

NASPE POLICY STATEMENT

Recommendations for Extraction of Chronically Implanted Transvenous Pacing and Defibrillator Leads: Indications, Facilities, Training

NORTH AMERICAN SOCIETY OF PACING AND ELECTROPHYSIOLOGY LEAD EXTRACTION CONFERENCE FACULTY: CHARLES J. LOVE, BRUCE L. WILKOFF, CHARLES L. BYRD, PETER H. BELOTT, JEFFREY A. BRINKER, NEAL E. FEARNOT, RICHARD A. FRIEDMAN, SEYMOUR FURMAN, LOUIS B. GOODE DAVID L. HAYES, DAVID T. KAWANISHI, VICTOR PARSONNET, CHRISTOPHER REISER, and HEIDI J. VAN ZANDT, (ADDITIONAL CONSULTANT)

Introduction

In the years following the commercial introduction of chronically implanted transvenous pacing leads, a wide variety of methods for removing such leads began to appear in the literature.¹⁻⁵ The simplest in concept is traction—applying a longitudinal force to the lead body after exteriorizing the proximal end of the lead. In some instances, manipulation of the lead and only gentle traction is required. For patients with exuberant fibrotic overgrowth,⁶ more aggressive methods were developed, including traction applied by weights, elastic bands, or other inventive methods. A few reports describe grasping the lead with forceps⁷ or catheters in an effort to overcome the limited tensile strength or the short length of some leads.

Complications⁸⁻¹¹ and difficulties¹²⁻¹⁴ encountered when using traction for lead removal led some investigators to surgical approaches.^{11,15-17} Exposing the heart and great veins via sternotomy or thoracotomy allows extraction of a lead via a transmural incision in the atrium or ventricle. A limited surgical technique, via the right intercostal space, has also been described.¹⁸ In experienced hands these techniques produced high success rates, but required skills not typically practiced by the majority of implanting physicians. In addition, these techniques are associated with the morbidity and economic impact of thoracotomy.

The desire for safe extraction techniques, performed via the implant vein and compatible with the pectoral-pocket transvenous implant method,

led to the development of intravascular counterpressure and countertraction.^{5,19-30} By using telescoping sheaths made of polymer and/or steel material which slide over the lead body, a countering force is applied to the intravascular fibrotic overgrowth that resists the traction force applied to the lead.^{5,21-25} This technique of intravascular counterpressure localizes shear stress on the fibrotic tissue and aids in blunt dissection or dilation of the tissue away from the lead circumference. Use of a locking stylet within the inner coil is fundamental to this system²²⁻³² so that adequate forces can be generated to overcome tissue adhesion, despite the limited tensile strength inherent in most lead designs. At the lead tip, the sheath is held in position near the heart wall while traction is applied to the lead in the countertraction maneuver. By minimizing the inversion of the ventricular cavity, the lead tip is sheared from the fibrotic tissue while minimizing the risk of heart wall tear. Recent introduction of the laser sheath³³⁻⁴⁰ has increased the ease of extractions from the implant vein.

When access or removal is not possible from the implantation vein, extraction has been achieved by a femoral venous approach using intravascular catheter-based tools.^{21-25,41-45} Various snares, deflecting wires, and grasping means have been deployed via the inferior vena cava to grasp the lead body in the right atrium. Traction and/or countertraction can be applied to free the lead and remove it through the femoral vein access sheath.^{21-25,46}

The development, training, and use of the procedure for removal of chronically implanted transvenous lead systems has proceeded without formal guidelines since the market release of the transvenous tools in the early 1990s. Since that time the number of physicians and centers where the procedure of lead removal is performed has

Address for reprints: NASPE c/o Marilyn Bishop, Six Strathmore Road, Notch, MA 01760-2499. Fax: (508)647-0124.

Received January 11, 2000.

grown rapidly.⁴⁷⁻⁵⁷ Clinical experience accumulated by the U.S. Lead Extraction Database,⁴⁹⁻⁵⁷ the Accufix Research Institute Database,⁵⁸ and the results of the PLEXES Trial^{34,35,40} have highlighted the lack of formalized standards for (1) training physicians in extraction techniques, (2) availability of equipment and emergently needed support staff at each institution, and (3) indications and contra-indications for lead extractions. Standard definitions and recommendations for the clinical practice of lead extraction are clearly needed.^{35,51,57-60} To achieve these goals, a Policy Conference was held on May 11, 1997 in New Orleans, LA. The conclusions of that conference have been supplemented in this summary paper by ongoing experience and new device development. The purpose of this publication is to elucidate the consensus of the Conference in the form of standardizing language and forward-looking recommendations.

I. Definitions

Definition of the Procedure

Within the general category of "lead removal," distinctions must be made between simple procedures that can be performed via the implant vein without specialized tools ("lead explant"), and removal of leads involving more complex procedures ("lead extraction"). This is necessary when designing training programs, for classification of procedures in registries and databases, as well as for the goal of appropriate reimbursement levels for the different procedures.

Lead Removal: Removal of a pacing or defibrillator lead using any technique.

Lead Explant: Manipulation of a pacing or defibrillator lead so that the lead exits the vasculature via the implant vein using tools typically supplied for lead implant with the addition of manual traction, for a lead that has been implanted for less than one year.

Lead Extraction:

1. Removal of a lead with the assistance of specialized equipment regardless of the implant duration. This may include but is not limited to the use of specialized stylets that are not included as part of the typical implant package, sheaths with or without additional cutting capability (e.g., metal composition, laser, and radiofrequency current), snares, grasping devices, or other devices used to engage or entrap and remove the lead or lead fragments.
2. Removal of a lead from a route other than via the implant vein.
3. Removal of any lead that has been implanted for more than one year.

Definition of Success

Though most leads are removed safely and completely,^{32,40,51,57} some portion of the lead may be left *in situ*. In many instances this, nevertheless, results in the desired clinical outcome, which may include many separate clinical goals. Such goals may include preservation of the implant site, implantation of leads and generator, elimination of infection, etc. Thus, the "success" may be defined in the following ways:

Radiographic Outcome (considered for each lead):

Complete Success: Removal of all lead material from the vascular space.

Partial Success: Removal of all but a small portion of the lead. This may be the electrode, 4 cm or less of conductor coil and/or insulation, or the latter two combined.

Failure: Abandoning a significant length of lead (more than 4 cm) after attempting to remove it.

Clinical Outcome (considered for the entire procedure):

Success: Achieved all clinical goals associated with the indication for lead removal. At a minimum, the clinical goals should include:

1. Resolution of the clinical indication for lead removal, such as:
 - a. elimination of infection at a previously infected incision site if the indication for extraction was infection
 - b. access for new leads if the indication was obliteration of all useable veins
 - c. removal of the identified risk if the indication was a recalled lead
2. Absence of major complications.
3. Control of pacing status.

Failure: Inability to achieve all of the clinical goals.

Definition and Classification of Complications

The assessment of complications requires both a time frame and a level of severity. Several procedures may be performed on the patient in rapid succession, for example, removal of several leads and implantation of replacement leads. Because the cause of the complication cannot always be attributed to a specific procedure, reporting consistency will be improved if complications are considered for the entire patient admission categorized by time of occurrence. The definitions for time frames are:

NASPE POLICY STATEMENT

Intra-operative: Any event related to the performance of a procedure that occurs or becomes evident from the time the patient enters the operating room until the time the patient leaves the operating room. This includes complications related to the preparation of the patient and the delivery of anesthesia, opening and closing, and the intervening time period.

Peri-operative: Any event related to the procedure that occurs or becomes evident during the 24 hour period following the procedure.

Post-operative: Any event related to the procedure that occurs or becomes evident after the peri-operative period (24 hours after the procedure) and within the 30-day period following the procedure.

Late: Any event related to the procedure (such as infection or venous thrombosis) that occurs or becomes evident after the 30 day post-operative period.

Events are classified as major complications, minor complications, or observations, according to their severity, as described below. Examples of classifications using these definitions are shown in Table I.

Major: Any complication related to the procedure that requires procedural intervention or transfusion to prevent death or threat to life, or any complication related to the procedure that results in death or serious harm to bodily function or structure.

Minor: Any complication related to the procedure that requires medical or minor procedural intervention to remedy, or prolongs hospital stay, or limits the patient's function, but does not threaten life, cause death, or cause serious harm to bodily function or structure.

Observation: Unintended result that does not require intervention, prolong hospital stay or impair the patient's function.

Table I.
Examples of Complications

Classification	Examples
Major Complication	<ol style="list-style-type: none"> 1. Death* 2. Cardiac avulsion or tear requiring thoracotomy, pericardiocentesis, chest tube, or surgical repair 3. Vascular avulsion or tear requiring thoracotomy, pericardiocentesis, chest tube, or surgical repair 4. Hemothorax or severe bleeding from any source requiring transfusion 5. Pneumothorax requiring chest tube drainage 6. Pulmonary embolism requiring surgical intervention 7. Respiratory arrest 8. Septic shock 9. Stroke
Minor Complication	<ol style="list-style-type: none"> 1. Pericardial effusion not requiring pericardiocentesis or surgical intervention. 2. Hemodynamically significant air embolism 3. Pulmonary embolism not requiring intervention 4. Vascular repair near the implant site or venous entry site 5. Arrhythmia requiring cardioversion 6. Hematoma at the pocket requiring drainage 7. Arm swelling or thrombosis of implant veins resulting in medical intervention 8. Sepsis in a previously non-septic patient with infection 9. Pacing system related infection of a previously non-infected site
Observation	<ol style="list-style-type: none"> 1. Transient hypotension that responds to fluids or minor pharmacologic intervention 2. Non-significant air embolism 3. Small pneumothorax not requiring intervention 4. Ectopy not requiring cardioversion 5. Arm swelling or thrombosis of implant veins without need for medical intervention 6. Pain at cut-down site 7. Myocardial avulsion without sequelae 8. Migrated lead fragment without sequelae

* Death from multisystem or associated patient conditions would be included if the procedure caused or contributed to the final event. Death clearly unrelated to the procedure would not be included. For example, death in a septic patient who had a perforation and could not be resuscitated would be included. However, death in a septic patient who underwent extraction and later died of sepsis would not be included.

II. Indications for Lead Removal

The indications for lead removal have generally been described according to the "Byrd Classification."⁵ The categories of "Mandatory", "Necessary", and "Discretionary" have served well during the developmental phase of lead extraction technology and physician skills. At this time it is appropriate to formalize the classes of indications for lead removal procedures using transvenous techniques.

Indications for Lead Removal Using Transvenous Techniques

Class I (conditions for which there is general agreement that leads should be removed)

- a. Sepsis (including endocarditis) as a result of documented infection of any intravascular part of the pacing system, or as a result of a pacemaker pocket infection when the intravascular portion of the lead system cannot be aseptically separated from the pocket.
- b. Life-threatening arrhythmias secondary to a retained lead fragment.
- c. A retained lead, lead fragment, or extraction hardware that poses an immediate or imminent physical threat to the patient.
- d. Clinically significant thromboembolic events caused by a retained lead or lead fragment.
- e. Obliteration or occlusion of all useable veins, with the need to implant a new transvenous pacing system.
- f. A lead that interferes with the operation of another implanted device (e.g., pacemaker or defibrillator).

Class 2 (conditions for which leads are often removed, but there is some divergence of opinion with respect to the benefit versus risk of removal)

- a. Localized pocket infection, erosion, or chronic draining sinus that does not involve the transvenous portion of the lead system, when the lead can be cut through a clean incision that is totally separate from the infected area.*
- b. An occult infection for which no source can be found, and for which the pacing system is suspected.
- c. Chronic pain at the pocket or lead in-

*The lead can be cut and the clean incision closed; then, the infected area can be opened, the clean distal portion of the lead pulled into the infected area, and that portion removed. This allows a total separation of the retained lead fragment from the infected area.

sertion site that causes significant discomfort for the patient, is not manageable by medical or surgical technique without lead removal, and for which there is no acceptable alternative.

- d. A lead that, due to its design or its failure, may pose a threat to the patient, though is not immediate or imminent if left in place.
- e. A lead that interferes with the treatment of a malignancy.
- f. A traumatic injury to the entry site of the lead for which the lead may interfere with reconstruction of the site.
- g. Leads preventing access to the venous circulation for newly required implantable devices.
- h. Non-functional leads in a young patient.

Class 3 (conditions for which there is general agreement that removal of leads is unnecessary)

- a. Any situation where the risk posed by removal of the lead is significantly higher than the benefit of removing the lead.
- b. A single non-functional transvenous lead in an older patient.
- c. Any normally functioning lead that may be reused at the time of pulse generator replacement, provided the lead has a reliable performance history.

In addition to the primary indication, several clinical factors must be taken into consideration when deciding whether or not to remove a lead, such as:

1. Age of the patient
2. Gender of the patient^{51,57}
3. Overall health (physical and mental) of the patient, such as: comorbidities, cardiovascular status, previous family and surgical history, ability to receive transfusion (religious-based limitations), surgical candidacy, and presence of malignancy
4. Presence of calcification involving the lead(s)
5. Presence of vegetations in the heart
6. Number of leads in the intravascular space
7. Duration of the implant
8. Fragility, condition, and physical characteristics of the lead
9. Experience of physician
10. Desires of the patient

Relative Contra-Indications for Transvenous Lead Removal

The overall clinical state of the patient may lead to relative contraindications for lead removal using transvenous techniques as follows:

1. Presence of calcification visible by x-ray involving the lead in the atrium or superior vena cava.
2. Unavailability of required equipment.
3. Patient is unsuitable candidate for emergent thoracotomy.
4. Known anomalous placement of the lead through structures other than the normal venous and cardiac structures (e.g., subclavian artery, pericardial space).

III. Physician Qualifications

Lead extraction is an invasive procedure requiring training and experience to perform safely and effectively. Physicians wishing to perform this procedure should be properly trained in technique. The simple act of watching an instructional video demonstration or observing an operator performing the procedure is not adequate. Other procedures with similar operator skill requirements and patient risk (e.g., percutaneous angioplasty of coronary or peripheral vessels) require at least an additional year of training. The following issues must be considered when determining a minimal number of extraction procedures that should be performed under supervision.

1. Analysis of lead extraction outcomes suggests that the frequency of procedural (radiographic) failure drops dramatically after the first 10–20 procedures have been performed.^{35,49,51}
2. Lower complication rates are associated with prior experience of 50 procedures.⁵⁷
3. A minimal number of procedures should be performed on an annual basis to maintain skills.
4. Performing a specific number of procedures does not guarantee proficiency, competency, or safety; outcome data are necessary to assess performance.
5. Training should be obtained at centers with adequate volume, experience, and expertise.
6. The number of lead extractions that need to be performed annually does not justify a wide dissemination of this technique.

Therefore, based on the available data, it is recommended that physicians being trained in this technique perform a *minimum* of 20 lead extractions as the primary operator under the direct supervision of a qualified training physician. Ex-

posure to venous entry site as well as femoral retrieval techniques should be included. The supervisor should have in excess of 100 lead extractions performed with an efficacy and safety record that is consistent with published data.

IV. Minimal Requirements for Facilities for the Performance of Lead Extraction

Intra-operative and peri-operative complications observed during lead extraction include life-threatening events, such as hemothorax and cardiac tamponade, leading to death in less than 1% of patients.^{51,57} As the possibility of vascular catastrophe is very real, the physician and the institution must both be capable of responding immediately and appropriately. To achieve this level of preparedness, the hospital must have the following services on site and immediately available during the lead extraction procedure:

Facility Requirements for Lead Extraction

1. An accredited cardiac surgery program on site.
2. An accredited cardiac catheterization program.
3. At least one physician who is properly trained and proficient in the technique of transvenous lead extraction.
4. Cardiothoracic surgeon on site and capable of initiating an emergent procedure promptly.
5. Anesthesiologist with working anesthesia equipment.
6. A full set of basic instruments for lead extraction.
7. High quality fluoroscopy.
8. Transthoracic ultrasound and transesophageal ultrasound capability immediately available.
9. Monitoring equipment for arterial pressure (invasive or noninvasive) and oxygen saturation.
10. Pericardiocentesis tray in the procedure room, and availability of personnel trained in the technique of pericardiocentesis.
11. Thoracotomy tray immediately available.
12. Temporary pacing and defibrillation/cardioversion equipment in the procedure room.
13. Fluids, pressors, and other emergency medication available in the procedure room.

Of these items, the value of a high-quality fluoroscopy system cannot be overstressed. Visualization of small lead components, such as the position of fixation screws on leads with retractable screws, is necessary for the safe application of extraction technique. It is also recommended that a

designated “extraction coordinator” be identified to coordinate the procurement, storage and re-ordering of the extraction equipment. This person would also be responsible for maintaining protocols, in concert with the hospital’s requirements, that insure patient safety throughout the procedure.

V. Patient Preparation

As this procedure may result in life-threatening complications, it is imperative that the patient be prepared and that the conditions noted in section IV of this document be present.

Patient Preparation Requirements for Lead Extraction

1. Patient should be informed of the procedure, the risks, benefits and alternatives to the intended procedure.
2. Patient history and physical examination should be performed with attention to any anatomic details that may influence the efficacy and safety of the procedure.
3. The models and implant dates of the devices should be obtained.
4. The degree of pacemaker dependency should be assessed and stable temporary pacing should be established if necessary.
5. External pacing and defibrillation capability, preferably with pre-applied pads, should be established as well.
6. Basic lab studies including coagulation status must be evaluated.
7. The patient should be screened or cross-matched for blood.
8. Chest X-ray and/or fluoroscopic images of the lead(s), vasculature, and heart should be evaluated, including ilio-femoral access site.
9. Continuous blood pressure monitoring, preferably by intra-arterial catheter, should be used. Automatic non-invasive monitoring may be used, but does not provide the immediate feedback that may be required.
10. Large bore intravenous access should be established.
11. Adequate anesthesia should be provided to prevent significant patient discomfort during the procedure.

VI. Lead Extraction Patient Registry (Quality Assurance)

Maintenance of a physician’s privileges should include participation in a Joint Commission on Accreditation of Health Care Organiza-

tions-mandated quality assurance program. A data registry should be established at each hospital site where lead extraction is performed; participation in a national database is strongly recommended.

Lead Extraction Registry Requirements

1. Enroll *all* patients who undergo procedures in which lead removal is attempted using transvenous techniques.
2. Compile patient statistics regarding clinical characteristics.
3. Record lead extraction data on the procedure, success and complications, consistent with the data requirements of the national registry.
4. Obtain follow-up at the end of the post-operative period (30 days).
5. Data analysis should be reviewed at least on an annual basis. Review of individual physician’s data should be done in a confidential manner and compared to national or regional statistics.
6. Submission of *all* cases to a national registry. The individual physician may be identified by name or code, at the discretion of the physician and the reporting institution.

VII. Reimbursement

The current CPT codes have recently been modified to deal with routine lead explant, but currently there are no CPT codes that adequately describe or address lead extraction. These codes do not reflect the additional effort, risk, expertise or time required to perform lead extraction. Thus, new codes must be developed in the near future to address the growing use of these techniques. It is recommended that a single code for lead extraction that utilizes these specialized techniques be assigned. This code may be utilized multiple times for multiple lead removal procedures performed during an operative session.

VIII. New Devices and Techniques

The introduction of new devices and their use is regulated in the United States by the Food and Drug Administration. The purpose of this oversight is to assure that newly released devices are safe and effective when used according to the device labeling. It must be understood that a single device or technique is unlikely to be proven safe and effective in all situations. Rather, as with many surgical techniques, the instruments used are chosen in a given situation due to the specific needs as they present during the procedure. Further, devices are often used in combination, such as locking stylets and telescoping sheaths, or in tandem, such as laser sheaths followed by polymer sheaths.

This makes the design of a clinical trial to test a new device or technique somewhat problematic because the effects of the new device or technique alone may be difficult to separate from the effects of all the devices and techniques used as a group. The interpretation of results from such trials is further complicated by difficulties in the definitions of success and complications, by the lack of adequate data, by sources of bias such as unbalanced crossover, and by patient selection criteria.

These considerations suggest that guidelines for evaluation of new lead extraction devices and techniques may be advantageous.

Guidelines for Clinical Evaluation of Lead Extraction Devices

1. The clinical trial design should be appropriate to assess the marginal effects of a new device on safety and effectiveness, given the combined use with existing devices.

2. The clinical trial design should have a statistical plan addressing adequate sample size, stratification (e.g., ICD vs pacing lead), crossover bias if applicable, assessment of covariates, and appropriate methods for hypothesis testing.

3. Clinical studies should use the definitions of indications, success, and complications (in-

cluding time period and severity) listed above, and use written definitions for other measures.

4. The clinical trial Case Report Form should acquire at the least the data obtained in institution and national registries, and data and factors known to predict outcome.

IX. Summary

The procedure of lead removal has recently matured into a definable, teachable art with its own specific tools and techniques. It is now time to recognize and formalize the practice of lead removal according to the current methods of medicine and the health care industry. In addition, since at this time the only prospective scientific study of lead extraction is the PLEXES trial, we suggest that studies relating to the techniques of and indications for lead extraction be designed. Recommendations for a common set of definitions, for a framework of training and reviewing physicians in the art, for general methods of reimbursement, and for consistency among clinical trials have been made. Implementation of these recommendations will require additional effort and cooperation from practicing physicians, medical societies, hospital administrations, and industry.

References

- Wallace H, Sherfat M, Blakemore WS. The stubborn pacemaker catheter. *Surgery* 1970; 68:914-915.
- Bilgutay AM, Jensen NK, Schmidt WR, et al. Incarceration of transvenous pacemaker electrode. Removal by traction. *Am Heart J* 1969; 77:377-379.
- Imparato A, Kim GE. Electrode complications in patients with permanent cardiac pacemakers. *Arch Surg* 1972; 105:705-710.
- Myers MR, Parsonnet V, Bernstein AD. Extraction of implanted transvenous pacing leads: a review of a persistent clinical problem. *Am Heart J* 1991; 121:881-888.
- Byrd CL, Schwartz SJ, Hedin N. Lead extraction: Indications and techniques. *Cardiol Clin* 1992; 10:735-748.
- Smith HJ, Fearnot NE, Byrd CL, et al. Where does scar tissue form to inhibit extraction of chronic pacemaker leads? (abstract) *J Am Coll Cardiol* 1992; 19(3):148A.
- Kratz JM, Leman R, Gillette, P. Forceps extraction of permanent pacing leads. *Ann Thorac Surg* 1990; 49(4):676-677.
- Garcia-Jiménez A, Albá CMB, Cortés JMG, et al. Myocardial rupture after pulling out a tined atrial electrode with continuous traction. *PACE* 1992; 15:5-8.
- Sonnhaag C, Walfridsson H. Extraction of chronically infected pacemaker leads: two cases with serious complications. (abstract) *PACE* 1989; 12:1204.
- Lee ME, Chaux A, Matloff JM. Avulsion of a tricuspid valve leaflet during traction on an infected, entrapped endocardial pacemaker electrode. *J Thorac Cardiovasc Surg* 1977; 74:433-435.
- Järvinen A, Harjula A, Verkkala K. Intrathoracic surgery for retained endocardial electrodes. *Thorac Cardiovasc Surgeon* 1986; 34:94-97.
- Madigan NP, Curtis JJ, Sanfelippo JF, et al. Difficulty of extraction of chronically implanted tined ventricular endocardial leads. *JACC* 1984; 3:724-731.
- Rettig G, Doenecke P, Sen S, et al. Complications with retained transvenous pacemaker electrodes. *Am Heart J* 1979; 98:587-594.
- Shennib H, Chiu R, Rosengarten M, et al. The nonextractable tined endocardial pacemaker lead. *Can J Cardiol* 1989; 5:305-307.
- Dubernet J, Irarrazaval MJ, Lema G, et al. Surgical removal of entrapped endocardial pacemaker electrodes. *Clin Prog Electrophysiol Pacing* 1986; 4:147-152.
- Yarnoz MD, Attai LA, Furman S. Infection of pacemaker electrode and removal with cardiopulmonary bypass. *J Thorac Cardiovasc Surg* 1974; 68:43-36.
- Frame R, Brodman R, Furman S, et al. Surgical removal of infected transvenous pacemaker leads. *PACE* 1993; 16:2343-2348.
- Byrd CL, Schwartz SJ, Sivina M, et al. Technique for the surgical extraction of permanent pacing leads and electrodes. *J Thorac Cardiovasc Surg* 1985; 89:142-144.
- Meibom J. A new method for transvenous electrode explantation. (abstract) *PACE* 1985; 8:A-54.
- Byrd CL, Schwartz SJ, Sivina M, et al. Experience with 127 pacemaker lead extractions. (abstract) *PACE* 1986; 9:282.
- Byrd CL, Schwartz SJ, Giraldo RJ, et al. Update on transvenous countertraction lead extraction experience. (abstract) *PACE* 1987; 10:443.
- Byrd CL, Schwartz SJ, Hedin NB, et al. Intravascular lead extraction using locking styles and sheaths. *PACE* 1990; 13:1871-1875.
- Byrd CL, Schwartz SJ, Hedin N. Intravascular techniques for extraction of permanent pacemaker leads. *J Thorac Cardiovasc Surg* 1991; 101:989-997.
- Byrd CL, Schwartz SJ, Hedin NB. Lead extraction: techniques and indications. In Barold SS and Mugica J, eds. *New Perspectives in Cardiac Pacing*, 3. Mt. Kisco, NY: Futura, 1993:29-55.
- Byrd CL. Management of implant complications. In Ellenbogen KA, Kay GN, Wilkoff BL, eds. *Clinical Cardiac Pacing*. Philadelphia: W.B. Saunders Company, 1995:491-522.
- Brodell GK, Castle LW, Maloney JD, et al. Chronic transvenous pacemaker lead removal using a unique, sequential transvenous system. *Am J Cardiol* 1990; 66:964-966.
- Fearnot NE, Smith HJ, Goode LB, et al. Intravascular lead extraction using locking stylets, sheaths, and other techniques. *PACE* 1990; 13:1864-1875.
- Goode LB, Byrd CL, Wilkoff BL, et al. Development of a new tech-

NASPE POLICY STATEMENT

- nique for explantation of chronic transvenous pacemaker leads: five initial case studies. *Biomedical Instrumentation & Tech* 1991; 25:50–53.
29. Love CJ, Nelson SD, Schaal SF. Extraction of permanent pacemaker leads using the Cook extraction set; initial clinical experience. (abstract) *JACC* 1990; 15(2):50A.
 30. Colavita PG, Zimmem SH, Gallagher JJ, et al. Intravascular extraction of chronic pacemaker leads: efficacy and follow-up. *PACE* 1993; 16:2333–2336.
 31. Alt E, Theres H, Reinhard J. First clinical use of a new extraction stylet for removal of infected leads. (abstract) *PACE* 1992; 15:572.
 32. Alt E, Neuzner J, Binner L, et al. Three-year experience with a stylet for lead extraction: a multicenter study. *PACE* 1996; 19:18–25.
 33. Byrd CL. Extracting chronically implanted pacemaker leads using the Spectranetics excimer laser: initial clinical experience. (abstract) *PACE* 1996; 19:567.
 34. Byrd CL, Wilkoff BL, Love CJ, et al. Update of the PLEXES trial: two-year experience. (abstract) *PACE* 1998; 21:817.
 35. Bracke FA, Meijer A, Van Gelder, B. Learning curve characteristics of pacing lead extraction with a laser sheath. *PACE* 1998; 21:2309–2313.
 36. Al-Khadra AS, Wilkoff BL, Byrd CL, et al. Extraction of nonthoracotomy defibrillator leads using the Spectranetics LASER sheath: the US experience. (abstract) *PACE* 1998; 21:889.
 37. Krishnan S, Epstein L. Initial experience with a laser sheath to extract chronic transvenous implantable cardioverter-defibrillator leads. *Am J Cardiol* 1998; 82:1293–1295.
 38. Reiser C, Taylor K, Lippincott R. Large laser sheaths for pacing and defibrillator lead removal. *Lasers Surg Med* 1998; 22:42–45.
 39. Varma N, Selke FW, Epstein LM. Chronic atrial lead explantation using a staged percutaneous laser and open surgical approach. *PACE* 1998; 21:1483–1485.
 40. Wilkoff BL, Byrd CL, Love CJ, et al. Pacemaker lead extraction with the laser sheath: results of the pacing lead extraction with the excimer sheath (PLEXES) trial. *J Am Coll Cardiol* 1999; 33(6):1671–1676.
 41. Foster CJ, Brownlee WC. Percutaneous removal of ventricular pacemaker electrodes using a Dormier basket. *Int J Cardiol* 1988; 21:127–134.
 42. Hayes DL, Vlietstra RE, Neubauer S. Snare retrieval of entrapped infected transvenous pacing leads to avoid thoracotomy. (abstract) *PACE* 1987; 10:686.
 43. Tallercio CP, Vlietstra RE, Hayes DL. Pigtail catheter for extraction of pacemaker lead. (letter) *J Am Coll Cardiol* 1985; 5:1020.
 44. Ramsdale DR, Arumugam N, Pidgeon JW. Removal of fractured pacemaker electrode tip using Dotter basket. *PACE* 1985; 8:759–760.
 45. Espinosa RE, Hayes DL, Vlietstra RE, et al. The Dotter retriever and pigtail catheter: efficacy in extraction of chronic transvenous pacemaker leads. *PACE* 1993; 16:2337–2342.
 46. Byrd CL, Schwartz SJ, Hedin NB, et al. Inferior vena cava extraction technique. (abstract) *PACE* 1992; 15:571.
 47. Weinberg D, Shaner S, Smith C, et al. Pacemaker lead extraction experience at a community hospital. (abstract) *PACE* 1992; 15:513.
 48. Smith CW, Messenger JC, Schaner SP, et al. Cardiac pacemaker electrodes: improved methods of extraction. *Radiology* 1994; 193:739–742.
 49. Smith HJ, Fearnot NE, Byrd CL, et al. Intravascular extraction of chronic pacing leads: the effect of physician experience. (abstract) *PACE* 1992; 15:513.
 50. Wilkoff BL, Smith HJ, Fearnot NE, et al. Intravascular lead extraction: multicenter update for 523 patients. (abstract) *PACE* 1992; 15:513.
 51. Smith HJ, Fearnot NE, Byrd CL, et al. Five-years experience with intravascular lead extraction. *PACE* 1994; 17:2016–2020.
 52. Maloney JD, Wilkoff BL, Smith HJ, et al. Feasibility of percutaneous extraction of transvenous defibrillator leads. (abstract) *Circulation* 1995; 92(Suppl.):1–151–2.
 53. Wilkoff BL, Morant VA, Kidwell GA, et al. Seven year single center analytical experience of transvenous lead extraction. (abstract) *PACE* 1996; 19:576.
 54. Friedman RA, Van Zandt H, Collins E, et al. Lead extraction in young patients with and without congenital heart disease using the subclavian approach. *PACE* 1996; 19:778–83.
 55. Niebauer M, Wilkoff B, Van Zandt H, et al. Nonthoracotomy defibrillator lead extraction: comparison with ventricular pacing leads. (abstract) *PACE* 1997; 20:1071.
 56. Wilkoff BL, Byrd CL, Love CJ, et al. Risks of intravascular extraction of chronic pacemaker and ICD leads: a multicenter analysis of 1895 patients. (abstract) *PACE* 1998; 21:826.
 57. Byrd CL, Wilkoff BL, Love CJ, et al. Intravascular extraction of problematic or infected permanent pacemaker leads: 1994–1996. *PACE* 1999; 22:1346–1355.
 58. Love C, Brinker J, Gross, J, et al. Predictors of life threatening and major intravascular extraction complications with an ACCUFIX atrial J lead. (abstract) *PACE* 1998; 21:817.
 59. Belott P. *Endocardial Lead Extraction*. Armonk, NY: Futura Publishing Company, 1998.
 60. Pinski SL, Ching EA, Sgarbossa EB, et al. Pacemaker lead replacement without extraction is not a trivial operation. (abstract) *PACE* 1996; 19:577.