Boston Scientific Advisory regarding the potential for shock coil calcification and reduced shock efficacy for RELIANCE G defibrillation leads with Gore ePTFE coated shock coils manufactured between 2002 and 2021

July 29, 2025

On July 24, 2025, Boston Scientific began informing clinicians of the potential for gradually rising low-voltage shock impedance (LVSI) associated with shock coil calcification in RELIANCE™ defibrillation leads [both single coil (SC) and dual coil (DC)] coated with expanded polytetrafluoroethylene (ePTFE/GORE). This gradual impedance rise could reduce shock efficacy, and instances of failed shock therapy have been reported. Sensing and pacing performance of these leads are not known to be compromised.

Authors

Molly Sachdev, MD, MPH; Christopher F. Liu, MD; Lisa Miller, MS; Anne Marie Smith, MBA; Helmut Pürerfellner, MD; Haran Burri, MD; Jose L. Merino, MD, PhD; Sana M. Al-Khatib, MD, MHS; Mina K. Chung, MD; Amit J. Shanker, MD

Correspondence

Policy@HRSonline.org

Impacted Leads:

The affected device population includes all BSC RELIANCE defibrillation leads with ePTFE coated coil(s) listed within Appendix A below; we note that these leads were available for implantation between 2002 and 2021 and are no longer distributed. BSC estimates that approximately 354,000 leads remain in service, 250,000 of which are in the United States. Current data suggest that approximately 6.4% of ePTFE leads will meet criteria for gradual rise LVSI at 10 years. Of these, approximately 8.9% will be at a LVSI of ≥150 ohms (Figure 6). The rate at which LVSI reaches ≥150 ohms once gradual rise has been identified is shown in Figure 7 of the BSC advisory.

Issue Summary:

The association of calcified defibrillation lead coil(s) with a pattern of gradually rising LVSI measurements has been reported to BSC and described in several publications (references in the BSC notification letter). BSC has now completed a comprehensive investigation of ePTFE (GORE) RELIANCE lead performance and has issued a communication on managing patient safety risks associated with the calcification phenomenon.

The ePTFE leads were initially developed to prevent tissue ingrowth. However, it has now been recognized that the ePTFE membrane allows for cell debris, proteins and minerals to enter, which can lead to dystrophic calcification over time. The accumulation of a calcific encapsulant

over the shock coils may reduce the electrical conductivity and increase both low and high voltage shock impedances.

High, out-of-range LVSI and/or high voltage shock impedance (HVSI) measurements have the potential for reduced shock efficacy. If HVSI exceeds 145Ω, BSC defibrillators, by design, limit shock duration of the first shock phase to 20ms. **If this occurs, the shock's bi-phasic waveform may be truncated and a monophasic shock is delivered, potentially reducing shock efficacy.** A high delivered shock impedance alert (**Code-1005**) is seen on device check after these shock instances. This phenomenon can occur irrespective of lead polarity. However, the fault code (Code-1005) is 4.5x more likely in reversed (RV+) polarity compared to Initial (RV-) polarity. Sensing and pacing performance of these leads are not known to be compromised.

BSC estimated that the potential for life-threatening harm due to arrhythmic death in all patients with these ePTFE leads is at 0.0021% (1 in 47,500 ePTFE leads at 10 years). Ten deaths due to failure to convert a sustained ventricular arrhythmia in the last 10 years have been associated with this phenomenon. Although precise data are not available at this point, patient harm has also been reported in those who underwent lead extraction, possibly related to calcification of the shock coils complicating lead extraction attempts.

However, for leads with LVSI < 150 ohms programmed in initial polarity the first shock and episode success rates remain quite high, and are consistent with historical controls. Please see Figure 1 from the BSC Physician letter.

Diagnosing lead calcification by lead impedance pattern:

It is important to distinguish gradually rising LVSI due to lead calcification, from other LVSI patterns. During the post-implant period, gradual rises in LVSI are common. In addition, other lead performance issues (lead fractures, insulation issues, etc.) usually produce abrupt changes in lead impedance.

BSC criteria for data analysis of a gradual rise in LVSI consistent with lead calcification include a **20Ω rise** from baseline, at least three (3) years post implant, to a **minimum of 90Ω for SC leads, 70Ω for DC leads**, excluding rises in excess of 30Ω per quarter.

In addition, BSC defibrillators include a high, delivered shock impedance alert (Fault Code 1005) if a HVSI exceeds 145Ω which is also suggestive of a shock coil encapsulant.

Notably, these criteria apply primarily to ePTFE RELIANCE defibrillation leads connected to BSC generators. Presently, the criteria for these leads when connected to ICD generators from other manufacturers remain less certain.

Progression of lead calcification over time:

The average time to detect calcification of an ePTFE lead through a pattern of gradual rise LVSI is eight (8) or more years.

Once a lead has reached a threshold of 90ohms for SC leads/ 70 ohms for DC leads, the rate of progression to 150 ohms and, hence, consideration of lead replacement is highly variable. At 7 years post reaching this threshold value, 38% of SC leads, and 18% of dual coil leads reach this threshold for consideration of replacement. That is, the majority of leads will likely not need to be replaced. Please see Figure 7 from the BSC letter.

Boston Scientific Recommendations (Summarized):

There are no changes to the scheduled follow-up interval for patients with ePTFE lead models.

1. Continue routine follow-up of defibrillation systems with ePTFE leads either via in-person or remote monitoring (RM) with consideration that RM can facilitate early detection of this pattern.
2. During routine follow-up of affected leads, determine the most recent approximate 28-day average LVSI that has not been influenced by the delivery of a shock and review HVSI for all shocks from the most recent episode since the last system check using the criteria in the table1 and figure 1 below. (**Note: A temporary reduction in LVSI after delivery of a shock has been observed clinically and can be misleading. LVSI returns to pre-shock levels in approximately 50% of cases within six months.)**
3. If lead replacement is planned, carefully consider the risk/benefit of lead extraction versus abandonment. **Based on implant time and likely coil calcification, these leads may pose an increased risk of extraction-related complications.**
4. There may be circumstances such as routine defibrillator replacement that merit complex decision making. Contact BSC Technical Services for further assistance if necessary.

Table 1 Guidance for mitigating risk by assessing 28-day average LVSI and Code-1005 alerts of defibrillation systems with ePTFE leads

Criteria	Lead Coil(s) † SC	DC	Assessment and Recommended Risk Mitigations for Calcifying Defibrillation Lead Coil(s)
Most recent 28-day average LVSI not affected by delivery of a shock (see Appendix C)	>90Ω	>70Ω	• Program Shock Polarity to Initial (RV-) and all shocks to maximum energy. • For patients who cannot be reprogrammed for clinical reasons to Initial (RV-) polarity, further management should be guided by the data in Figure 1 including consideration for lead replacement if LVSI increases.
	≥150Ω		Lead replacement should be considered. • For Initial (RV-) polarity shocks, there is a 24.9% likelihood of an associated Code-1005 and the defibrillator-determined first shock success rate decreases in absolute and relative terms versus other intervals (Figure 1). • Contact BSC Technical Services for additional technical guidance to support informed lead replacement decision-making.
High-Voltage Shock Impedance (HVSI), Code-1005 alert	X	X	Lead replacement should be considered. • Contact Technical Services as directed by alert message to rule out non-invasive options. • The urgency for lead replacement should be commensurate with the likelihood of the patient requiring shock therapy.

†If the system includes a DC lead programmed RV2CAN, treat the system as a SC system; if DC lead programmed RV2RA treat as DC; if SC lead connected to SQ array treat as DC.

HRS Recommendations:

1. HRS strongly encourages its members worldwide to read the Boston Scientific Safety Notification.
2. Given the highly technically nuanced nature of this advisory, clinicians should maintain a low threshold to **discuss lead concerns with BSC technical services** for additional guidance to support informed lead replacement decision-making.
3. Gradual impedance rises are defined by **28-day averages** based on visual estimates (from the shock impedance graph) and excludes rapid changes that may indicate a need to investigate other causes of lead malfunction, such as lead conductor fracture or connection issues. Gradual impedance rise includes a **20Ω rise** from baseline, at least three (3) years post implant, to an average of >**90Ω for SC leads, >70Ω for DC leads** (excluding average rises in excess of 30Ω per quarter). Boston Scientific Technical Services may assist with estimates. All impedances described below are 28-day averaged LVSI.
4. Patients should be followed by **remote monitoring**, if possible.
5. Enhanced follow-up should be considered in patients who are not participating in remote monitoring, at a minimum of every 6 months, or if gradual impedance rises are observed to LVSI of >90 ohms for SC and >70 ohms for DC leads then every 3-6 months.
6. In patients who meet criteria for gradual LVSI consistent with lead calcification, clinicians should **program Shock Polarity to Initial (RV-) and all shocks to maximum energy**.
7. In patients who cannot be programmed to initial (RV-) shock polarity, but exhibit gradual rise to LVSI of >90 ohms for SC and >70 ohms for DC leads, clinicians should have a discussion with Boston Scientific Technical Services, and consider initiating shared decision making for potential future lead replacement if impedance continues to rise.
8. **Lead replacement** should be strongly considered in all patients (irrespective of the programmed polarity) with LVSI > 150 ohms or for whom HVSI Code-1005 alert has been detected.
9. **There is no recommendation for commanded shocks/ DFT testing to assess HVSI**. LVSI can be lower immediately post shock delivery, but again rise, thus providing a false sense of security. In addition, shock success at DFT testing is not predictive of future success in the setting of ongoing lead calcification.
10. The final decision to replace a lead should be made with the patient via a **shared decision-making** model based on individual patient characteristics, care goals, and preferences and the data provided by BSC.
11. **If lead replacement is planned, clinicians should carefully consider the risk/benefit of lead extraction versus abandonment. Based on implant time and likely coil calcification, these leads may pose an increased risk of extraction-related complications. However, this must be balanced by potential complications of abandoned leads and that extraction risk may be higher with longer lead dwell times. At this time, there are little data on whether these leads are at higher risk for**

extraction than other leads. When appropriate, alternative strategies such as a non-vascular ICD system or addition of another transvenous lead should be considered.

12. As always, patients and providers seeking **financial assistance** for services (including replacement) related to products under warranty, should contact their local representative. Boston Scientific's RELIANCE Gore (ePTFE) includes a **limited lifetime warranty**. Terms and conditions are available online at www.BostonScientific.com/warranty. Boston Scientific's warranty administration team is available to answer questions at warranty@bsci.com.

Reporting Contact:

Physicians may report serious adverse events or product quality problems with the use of this catheter to Boston Scientific by calling 1-800-811-3211 and to the FDA's MedWatch.

FDA's MedWatch
Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report Online: **www.fda.gov/medwatch/report.htm**
- Regular Mail or Fax: **Download form** or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

Appendix A:

The affected device population includes all BSC RELIANCE defibrillation leads with ePTFE coated coil(s) listed within the table below; note that these leads were manufactured between 2002 and 2021 and are no longer distributed. BSC estimates that approximately 354,000 remain in service. All serial numbers associated with the referenced lead models are included in the population. A device lookup tool is available (www.BostonScientific.com/lookup) to identify affected leads. Coil(s) refers to whether a given model has dual-coil (DC) or single-coil (SC) configuration.

Product Name	Model	Coil(s)	Terminal
ENDOTAK RELIANCE	0160	SC	DF-1
ENDOTAK RELIANCE	0161	SC	DF-1
ENDOTAK RELIANCE	0162	SC	DF-1
ENDOTAK RELIANCE	0164	DC	DF-1
ENDOTAK RELIANCE	0165	DC	DF-1
ENDOTAK RELIANCE	0166	DC	DF-1
ENDOTAK RELIANCE	0167	DC	DF-1
ENDOTAK RELIANCE	0170	SC	DF-1
ENDOTAK RELIANCE	0171	SC	DF-1
ENDOTAK RELIANCE	0172	SC	DF-1
ENDOTAK RELIANCE	0173	SC	DF-1
ENDOTAK RELIANCE	0174	DC	DF-1
ENDOTAK RELIANCE	0175	DC	DF-1
ENDOTAK RELIANCE	0176	DC	DF-1
ENDOTAK RELIANCE	0177	DC	DF-1
ENDOTAK RELIANCE	0180	SC	DF-1
ENDOTAK RELIANCE	0181	SC	DF-1
ENDOTAK RELIANCE	0182	SC	DF-1
ENDOTAK RELIANCE	0183	SC	DF-1
ENDOTAK RELIANCE	0184	DC	DF-1
ENDOTAK RELIANCE	0185	DC	DF-1
ENDOTAK RELIANCE	0186	DC	DF-1
ENDOTAK RELIANCE	0187	DC	DF-1
RELIANCE 4-SITE	0282	SC	DF4
RELIANCE 4-SITE	0283	SC	DF4
RELIANCE 4-SITE	0285	DC	DF4
RELIANCE 4-SITE	0286	DC	DF4
RELIANCE 4-SITE	0292	SC	DF4
RELIANCE 4-SITE	0293	SC	DF4
RELIANCE 4-SITE	0295	DC	DF4
RELIANCE 4-SITE	0296	DC	DF4
RELIANCE 4-FRONT	0657	SC	DF4
RELIANCE 4-FRONT	0658	DC	DF4
RELIANCE 4-FRONT	0682	SC	DF4
RELIANCE 4-FRONT	0683	SC	DF4
RELIANCE 4-FRONT	0685	DC	DF4
RELIANCE 4-FRONT	0686	DC	DF4
RELIANCE 4-FRONT	0692	SC	DF4
RELIANCE 4-FRONT	0693	SC	DF4
RELIANCE 4-FRONT	0695	DC	DF4
RELIANCE 4-FRONT	0696	DC	DF4

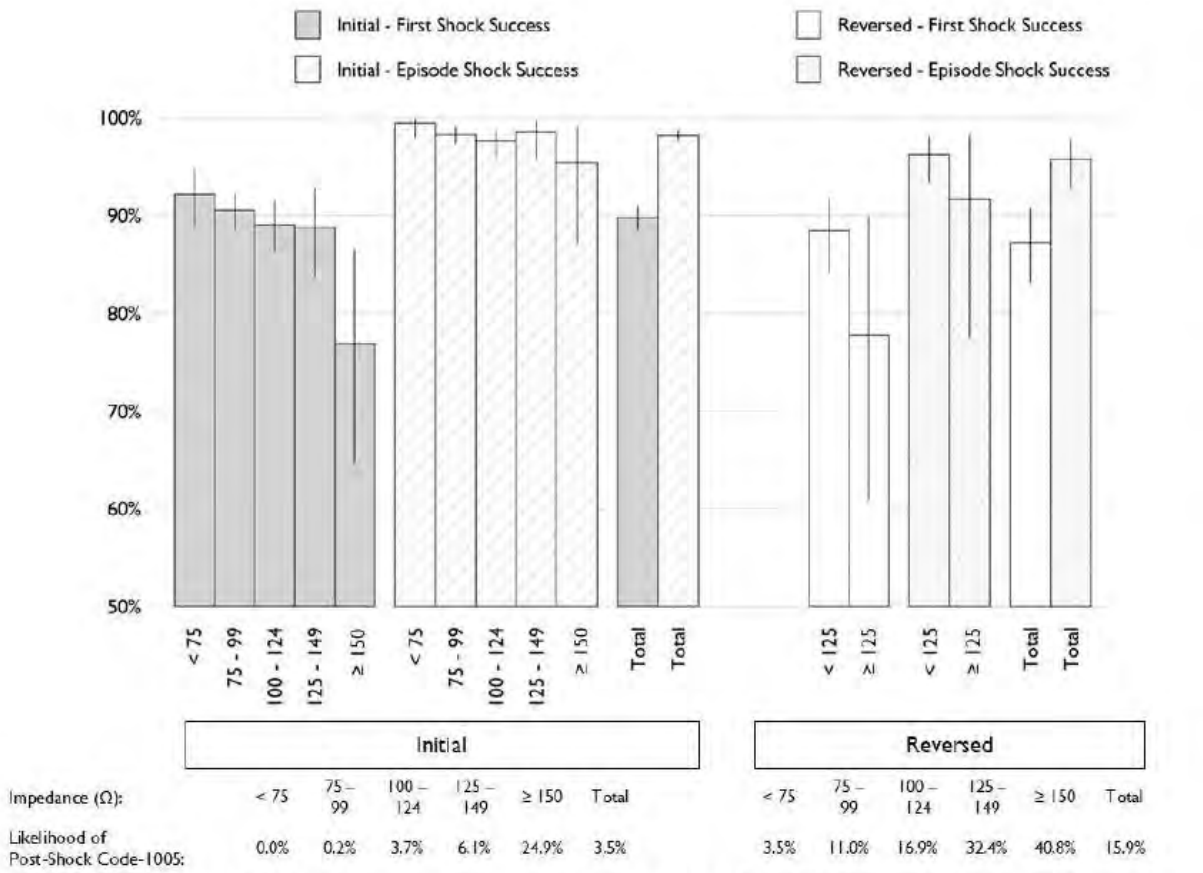
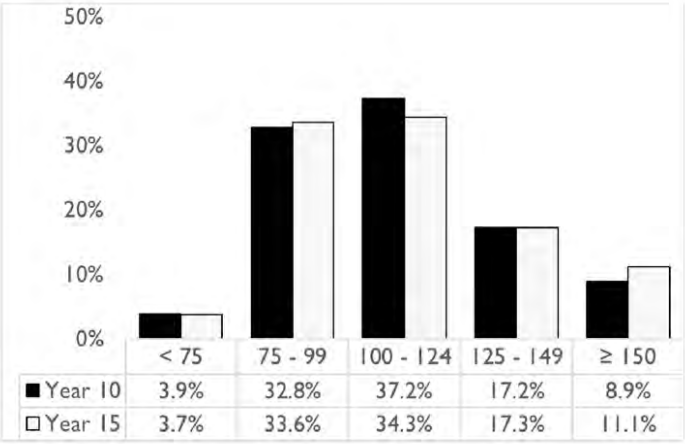


Figure 1 Defibrillator-determined shock success based on programmed polarity and post-shock Code-1005 likelihood based on polarity of individual shocks for defibrillation systems with ePTFE leads relative to preceding 28-day averaged LVSI. X-axis: LVSI Intervals and Y-axis: Defibrillator-Determined Shock Success Rate.

BSC recommendations regarding the lead impedance cut offs are based on the above data, which suggest that lead impedances below 150 ohms when programmed to initial polarity show shock and episode success rates comparable to historical controls. However, at 150 ohms this is no longer the case. In reversed polarity, episode success is reduced at lower LVSI (≥125 ohms).



	< 75	75 - 99	100 - 124	125 - 149	≥ 150
■ Year 10	3.9%	32.8%	37.2%	17.2%	8.9%
□ Year 15	3.7%	33.6%	34.3%	17.3%	11.1%

Figure 6 Highest 28-day average LVSI in de-identified US LATITUDE RM dataset at 10 and 15 years post-implant. X-axis: LVSI impedance intervals for 10 or 15 years; Y-axis: percent of defibrillators with LVSI. Note, not all devices from this dataset remain active.

This graph stratifies the LVSI values of the subgroup of leads that have met criteria for the gradual rise phenomenon in year 10 and again in year 15. This does not involve all ePTFE Gore leads, as the majority of ePTFE Gore leads will not exhibit this gradual rise phenomenon. Therefore, at year 10, 8.9% of the 6.4% of BSC leads that have met the gradual rise criteria will have reached a 28-day average LVSI of ≥ 150 ohms, and at year 15, 11.1% will have reached this threshold value.

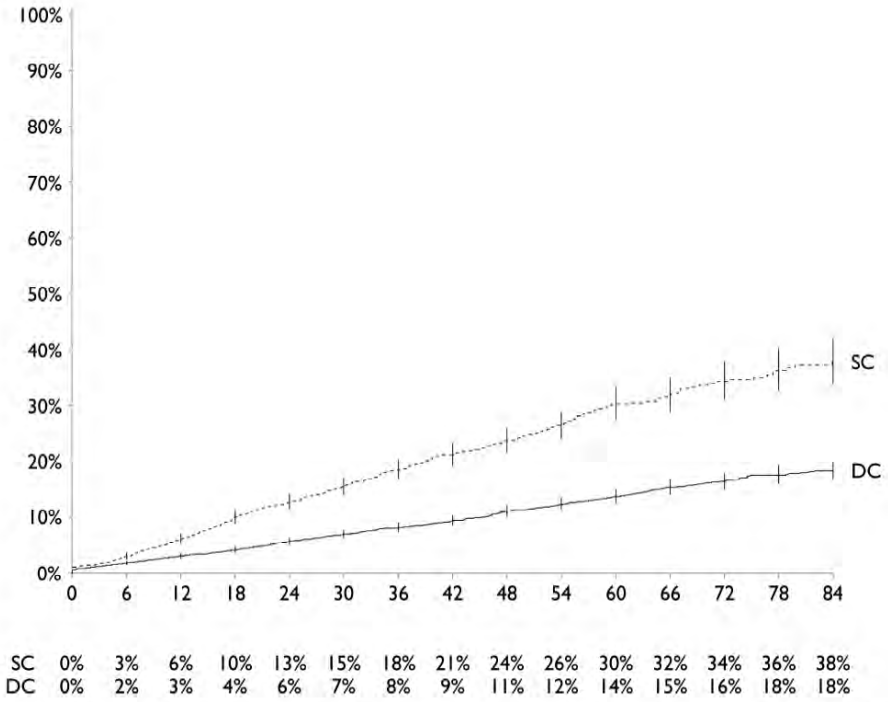


Figure 7 Likelihood of a lead reaching a 28-day average LVSI of at least 150Ω following a gradual rise in LVSI over time. X-axis: Months from the onset of gradual rise in LVSI; Y-axis: Leads that reach 28-day average LVSI of 150Ω (%).

In this figure, Time 0 represents meeting the BSC criteria for gradual rise in LVSI, i.e. a 20Ω rise from baseline, at least three (3) years post implant, to ≥90Ω for SC leads, ≥70Ω for DC leads. The rate of progression to 150 ohms for SC leads is much greater than for DC leads. At 84 months (7 years) following detection of a gradual rise in LVSI, 38% of SC leads and 18% of DC leads reached 150 ohms for which replacement is strongly considered. However, the majority of leads will not have progressed to this point.