728-37.

34. Zhou X, Ze F, Li D, Wang L, Duan J, Yuan C, et al. Transfemoral extraction of pacemaker and implantable cardioverter defibrillator leads using Needle's Eye Snare: a single-center experience of more than 900 leads. Heart Vessels. 2020;35(6):825-34.

35. Akhtar Z, Kontogiannis C, Georgiopoulos G, Starck CT, Leung LWM, Lee SY, et al. Comparison of non-laser and laser transvenous lead extraction: a systematic review and meta-analysis. Europace. 2023;25(11).

36. Lee SY, Allen IE, Diaz C, Guo X, Pellegrini C, Beygui R, et al. Efficacy and mortality of rotating sheaths versus laser sheaths for transvenous lead extraction: a meta-analysis. J Interv Card Electrophysiol. 2023;66(5):1067-75.

37. Hayashi K, Callahan T, Rickard J, Baranowski B, Martin DO, Nakhla S, et al. Comparison of outcomes and required tools between transvenous extraction of pacemaker and implantable cardioverter defibrillator leads: Insight from single high-volume center experience. J Cardiovasc Electrophysiol. 2024;35(7):1382-92.

38. Zucchelli G, Di Cori A, Segreti L, Laroche C, Blomstrom-Lundqvist C, Kutarski A, et al. Major cardiac and vascular complications after transvenous lead extraction: acute outcome and predictive factors from the ESC-EHRA ELECTRa (European Lead Extraction ConTRolled) registry. Europace. 2019;21(5):771-80.

39. Polewczyk A, Jachec W, Nowosielecka D, Tomaszewski A, Brzozowski W, Szczesniak-Stanczyk D, et al. Tricuspid Valve Damage Related to Transvenous Lead Extraction. Int J Environ Res Public Health. 2022;19(19).

40. Dagher L, Tfaily MA, Vavuranakis M, Bhatia NK, Westerman SB, Shah AD, et al. Safety of same-day discharge after lead extraction procedures. Heart Rhythm. 2023;20(12):1669-73.

41. Atteya G, Alston M, Sweat A, Saleh M, Beldner S, Mitra R, et al. Same-day discharge after transvenous lead extraction: feasibility and outcomes. Europace. 2023;25(2):586-90.

Section 11. Implant lead selection, approach and techniques to mitigate lead malfunction

When implanting pacemaker or defibrillator leads, there are a variety of factors that must be considered. Although the priority is to place leads that provide optimal pacing or defibrillation, leads should also be implanted in a manner that maximizes their longevity, minimizes the access complications, injury to the heart and limits the risks of future lead extractions.

11.1. Venous Access

Recommendations for Venous Access			
COR	**LOE**	**Recommendations**	**References**
1	**B-R**	**1. When obtaining access for lead implantation, an extrathoracic axillary vein puncture or a cephalic vein cutdown should be performed (versus subclavian vein puncture) to decrease the risk of pneumothorax and premature lead failure.**	1, 2,3
2a	**B-R**	**2. Ultrasound-guidance or contrast-guided fluoroscopy can be useful for axillary vein puncture.**	4, 5, 6

Synopsis

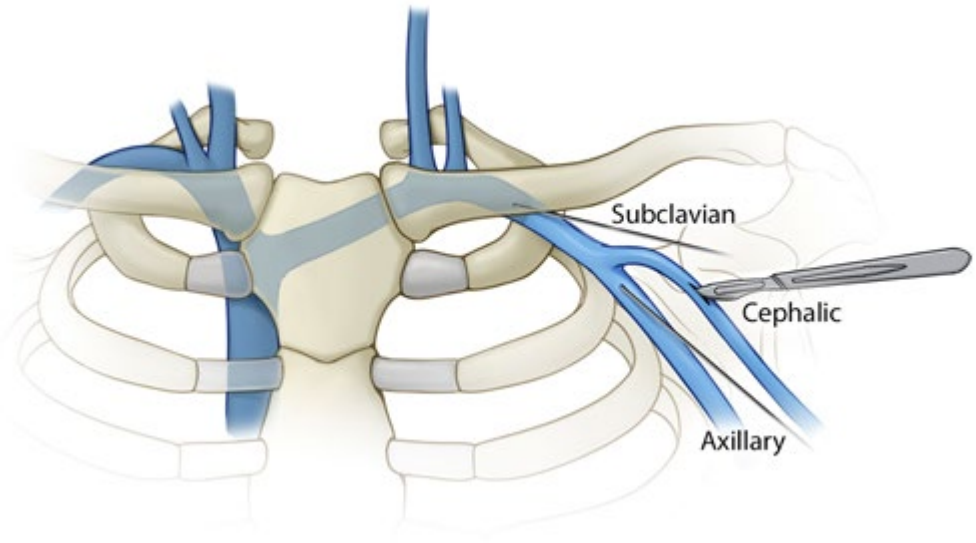
The method of implanting leads has continued to evolve. Initially, cephalic vein cutdown was the primary method for lead implantation; however, with the advent of peel-away sheaths, the subclavian approach became the preferred route of venous access by a

majority of device implanters. Although faster, puncturing the subclavian vein carries a higher risk for lung injury, and lead malfunction from “subclavian crush”, with leads entrapped between the clavicle and first rib. Axillary vein puncture has become the preferred alternative. As with a cephalic vein cutdown, it provides extrathoracic access, limiting the risks of pneumothorax and subclavian crush, but shares the convenience of subclavian vein access, requiring less surgical time and skill. Ultrasound guidance represents an additional tool to minimize complications (especially inadvertent arterial puncture) and to decrease radiation exposure.

Recommendation-specific supportive text

Recommendation 1: Subclavian vein puncture (SVP), cephalic vein cutdown (CVC), and axillary vein puncture (AVP) are the most common options for transvenous lead insertion (**Figure 11.1**)**.** Subclavian vein puncture has been associated with procedural complications, including pneumothorax and hemothorax, and can result in premature lead failure secondary to the subclavian crush syndrome. Extrathoracic access with CVC or AVP has proven to lower these risks without significantly affecting procedural success [1, 2]. Although CVC used to be the primary method of venous access, AVP has become the preferred method of venous access for some providers – complication rates between these two techniques are not significantly different, but AVP has been associated with faster access and procedural success [3]. Subclavian vein access may still be required in certain scenarios, including patients with abnormal venous anatomy or venous obstruction. In these instances, accessing the vein as laterally as possible is recommended to minimize the risk of complications.

Figure 11.1: Most common access sites for transvenous lead insertion. Extrathoracic access using a cephalic vein cutdown or axillary vein puncture (over the 1st or 2nd rib) is recommended. Access within the intrathoracic subclavian vein, medial to the inferior border of the clavicle, has been associated with more complications.



Recommendation 2: Image guidance can be useful in obtaining axillary access. Both fluoroscopy and ultrasound can be used to decrease the time to obtain access and increase the success in gaining access [4]. Ultrasound guidance has the benefit of decreasing radiation exposure and decreasing the risk of inadvertent axillary artery puncture. In total, these benefits can make AVP more efficient than CVC [5, 6].

11.2. Lead Choice

Recommendations for Lead Choice			
COR	**LOE**	**Recommendations**	**References**

1	**B-NR**	**3. When implanting a transvenous ICD, a single coil (versus dual coil) lead is recommended.**	9,10,11,12,13,14,15
1	**B-NR**	**4. When implanting transvenous leads, consideration of lead design and fixation mechanisms is recommended in case of the need for future extraction.**	16,17,18,19,20

Synopsis

The lead(s) chosen at implant can have a profound impact on future lead management. Some leads are known to have longer longevity than others [7, 8], but the risk of premature lead malfunction should not be the only factor considered when deciding on a lead implant. Lead design and fixation mechanisms should also be considered, as they can affect the complexity of future lead extractions.

Recommendation-specific supportive text

Recommendation 3: Dual coil leads, with a coil in the superior vena cava (SVC) and another in the right ventricle, were once the most common ICD lead implanted. However, studies over the last decade have shown that the presence of an SVC coil does not significantly improve the defibrillation threshold (DFT), first-shock efficacy, or mortality [9-12]. Moreover, the presence of a coil in the SVC can result in more adhesions in the innominate vein and SVC [13]. This can lead to more difficult extractions, with longer procedural times, a need for advanced techniques, and more complications [14, 15]. As such, in the majority of cases, single-coil leads should be chosen at the time of implant. Dual coil leads may be

reserved at the operator's discretion for individual patient needs and complex anatomical situations.

Recommendation 4: Multiple factors influence how difficult lead extraction will be. Amongst these is lead design. Active fixation leads, with the ability of the screw to retract or straighten out with traction, are more easily extracted compared to passive fixation leads that anchor more firmly into the trabeculated myocardium. The complication rate when extracting active vs. passive fixation leads is similar, but removal of passive fixation leads often requires longer procedures and the need for advanced extraction techniques [16, 17]. Passive fixation leads are also more likely to break during extraction [18, 19]. Lead break can increase the difficulty of extraction, increasing procedural complexity and complications, while also increasing the risk of residual lead fragments remaining after extraction. Leads that are more prone to break include leads that have a coradial (vs. coaxial) design and leads with a non-polyurethane insulation [19]. Leads that do not require a stylet, specifically Medtronic 3830 lead, are also less likely to break, resulting in extractions with lower complexity and a higher rate of complete procedural success [20].

11.3. Tricuspid valve regurgitation

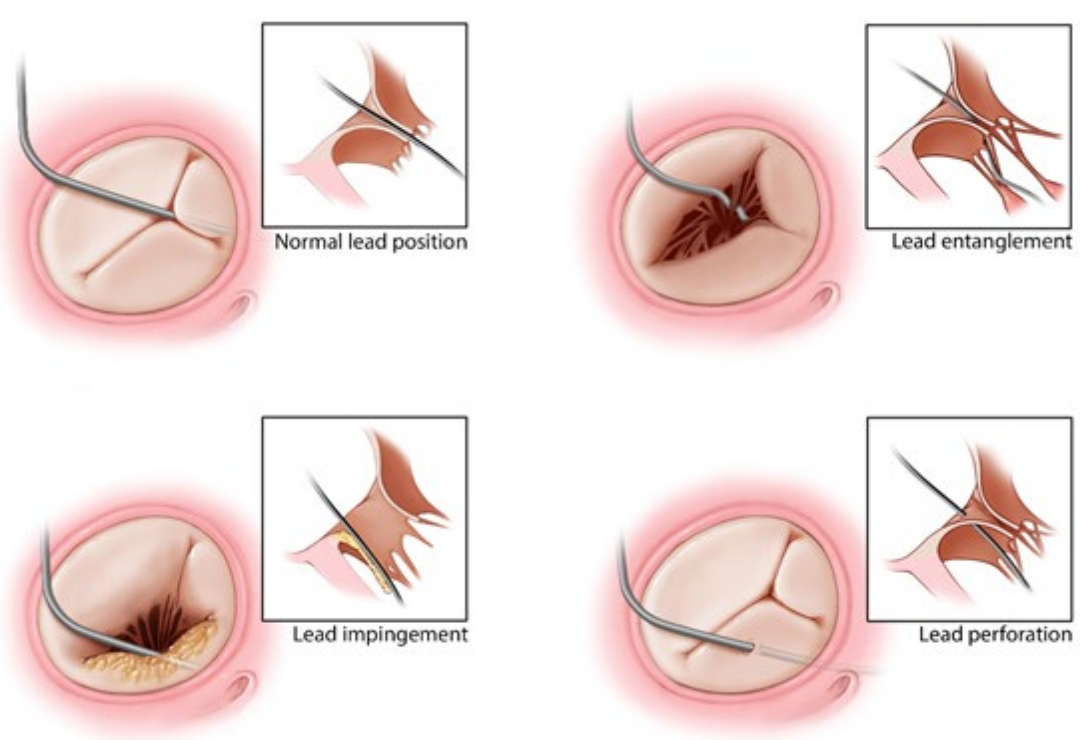
Recommendations for limiting tricuspid valve regurgitation			
COR	**LOE**	**Recommendations**	**References**
1	**C-LD**	**5. Ventricular lead implantation should be performed in a manner to decrease tricuspid valve regurgitation.**	21,25,26,27,28,29,30,31

1	**C-EO**	**6. Assessment for lead-related significant tricuspid valve regurgitation should be considered within 1 year after ventricular lead implantation.**	22,32

Synopsis

Tricuspid valve regurgitation is common, but its incidence and severity may be increased in patients with transvenous CIEDs [21]. This can have significant effects on a patient's clinical status, leading to volume overload, heart failure, and death [22, 23]. How a lead is implanted and positioned can influence the degree of tricuspid regurgitation (**Figure 11.2**). Over time, further interaction with the valve can cause significant binding and adhesions – extraction of these leads can result in severe regurgitation or flail leaflets [24]. Given these concerns, close monitoring of tricuspid valve function should be performed after a lead is implanted across the valve.

Figure 11.2: Examples of lead interaction with the tricuspid valve. The lead ideally passes through the central part of the valve, limiting its interaction with the tricuspid valve leaflets. Leads that rest more of the leaflets can result in fibrosis and scar formation, causing lead impingement. Leads can also be trapped within the tricuspid valve apparatus, getting entangled with the chordae or perforating the leaflet itself at implant. Extraction of these leads can result in severe tricuspid regurgitation.

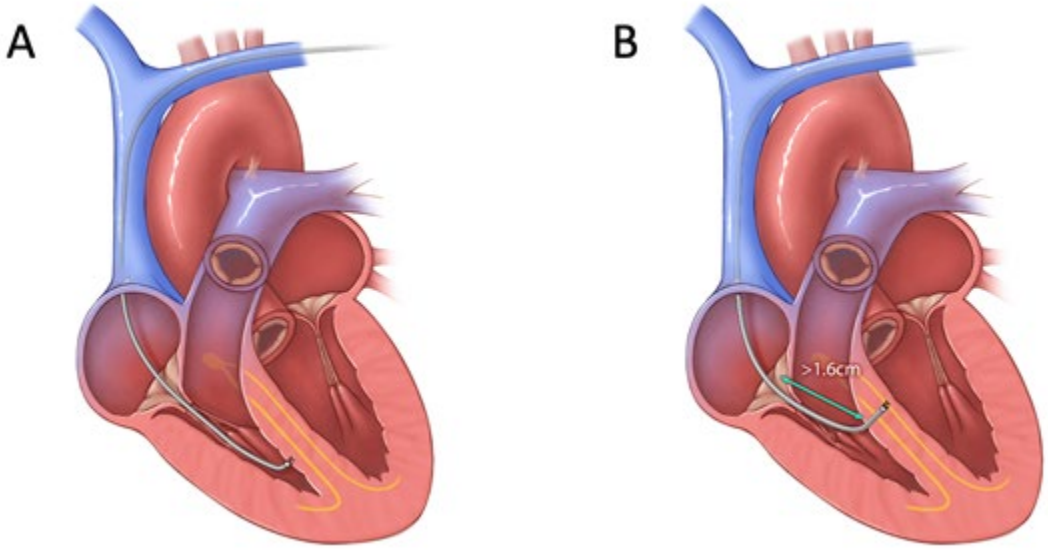


Recommendation-specific supportive text

Recommendation 5: Tricuspid valve regurgitation can increase significantly after ventricular lead implantation. Patients with dilated right atria or elevated right-sided pressures may be at higher risk[21]. Ideally, leads should pass directly through the tricuspid valve orifice or site within a commissure (most commonly the posteroseptal commissure) to decrease the risk of tricuspid regurgitation. Prolapsing the lead through the valve at the time of implant can decrease the risk of tricuspid regurgitation[25]. Leaving an adequate amount of slack is also imperative – excess loops in the right atrium, however, can result in prolapse of the loop into the ventricle and affect leaflet motion[26]. Leads may also be too taut, impinging on leaflet motion. Lead impingement and adherence are the most common

causes of tricuspid valve regurgitation; lead entanglement and lead perforation may also occur, but are less prevalent[27, 28]. Lead location – apical vs. septum – has not been found to influence the degree of regurgitation[29]; however, when evaluating septal leads alone, distance of lead fixation from the tricuspid valve annulus has been found to be significant, with a longer distance (greater than 16.1 mm) associated with less tricuspid regurgitation (**Figure 11.3**)[30, 31].

Figure 11.3: (A) Placement of leads on the right ventricular septum (versus apical pacing) has not been associated with worsening tricuspid regurgitation. (B) When implanting leads for left bundle branch area pacing, a shorter lead to tricuspid annulus distance can result in more tricuspid regurgitation. Placing a lead at least 1.6cm distal from the tricuspid annulus is recommended.



Recommendation 6: Tricuspid valve regurgitation can often be underappreciated or unrecognized. As tricuspid regurgitation can have a significant impact on a patient's long-

term health, close monitoring of valve function is recommended[22]. An evaluation for significant regurgitation secondary to lead interaction should be performed within a year of implantation, as these leads can be removed or repositioned safely to effectively improve valve function. Leads that have been in place for longer durations (>7 years) may cause irreversible valve injury due to the formation of adhesions that plaster the leaflets in place[32]. Removal of leads at this point is unlikely to improve valve function. These patients often need to undergo some form of tricuspid valve intervention, either via catheterization or open-heart surgery for valve repair or replacement.

11.4. Number of Leads

Recommendations for Number of Leads Implanted			
COR	**LOE**	**Recommendations**	**References**
1	**C-LD**	**7. For a patient receiving a transvenous device, the number of leads implanted should be minimized. Particular consideration should be given to lead burden in special groups such as pediatric patients.**	33,34,39,40,41,42,43
1	**B-NR**	**8. For patients receiving a transvenous ICD, an additional atrial lead should only be implanted if atrial pacing or atrioventricular synchronous pacing is necessary, and not**	44,45,46

		for arrhythmia discrimination (SVT versus VT).	

Synopsis

The number of leads implanted is a known risk factor for lead extractions, increasing the complexity of the extraction and complication rate[33]. As such, implanters should consider whether each lead being implanted is necessary, with the number of leads placed kept to a minimum. Each additional lead has the potential to worsen lead-lead binding, venous obstruction, and valvular regurgitation[22, 34, 35]. Though a lead may be beneficial, its true clinical value should be weighed against these complications[36, 37]. Finally, the patient's age must be considered when leads are implanted. Transvenous leads placed early in life can be more difficult to extract, complicating lead management in patients who will need many CIED lead revisions over a lifetime[38, 39].

Recommendation-specific supportive text

Recommendation 7: Studies have shown that the number of leads present increases the risks of extraction. This can result in longer procedural times, a need for complex extraction techniques and a higher risk for major complications[33, 40]. Thus, the clinical need for each lead implanted must be assessed. This can range from the need for a ventricular lead in patients with sinus node dysfunction, an atrial lead in patients with complete heart block, or a coronary sinus lead in patients with ventricular dyssynchrony and dysfunction. Special consideration should be taken in children and young adults – not only does their smaller size increase the risk for venous obstruction, but younger patients often require

more complex extractions, thought to be due to increased adhesions and dense fibrosis around their leads[34, 39, 41]. Patients with congenital heart disease may also be more prone to obstruction, and young patients with or without congenital heart disease may be at higher risk for atrioventricular valve injury during extractions[42, 43]. As young patients will need their leads managed over a span of many decades, strategies should be taken to minimize the number of leads present.

Recommendation 8: Defibrillator leads can be more difficult to extract compared to pacing leads, requiring longer procedural times and the need for more extraction tools[44]. Limiting additional risks should be a priority. A primary consideration is whether an atrial lead is required. Atrial leads are often implanted to aid with rhythm discrimination, with the presence of an atrial electrogram thought to improve the ability to differentiate between supraventricular and ventricular tachycardia. This has not proven to be the case[45, 46.] An atrial lead should only be implanted if the patient would benefit from atrial pacing (ie, symptomatic sinus bradycardia, tachy-brady syndrome), or to optimize hemodynamics with atrioventricular synchrony. Conversely, a Biotronik VDD lead can be considered – this single ICD lead has an integrated atrial dipole that sits in the right atrium, providing atrial sensing without the need for an additional lead. The incremental benefits provided for rhythm discrimination should be weighed against the adhesions that could develop around the dipole, potentially making extraction more difficult.

References

1. Atti, V, Turagam, MK, Garg, J, et al. Subclavian and Axillary Vein Access Versus Cephalic Vein Cutdown for Cardiac Implantable Electronic Device Implantation: A Meta-Analysis. JACC Clin Electrophysiol. 2020;6:661-671.

2. Benz, AP, Vamos, M, Erath, JW and Hohnloser, SH. Cephalic vs. subclavian lead implantation in cardiac implantable electronic devices: a systematic review and meta-analysis. Europace. 2019;21:121-129.

3. Vetta, G, Magnocavallo, M, Parlavecchio, A, et al. Axillary vein puncture versus cephalic vein cutdown for cardiac implantable electronic device implantation: A meta-analysis. Pacing Clin Electrophysiol. 2023;46:942-947.

5. Charles, P, Ditac, G, Montoy, M, et al. Intra-pocket ultrasound-guided axillary vein puncture vs. cephalic vein cutdown for cardiac electronic device implantation: the ACCESS trial. Eur Heart J. 2023;44:4847-4858.

6. Tagliari, AP, Kochi, AN, Mastella, B, et al. Axillary vein puncture guided by ultrasound vs cephalic vein dissection in pacemaker and defibrillator implant: A multicenter randomized clinical trial. Heart Rhythm. 2020;17:1554-1560.

7. El-Chami, MF, Rao, B, Shah, AD, et al. Long-term performance of a pacing lead family: A single-center experience. Heart Rhythm. 2019;16:572-578.

8. De Pooter, J, Breitenstein, A, Ozpak, E, et al. Lead Integrity and Failure Evaluation in Left Bundle Branch Area Pacing: The LIFE-LBBAP Study. JACC Clin Electrophysiol. 2025;11:158-170.

9. Kumar, P, Baker, M and Gehi, AK. Comparison of Single-Coil and Dual-Coil Implantable Defibrillators: A Meta-Analysis. JACC Clin Electrophysiol. 2017;3:12-19.

10. Neuzner, J, Hohnloser, SH, Kutyifa, V, et al. Effectiveness of single- vs dual-coil implantable defibrillator leads: An observational analysis from the SIMPLE study. J Cardiovasc Electrophysiol. 2019;30:1078-1085.

11. Sunderland, N, Kaura, A, Murgatroyd, F, Dhillon, P and Scott, PA. Outcomes with single-coil versus dual-coil implantable cardioverter defibrillators: a meta-analysis. Europace. 2018;20:e21-e29.

12. Hsu, JC, Saxon, LA, Jones, PW, Wehrenberg, S and Marcus, GM. Utilization trends and clinical outcomes in patients implanted with a single- vs a dual-coil implantable ardioverter-defibrillator lead: Insights from the ALTITUDE Study. Heart Rhythm. 2015;12:1770-5.

13. Segreti, L, Di Cori, A, Soldati, E, et al. Major predictors of fibrous adherences in transvenous implantable cardioverter-defibrillator lead extraction. Heart Rhythm. 2014;11:2196-201.

14. Epstein, LM, Love, CJ, Wilkoff, BL, et al. Superior vena cava defibrillator coils make transvenous lead extraction more challenging and riskier. J Am Coll Cardiol. 2013;61:987-9.

15. Kutarski, A, Jachec, W, Stefanczyk, P, Brzozowski, W, Glowniak, A and Nowosielecka, D. Analysis of 1051 ICD Leads Extractions in Search of Factors Affecting Procedure

Difficulty and Complications: Number of Coils, Tip Fixation and Position-Does It Matter? J Clin Med. 2024;13:

16. Jachec, W, Nowosielecka, D, Ziaja, B, Polewczyk, A and Kutarski, A. LECOM (Lead Extraction COMplexity): A New Scoring System for Predicting a Difficult Procedure. J Clin Med. 2023;12:

17. Levi, N, Bongiorni, MG, Rav Acha, M, et al. Lead fixation mechanism impacts outcome of transvenous lead extraction: data from the European Lead Extraction ConTRolled Registry. Europace. 2022;24:817-827.

18. Kutarski, A, Jachec, W, Czajkowski, M, et al. Lead Break during Extraction: Predisposing Factors and Impact on Procedure Complexity and Outcome: Analysis of 3825 Procedures. J Clin Med. 2024;13:

19. Morita, J, Yamaji, K, Nagashima, M, et al. Predictors of lead break during transvenous lead extraction. J Arrhythm. 2021;37:645-652.

20. Shepherd, E, Stuart, G, Martin, R and Walsh, MA. Extraction of SelectSecure leads compared to conventional pacing leads in patients with congenital heart disease and congenital atrioventricular block. Heart Rhythm. 2015;12:1227-32.

21. Lee, RC, Friedman, SE, Kono, AT, Greenberg, ML and Palac, RT. Tricuspid Regurgitation Following Implantation of Endocardial Leads: Incidence and Predictors. Pacing Clin Electrophysiol. 2015;38:1267-74.

22. Delling, FN, Hassan, ZK, Piatkowski, G, et al. Tricuspid Regurgitation and Mortality in Patients With Transvenous Permanent Pacemaker Leads. Am J Cardiol. 2016;117:988-92.

23. Alnaimat, S, Doyle, M, Krishnan, K and Biederman, RWW. Worsening tricuspid regurgitation associated with permanent pacemaker and implantable cardioverter-defibrillator implantation: A systematic review and meta-analysis of more than 66,000 subjects. Heart Rhythm. 2023;20:1491-1501.

24. Polewczyk, A, Jachec, W, Nowosielecka, D, et al. Tricuspid Valve Damage Related to Transvenous Lead Extraction. Int J Environ Res Public Health. 2022;19:

25. Gabriels, JK, Schaller, RD, Koss, E, Rutkin, BJ, Carrillo, RG and Epstein, LM. Lead management in patients undergoing percutaneous tricuspid valve replacement or repair: a 'heart team' approach. Europace. 2023;25:

26. Schleifer, JW, Pislaru, SV, Lin, G, et al. Effect of ventricular pacing lead position on tricuspid regurgitation: A randomized prospective trial. Heart Rhythm. 2018;15:1009-1016.

27. Lin, G, Nishimura, RA, Connolly, HM, Dearani, JA, Sundt, TM, 3rd and Hayes, DL. Severe symptomatic tricuspid valve regurgitation due to permanent pacemaker or implantable cardioverter-defibrillator leads. J Am Coll Cardiol. 2005;45:1672-5.

28. Mediratta, A, Addetia, K, Yamat, M, et al. 3D echocardiographic location of implantable device leads and mechanism of associated tricuspid regurgitation. JACC Cardiovasc Imaging. 2014;7:337-47.

29. Yuyun, MF, Joseph, J, Erqou, SA, et al. Evolution and prognosis of tricuspid and mitral regurgitation following cardiac implantable electronic devices: a systematic review and meta-analysis. Europace. 2024;26:

30. Hu, Q, You, H, Chen, K, et al. Distance between the lead-implanted site and tricuspid valve annulus in patients with left bundle branch pacing: Effects on postoperative tricuspid regurgitation deterioration. Heart Rhythm. 2023;20:217-223.

31. Karwiky, G, Kamarullah, W, Pranata, R, Achmad, C and Iqbal, M. A meta-analysis of the distance between lead-implanted site and tricuspid valve annulus with postoperative tricuspid regurgitation deterioration in patients with left bundle branch area pacing. J Cardiovasc Electrophysiol. 2024;35:2220-2229.

32. Park, SJ, Gentry, JL, 3rd, Varma, N, et al. Transvenous Extraction of Pacemaker and Defibrillator Leads and the Risk of Tricuspid Valve Regurgitation. JACC Clin Electrophysiol. 2018;4:1421-1428.

33. Sood, N, Martin, DT, Lampert, R, Curtis, JP, Parzynski, C and Clancy, J. Incidence and Predictors of Perioperative Complications With Transvenous Lead Extractions: Real-World Experience With National Cardiovascular Data Registry. Circulation. Arrhythmia and electrophysiology. 2018;11:e004768.

34. Ferro, EG, Kramer, DB, Li, S, et al. Incidence, Treatment, and Outcomes of Symptomatic Device Lead-Related Venous Obstruction. J Am Coll Cardiol. 2023;81:2328-2340.

35. Duijzer, D, de Winter, MA, Nijkeuter, M, Tuinenburg, AE and Westerink, J. Upper Extremity Deep Vein Thrombosis and Asymptomatic Vein Occlusion in Patients With Transvenous Leads: A Systematic Review and Meta-Analysis. Front Cardiovasc Med. 2021;8:698336.

36. Bodin, A, Texier, I, Bisson, A, et al. Dual-chamber vs. single-chamber pacemaker in patients in sinus rhythm with an atrioventricular block: a nationwide cohort study. Europace. 2024;26:37.

Tan, RB, Pierce, KA, Nielsen, J, et al. Dual- Vs Single-Chamber Ventricular Pacing in Isolated Congenital Complete Atrioventricular Block in Infancy. JACC Clin Electrophysiol. 2025;

38. El-Chami, MF, Sayegh, MN, Patel, A, et al. Outcomes of lead extraction in young adults. Heart Rhythm. 2017;14:537-540.

39. Kutarski, A, Miszczak-Knecht, M, Brzezinska, M, et al. Transvenous Lead Extraction in Pediatric Patients - Is It the Same Procedure in Children as in Adults? Circulation journal : official journal of the Japanese Circulation Society. 2023;87:990-999.

40. Bashir, J, Lee, AJ, Philippon, F, et al. Predictors of perforation during lead extraction: Results of the Canadian Lead ExtrAction Risk (CLEAR) study. Heart Rhythm. 2022;19:1097-1103.

41. Konta, L, Chubb, MH, Bostock, J, Rogers, J and Rosenthal, E. Twenty-Seven Years Experience With Transvenous Pacemaker Implantation in Children Weighing <10 kg. Circulation. Arrhythmia and electrophysiology. 2016;9:e003422.

42. Gourraud, JB, Chaix, MA, Shohoudi, A, et al. Transvenous Lead Extraction in Adults With Congenital Heart Disease: Insights From a 20-Year Single-Center Experience. Circulation. Arrhythmia and electrophysiology. 2018;11:e005409.

43. Pham, TDN, Cecchin, F, O'Leary, E, et al. Lead Extraction at a Pediatric/Congenital Heart Disease Center: The Importance of Patient Age at Implant. JACC Clin Electrophysiol. 2022;8:343-353.

44. Hayashi, K, Callahan, T, Rickard, J, et al. Comparison of outcomes and required tools between transvenous extraction of pacemaker and implantable cardioverter defibrillator leads: Insight from single high-volume center experience. J Cardiovasc Electrophysiol. 2024;35:1382-1392.

45. Friedman, PA, Bradley, D, Koestler, C, et al. A prospective randomized trial of single- or dual-chamber implantable cardioverter-defibrillators to minimize inappropriate shock risk in primary sudden cardiac death prevention. Europace. 2014;16:1460-8.

46. Peterson, PN, Greenlee, RT, Go, AS, et al. Comparison of Inappropriate Shocks and Other Health Outcomes Between Single- and Dual-Chamber Implantable Cardioverter-Defibrillators for Primary Prevention of Sudden Cardiac Death: Results From the Cardiovascular Research Network Longitudinal Study of Implantable Cardioverter-Defibrillators. Journal of the American Heart Association. 2017;6:

Section 12 Future Directions

1. Non-vascular CIEDs. One of the major advances since the last document in 2017 includes the improvements and expanded clinical application of leadless devices, which provide new options for patients who have suffered from CIED infection, lead failure, or lack of vascular access. These devices provide alternative treatment options for bradycardia pacing with a reduced infection rate and risk of lead extraction, but still have limitations in terms of battery longevity, optimal AV synchrony, non-physiological pacing, and safety of removal during the replacement procedure.[1,2] Similarly, defibrillation with non-transvenous devices has limitations, including higher rates of inappropriate therapy and a lack of pacing options for those who require high-burden pacing.[3] A leadless pacemaker coupled with a subcutaneous ICD can provide improved options with respect to the delivery of antitachycardia and bradycardia pacing, but is not yet widely available and requires a co-implant of 2 devices. S-ICD and EV-ICD have tachycardia-detection limitations to patient candidacy, yet the two technologies are complementary alternatives to mitigate the drawbacks. The second generation of leadless pacing has improved battery longevity. Leadless left bundle area pacing based on an active fixation prototype, which could eliminate transvenous lead-related complications and concomitantly achieve physiological pacing, is under initial phase investigation in humans.[4] AV sequential DDD leadless conduction system pacing is under investigation in animal studies. Although leadless device extraction has a high reported success rate in 5 years, its feasibility and safety after longer dwell time remain to be determined.

2. Standardization of TLE. Indications for transvenous lead extraction are increasing in parallel with an aging population, evolving new technologies, and expanded indications. Advancements in lead extraction tools and techniques have made lead removal safer for patients. However, patients have simultaneously become exceedingly more complex. Older patients with a higher comorbidity index, combined with the need for augmented CIED lead survival beyond their expected longevity, have heightened the complexity of the current paradigm of lead management.[5] Concerted efforts to increase perioperative safety through technological innovations and institutional advances have sparked lead extraction practice and active research.[6] CIED lead extraction requires a multidisciplinary team with expertise and collaborative endeavour. Creating a team structure that can accurately identify individuals with CIED infection or malfunction and efficiently channel them to appropriate expert care in a timely fashion could dramatically improve outcomes and unmet needs. Prompt referral and access to extraction would help to address and potentially resolve the barriers to care and practice gaps. But many questions in the field remain unanswered. Quantifying the potential risk for complications with lead extraction remains elusive; it is not well-defined by lead characteristics (model, dwell time, etc), patient characteristics, frailty, comorbidities, and extraction tool type. Further data from well-designed investigations are necessary to better elucidate how to best risk-stratify patients and improve outcomes. The future perspective in this area needs to emphasize a guideline-based and institutionally-endorsed CIED lead management strategy, continued effort in prospective registries and trials for lead-related management efficacy and safety outcomes.

3. Early extraction in infected CIEDs. Complete and early extraction has been found to be associated with significantly better clinical outcomes compared with no or late extraction.[7] However, significant gaps in knowledge, barriers to early diagnosis, referral, and appropriate therapy remain challenges. Quality metrics on assessing the efforts to improve access to experts and experienced extraction centers will be beneficial to the outcomes of CIED infection management.

4. Lead management in conduction system pacing. Conduction system physiological pacing has opened a new arena for bradycardia pacing and cardiac resynchronization. It mitigates RV pacing-induced cardiomyopathy and achieves comparable outcomes to biventricular pacing resynchronization from small, randomized studies. Large randomized clinical trials are on the way. As most active fixation leads nearly penetrate the ventricular septum and position at the left ventricular subendocardium, the lead durability in the long term and the outcome of extracting long-dwelling left bundle area pacing leads are limited and deserve future investigation.[8]

5. Transvenous lead and tricuspid valve function. The effect of lead placement on the tricuspid valve is unpredictable in individual patients, and its impact is often underrecognized. Severe tricuspid regurgitation associated with lead impingement or entanglement to the tricuspid structure can occur. .[9] The best practice to avoid impingement of the tricuspid valve at the time of lead placement needs to be established and adhered to by implanters. Appropriate and timely assessment of TR following transvenous lead placement is necessary and may be considered as standard care to identify patients who have developed significant lead-related TR and will benefit from early

lead revision, potentially avoiding surgical or transcatheter tricuspid valve replacement (TTVR). Equally important to the effects of leads on the tricuspid valve is the effect of tricuspid valve interventions on leads. Lead entrapment with TTVR may result in lead malfunction and potentially detrimental consequences in pacemaker-dependent and/or secondary prevention patients. Lead extraction with reimplantation of a tricuspid valve-sparing CIED system, when appropriate, is preferable to jailing the lead. While implanting a lead through the new valve is possible, the long-term effect on the valve performance is unknown and could be detrimental; hence, this approach should be avoided if possible. The risks and benefits of TLE need to be discussed with shared decision-making and a multidisciplinary heart team approach. More research evidence is required in this rapidly growing area.

6. CIEDs in congenital heart disease. Adult patients with congenital heart disease are an increasing population, many of whom have arrhythmic issues that require bradycardia or tachycardia support by the device. This population may merit special registries to elucidate better how they could be managed.

7. Uninterrupted anticoagulation during TLE. The initial experience in patients who undergo TLE with uninterrupted warfarin due to a mechanical valve in situ and a high risk of thromboembolism has shown no apparent increase in the risk of bleeding in selected patients. However, further investigations are needed to provide more evidence on assessing the risk of TLE-related bleeding with uninterrupted anticoagulation vs. heparin bridging.

8. The safety of MRI in patients with CIED. Insufficient MRI-conditional labeling is an example where patient safety may be compromised by avoiding MRI due to non-MRI-conditional systems, particularly when data exist to support the performance of such imaging safely, irrespective of MRI-conditional labeling (a limitation based on industry interests and regulatory scope). A larger scope of evidence is needed to demonstrate the safety of MRI in non-MRI-conditional CIEDs and leads, including abandoned leads. It is our hope that with additional safety data, future guidelines will facilitate MRI across the spectrum of CIEDs, so that lead extraction for this indication will grow increasingly rare in future practice.

References

1. Briongos-Figuero S, Estevez-Paniagua A, Sanchez Hernandez A, Jimenez S, Gomez-Mariscal E, Abad Motos A and Munoz-Aguilera R. Optimizing atrial sensing parameters in leadless pacemakers: Atrioventricular synchrony achievement in the real world. *Heart Rhythm*. 2022;19:2011-2018.

2. Garweg C, Breitenstein A, Clementy N, De Asmundis C, Iacopino S, Johansen JB, Sharman D, Theis C, Prat XV, Winter S and Reichlin T. Strategies to improve atrioventricular synchrony in patients with a Micra AV leadless pacemaker. *Europace*. 2024;26.

3. Swerdlow C, Gillberg J, Boersma LVA, Manlucu J, Zhang X, Zhang Y, Hernandez AA, Bhatia V and Murgatroyd F. Extravascular Implantable Cardioverter-Defibrillator Sensing and Detection in a Large Global Population. *JACC Clin Electrophysiol*. 2024;10:1896-1912.

4. Reddy VY, Nair DG, Doshi SK, Doshi RN, Chovanec M, Ganz L, Sabet L, Jiang C and Neuzil P. First-in-human study of a leadless pacemaker system for left bundle branch area pacing. *Heart Rhythm*. 2025.

5. Mehta VS, Elliott MK, Sidhu BS, Gould J, Kemp T, Vergani V, Kadiwar S, Shetty AK, Blauth C, Gill J, Bosco P and Rinaldi CA. Long-term survival following transvenous lead extraction: Importance of indication and comorbidities. *Heart Rhythm*. 2021;18:1566-1576.

6. Luria D, Tomer O, Przybylski A, Romanek J, Stein U, Briman Y, Shauer A and Elitzur Y. Novel concept and device for lead extraction, utilizing vibration energy: results from bench, animal and a first-in-human experiments. *EP Europace*. 2025;27.

7. Lakkireddy DR, Segar DS, Sood A, Wu M, Rao A, Sohail MR, Pokorney SD, Blomström-Lundqvist C, Piccini JP and Granger CB. Early Lead Extraction for Infected

Implanted Cardiac Electronic Devices: JACC Review Topic of the Week. *Journal of the American College of Cardiology*. 2023;81:1283-1295.

8. Friedman DJ, Shadrin I, Goldbarg S, Trulock KM, Patel A, Loring Z, Coles SA, Gandhi G, Upadhyay GA, Wold N, Jones PW, Ruble SB, Weinstock J and Latanich CA. Performance of an active fixation stylet-driven lead in left bundle branch area pacing: Results from INSIGHT-LBBA. *Heart Rhythm*. 2025.

9. Deharo JC, Dreyfus J, Bongiorni MG, Burri H, Defaye P, Glikson M, Lever N, Mangieri A, Mondésert B, Nielsen JC, Shah M, Starck CT, Rao A, Leclercq C, Praz F, Richter S, Amabile N, Breitenstein A, Cano Ó, Čurila K, Manlucu J, Schaller RD, Tse HF, Veltmann C and Whinnett Z. Management of patients with transvalvular right ventricular leads undergoing transcatheter tricuspid valve interventions: a scientific statement of the European Heart Rhythm Association and the European Association of Percutaneous Cardiovascular Interventions of the ESC endorsed by the Heart Rhythm Society, the Asian Pacific Heart Rhythm Society and the Canadian Heart Rhythm Society. *Europace*. 2025;27.

A Tribute and Dedication to Dr. Bruce Wilkoff

The 2026 HRS Expert Consensus Statement Update on Cardiovascular Implantable Electronic Device Lead Management and Extraction is dedicated to Bruce Wilkoff, M.D., who was selected as a Vice-Chair for this document but passed away on January 7, 2024. Dr. Wilkoff was an international leader in electrophysiology and served as President of the Heart Rhythm Society in 2011-2012. Throughout his storied career Dr. Wilkoff was dedicated to improving care in patients with cardiac implantable electronic devices but is perhaps most remembered as one of the original pioneers and primary voice for the development of lead extraction techniques. Of his >400 peer-reviewed manuscripts, he authored 170 articles on lead management and 72 articles specifically on lead extraction. Dr. Wilkoff was the Chair of the initial 2009 Heart Rhythm Statement on Facilities, Training, Indications, and Management on Lead Extraction and served as a co-chair for the 2017 Expert Consensus Statement on CIED Lead Management and Extraction. Beyond his many scientific contributions, he was a gifted educator, visionary leader, and dedicated mentor to many in our field. Dr. Wilkoff, you will be missed but always remembered.