Important Medical Device Information

Rhythm Management
4100 Hamline Avenue North
St. Paul, MN 55112-5798
www.bostonscientific.com

July 2025

Dear Healthcare Professional,
Cc: Chairman Medical Board and relevant Head of Department

Subject: Management of gradually rising daily subthreshold, low-voltage shock impedance (LVSI) pattern associated with calcification of expanded polytetrafluoroethylene (ePTFE) coated single coil (SC) and dual coil (DC) RELIANCE™ defibrillation leads manufactured by Boston Scientific Corporation (BSC) from 2002 to 2021 that are no longer available for distribution. See Appendix B for a list of affected lead models.

Description: 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[1,2,3,4,5,6]. This calcification phenomenon can biologically encapsulate and electrically insulate the defibrillation lead coil(s). BSC has completed a comprehensive investigation of ePTFE RELIANCE lead performance to identify the early signs of this phenomenon, characterize its potential effect on shock efficacy, and provide recommendations to mitigate the associated risk. Details of this investigation are described within Appendix A; key findings include:

- While fissuring of calcified ePTFE coating has been observed, calcification of the shock coil(s) does not compromise the physical or electrical integrity of the lead.
- A trend of gradually rising LVSI is correlated with shock coil calcification and is more prevalent with BSC RELIANCE ePTFE defibrillation leads compared to non-ePTFE defibrillation leads from BSC and other manufacturers; leads may be implanted for eight (8) or more years prior to manifestation of this trend.
- The shock coil encapsulant material may exhibit a polarity bias with Reversed (RV+) polarity having an elevated high voltage shock impedance (HVSI) relative to Initial (RV-) polarity[7]. Reversed (RV+) polarity shocks are 4.5 times more likely to initiate a high, delivered shock impedance alert (Code-1005), and defibrillation systems programmed to Reversed (RV+) polarity exhibiting a gradual rising LVSI have a lower defibrillator-determined shock success rate.
- When managing leads with calcified coil(s), delivery of commanded shocks is neither effective at permanently mitigating rising impedance risk nor predictive of future impedance as LVSI may initially decrease but typically returns to pre-shock values in less than six (6) months.

The most common harm is early lead replacement (1 in 238 at 10yrs). The most serious harm is death or need for cardiac resuscitation due to non-conversion of a sustained ventricular arrhythmia from a reduced shock energy due to high impedance (1 in 47,500 at 10yrs).

Recommendations: 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 (Appendix B) either via in-person or remote monitoring (RM) per labeling[8] or medical guidelines[9] with consideration that RM can facilitate early detection of this pattern[10].
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 (see examples in Appendix C) and review HVSI for all shocks from the most recent episode since the last system check using the criteria in Table 1 and data provided in Figure 1.
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	Lead Coil(s)† 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.

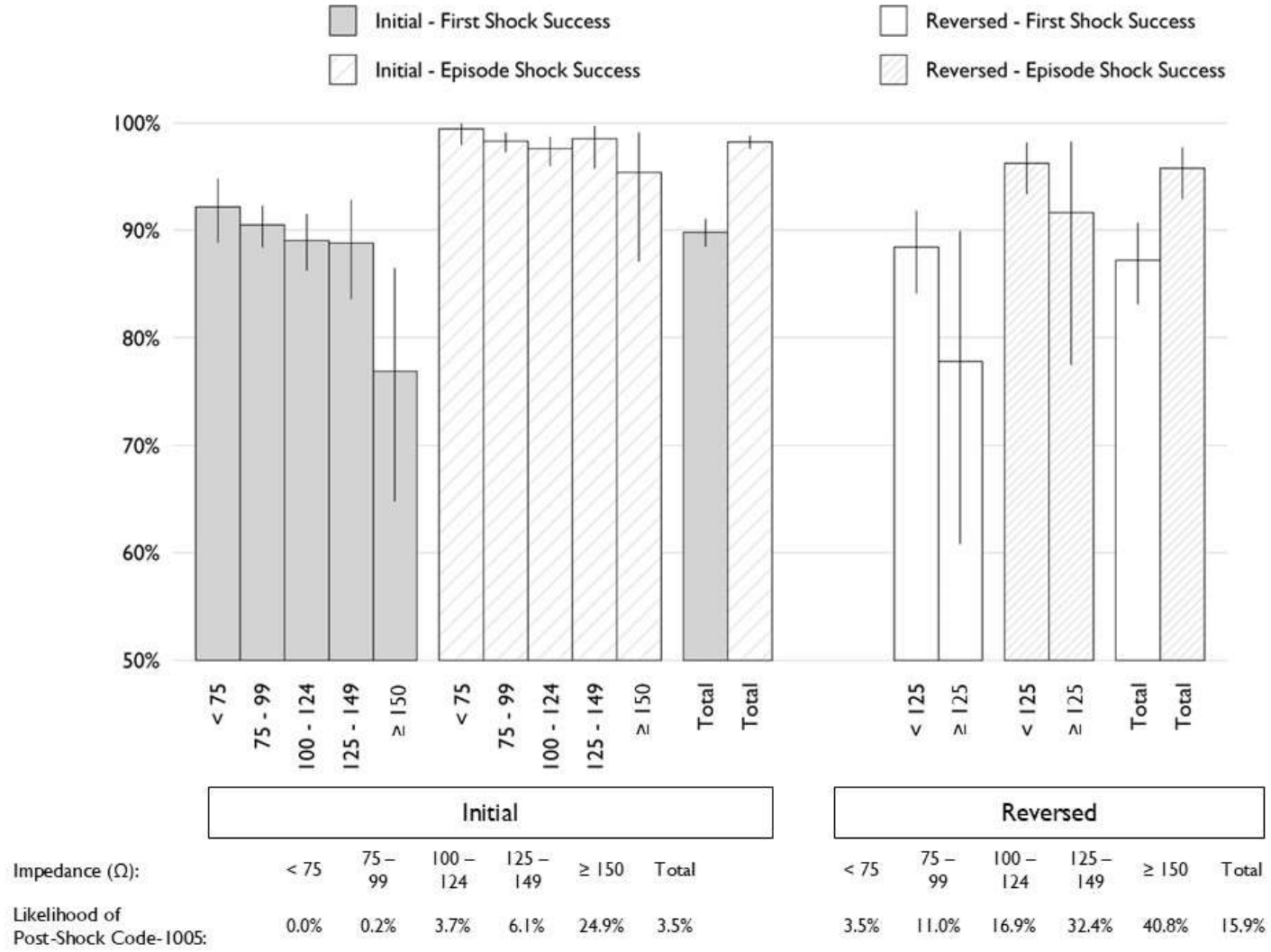


Figure 1 Defibrillator-determined shock success based on programmed polarity and post-shock Code-1005 likelihood based on polarity of individual shocks for defibrillation systems with ePTFE leads relative to preceding 28-day averaged LVSI. X-axis: LVSI Intervals and Y-axis: Defibrillator-Determined Shock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

Please distribute this letter to all healthcare professionals (HCPs) within your organization who need to be informed and include this letter in the patient's medical record. Regulatory Authorities have or are being notified of this communication. A patient letter is available upon request, which can be distributed to the patient.

Rhythm Management
4100 Hamline Avenue North
St. Paul, MN 55112-5798
www.bostonscientific.com

Dear Patient,

We have contacted your heart doctor with some new information about your implanted defibrillator and the connected lead. Your defibrillator system is designed to monitor your heart rhythm and treats both fast and slow rhythms.

Boston Scientific has received reports that some leads are showing signs of a build-up of calcium. Calcium is a mineral that occurs naturally in the human body. Early signs of this can occur on average at eight (8) or more years. Infrequently, these calcium deposits may build up to a level where abnormal lead function can occur.

Your doctor has the details about this topic. Not all patients will show signs of calcium deposits on their lead.

- The build-up of calcium is highly detectable through routine defibrillation system monitoring.
- Programming changes may be available for your defibrillator to maintain normal lead operation.
- In the rare case of abnormal lead function, your doctor may want to implant a new lead.
- Your doctor knows your individual situation best and can discuss the benefits and risks of these options.

Resources available to you:

- This information is available on our website at www.BostonScientific.com/advisory.
- To confirm if your lead is included in this update, visit www.BostonScientific.com/lookup.
  - Enter your preferred language
  - Enter model and serial numbers of your right ventricular lead as shown on your patient-ID card
- It is very important that you attend all scheduled appointments with your heart doctor, both in-person checks and remote checks.

At Boston Scientific, your health and safety are our priority and of utmost importance to us. Please do not hesitate to speak with your heart doctor about this information and how it affects you. Additionally, you may contact Boston Scientific Technical Services.

Alexandra Naughton
Vice President, Quality Assurance

Kenneth Stein, MD, FACC, FHRS
Chief Medical Officer, Boston Scientific

United States Technical Services
1.800.CARDIAC (227.3422), tech.services@bsci.com

International Technical Services
+32 2 416 7222, intltechservice@bsci.com

Asia Pacific Technical Services
+61 2 8063 8299, aptechservice@bsci.com

Appendix A

Background

ePTFE RELIANCE Defibrillation Leads

The first transvenous, endocardial defibrillation lead system was introduced by Cardiac Pacemakers Incorporated (BSC) in 1993 (ENDOTAK™). Subsequent publication of the MADIT studies[11] prompted rapid adoption of implantable cardioverter defibrillator (ICD) therapy in the prevention of sudden cardiac death (SCD).

Anticipating potential challenges for extracting endocardial leads, a version of the RELIANCE defibrillation lead was introduced in 2002 with an ePTFE (GORE[12]) coating on the shock coils. This ePTFE shock coil coating is a bilaminar membrane designed with an external facing cell-exclusive layer bonded to an internal cell-permissive inner layer, which permits biological fluid permeation to support electrical conductivity while preventing cellular and vascular tissue ingrowth.

Innovations in lead extraction tools and techniques precipitated by defibrillator lead recalls in 2007[13] and 2011[14] minimized the potential benefits of ePTFE coated coil(s) in lead extraction. Additionally, because ePTFE supply constraints challenged continued production, BSC discontinued manufacturing ePTFE leads in 2021 and has continued distributing non-ePTFE leads with a medical adhesive (MA) backfilled shock coil design. Active fixation RELIANCE defibrillation leads (ePTFE and non-ePTFE; SC and DC) have a 10-year survival of 97%-99%[15].

The association of calcified defibrillation lead coil(s) with a pattern of gradually rising LVSI measurements has been reported to BSC. Although fissuring of calcified ePTFE coating has been observed, calcification of the shock coil(s) does not compromise the physical or electrical integrity of the lead (e.g., shock coil(s), insulation, conductors, etc.). Within BSC's Product Performance Report[16], US defibrillation leads with complaints associated with LVSI that are not in service after one or more months of implant are counted within the U.S. Chronic Lead Complication table under abnormal defibrillation impedance.

This communication focuses on managing patient safety risks of gradually rising LVSI associated with the calcification phenomenon observed in BSC ePTFE RELIANCE defibrillation lead models described in Appendix B.

Assessing LVSI and HVSI in BSC Defibrillators

The importance of LVSI and HVSI for assessing lead and defibrillation system performance is documented in the system labeling and literature[17,18]. The nominal test pulse used for measuring LVSI daily (every 21 hours) varies by BSC product family. Previous BSC defibrillator families (COGNIS™/TELIGEN™ and INCEPTA™) deliver an 80uA LVSI test pulse, while more contemporary families (RESONATE™ and AUTOGEN™/DYNAGEN™) deliver a 320uA test pulse. As LVSI measurements are inversely related to the test pulse amplitude, it is common to see lower LVSI values when replacing previous BSC defibrillators with smaller test pulses (80uA) as compared to contemporary defibrillators with larger test pulses (320uA). The normal high shock impedance range and alerts for LVSI and HVSI are as follows.

- BSC RELIANCE leads have a normal shock impedance range of 20-125Ω.
- BSC defibrillators include a configurable high LVSI alert nominally set at 125Ω, but programmable to 200Ω in 25Ω increments.
- BSC defibrillators include a high, delivered shock impedance alert (Code 1005) if a HVSI exceeds 145Ω.

A pattern of gradual rising LVSI over several years (Figure 2) is associated with the accumulation of a calcific encapsulant over the shock coil(s) that may reduce the electrical conductivity and increase the LVSI and HVSI impedance.

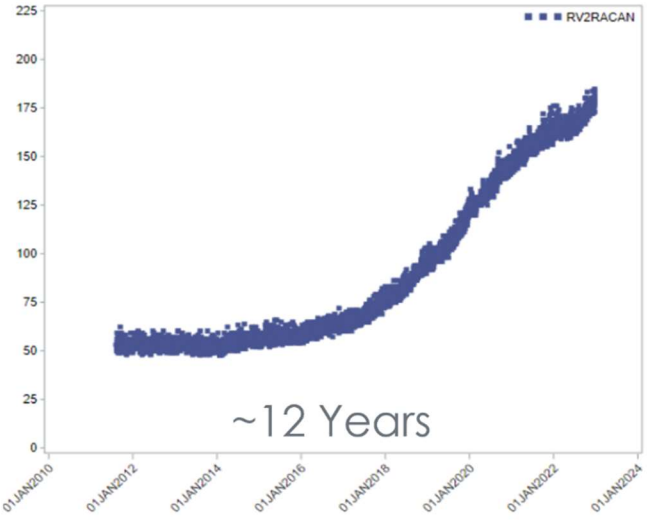


Figure 2 Example of gradual rising LVSI from Jan 2010 to Jan 2024 in a returned ePTFE RELIANCE SC defibrillation lead with calcified encapsulant visibly surrounding the coil

Daily LVSI trends and post-shock HVSI measurements are routinely evaluated during follow-up and alerts for high out-of-range LVSI or HVSI are presented to healthcare professionals (HCPs) via the LATITUDE programmer or LATITUDE™ NXT (LATITUDE) Remote Patient Management System (BSC's RM system). Absent any lead insulation/conductor abnormalities, HVSI measurements are less than LVSI measurements because shocks deliver several orders of magnitude more energy than LVSI test pulses. High, out-of-range LVSI and/or 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 is truncated and a monophasic shock is delivered, potentially reducing shock efficacy.

A comprehensive investigation of ePTFE RELIANCE lead performance was conducted to identify the early signs of this calcification phenomenon, characterize its effect on shock efficacy, and develop recommendations to mitigate the associated

risk. This investigation involved histological, mechanical, and electrical testing, along with analysis of a large de-identified, US dataset from the LATITUDE RM system. BSC is open to collaborating with other manufacturers to assist them in determining the criteria for their defibrillators connected to ePTFE RELIANCE defibrillation leads.

Histology Assessment of ePTFE Lead Samples

Detailed histologic assessment of returned RELIANCE ePTFE defibrillation lead samples with evidence of calcification was performed. The chronic calcification process appears to originate preferentially in the bilaminar ePTFE membrane. The ePTFE membrane allows for cell debris, proteins and minerals to enter, which can initiate dystrophic calcification. These ePTFE nucleation site(s) of calcification appear then to expand and propagate outward into mature collagen layers that often form on chronically implanted blood-contacting devices[19].

The combination of calcified ePTFE and collagen form the visible calcific shell seen around the shocking coils. No evidence of vascularized tissue (i.e., tissue in-growth) was observed. With sufficient encapsulation and subsequent calcification around the shock coil, this encasing shell-like reaction can be expected to function as an electrical insulator. Raman spectroscopy confirmed the calcific shell material contains hydroxyapatite, a natural component of bone. Raman and SEM analysis also occasionally found focal microscopic scale-like patches of calcification on the surface of the silicone lead body.

Examination of dissected transverse sections of calcified ePTFE samples showed evidence of microscopic fissuring of the calcified material and ePTFE coating down to the level of the shock coil. There was evidence of recalcification within these fissures, suggesting that they occurred prior to lead extraction.

Impact on Shock Delivery

Bench Test Conditions

A bench test was designed to replicate two observed field behaviors of suspected calcified defibrillation leads by assessing shock performance of a defibrillation system with various calcified ePTFE lead samples (returned leads) and a non-calcified lead sample (control) via tank testing to simulate *in-situ* conditions. Shocks delivered under these conditions can:

- Elicit electrolysis, which may produce faint bubbles that are the visible outgassing of molecules from solution (e.g., H_20 converted into Hydrogen and Oxygen molecules); and
- Replicate HVSI measurements through a series of shocks and polarities.

These test conditions were not intended and therefore did not replicate *in-situ* conditions such as the inherent biological conditions promoting calcification or the cyclical lead stresses associated with cardiac contractions.

Behavior #1: Successive shocks within an episode may display a noticeable reduction in HVSI and a subsequent temporary reduction in LVSI.

A non-calcified lead (control) sample produced a homogenous distribution of faint bubbles along the shock coil after shock delivery and produced consistent HVSIs throughout a series of shocks. In contrast, calcified lead samples produced heterogenous emissions of faint bubbles at various, discrete locations along the calcified coil after shock delivery. After repeated shocks from the calcified sample, the locations of faint bubbling occurred at different locations and HVSI decreased. The observations of bench testing samples in conjunction with other histopathology samples suggest that shocks may create micro fissures/fractures in the calcified encapsulant that increases electrical conductivity and reduces HVSI and LVSI measurements immediately following shock delivery.

Behavior #2: Code-1005 occurs disproportionately during shocks with Reversed (RV+) polarity. Specifically, episodes that begin with shocks in Initial (RV-) polarity without initiating a Code-1005, but once the last shock is delivered in Reversed (RV+) polarity a Code-1005 occurs.

- Samples with harder hydroxyapatite calcification had uniformly high HVSI for shocks delivered in either polarity.
- Samples with more flexible fibrotic encapsulant demonstrated a lower HVSI for shocks delivered in Initial (RV-) polarity and higher HVSI for Reversed (RV+) polarity, suggesting certain types of encapsulant perform with a directional electrical bias.

Impact on Pacing

Published literature[20,21] has reported an association of calcification with gradually rising pacing impedances. Commercially available BSC defibrillation leads utilize the right ventricular coil as the anode for pacing (integrated bipolar). The larger surface area of the coil relative to the smaller distal electrode (pacing cathode) promotes a lower pacing impedance. For lead models with ePTFE covered shock coils, the ePTFE coating does not extend over the distal area of the right ventricular coil. Based on this lead design and the absence of reported harm, pacing performance is not likely to be compromised by a gradual rise in LVSI.

Data Analysis from LATITUDE RM

Algorithm for Defining Gradually Rising LVSI

An algorithm was developed to quantitatively distinguish gradually rising LVSI from other LVSI patterns. Since no standard definition exists for this pattern, events from post-market surveillance showing a gradual rise in LVSI were carefully analyzed to inform the algorithm's development. At a minimum, the algorithm was iterated so that:

Appendix A

1. Detection of all Code-1005 events in a US historical, de-identified LATITUDE dataset that appeared to represent a gradual rise in LVSI was achieved.
2. Exclusion of all Code-1005 events associated with other etiologies for LVSI trends (e.g., fracture) was achieved.

The salient criteria to detect the onset of a gradual rise in LVSI included a rise over any interval after three (3) years post implant and a 20Ω rise from a post implant baseline to a minimum of 90Ω for SC leads and 70Ω for DC leads, excluding rises in excess of 30Ω per quarter. This approach eliminates normal gradual rises in LVSI during the early post-implant period and non-gradual rise patterns for other lead performance issues.

For the remainder of this document, gradually rising LVSI is defined as a lead >3yr post implant with at least a 20Ω rise to a minimum of 90Ω-SC/70Ω-DC.

Incidence of Gradually Rising LVSI

To identify how often a pattern of gradually rising LVSI occurs, the following de-identified US patient data[22] was obtained from the LATITUDE RM database.

- Approximately 250,700 patients with BSC defibrillators connected with either ePTFE leads or non-ePTFE BSC leads
- Approximately 5,700 patients with BSC defibrillators connected to non-BSC non-ePTFE leads

Table 2 shows that SC leads have a higher average baseline LVSI and shorter average onset for gradual rise of LVSI relative to DC leads. Based on the association of a gradual rise in LVSI to calcification, the average time for occurrence for any lead is eight (8) or more years. The incidence of gradually rising LVSI is described in Figure 3.

Table 2 LVSI descriptive statistics among non-gradually rising, contemporary BSC defibrillation systems

Lead Type	LVSI Average ± Standard Deviation
Single Coil (SC)	72.0 ± 10.2Ω
Dual Coil (DC)	47.5 ± 6.7Ω

Defibrillator-Determined Shock Success and Incidence of Code-1005 in Gradually Rising LVSI Leads

An unabated, continually rising LVSI has the potential for reduced shock efficacy and to precipitate a post-shock Code-1005 alert. While the overall probability of Code-1005 in a gradually rising LVSI ePTFE lead is approximately 1 in 1,111 (0.09%) at 10 years (Figure 4), these data do not inform management decisions for a continually rising LVSI. Therefore, the defibrillator-determined first shock and episode success as well as the likelihood of Code-1005 by preceding LVSI was evaluated using the de-identified US LATITUDE RM database.

Criteria utilizing device episode data were developed to select episodes in the de-identified US LATITUDE RM database which were likely to be appropriate for delivery of shock therapy. Those criteria were adjusted to achieve a 94% positive predictive value for appropriateness in a large expert adjudicated episode dataset. Device-determined shock success (e.g., non-adjudicated) was determined for these appropriate therapy episodes and were classified by the preceding 28-day average LVSI in 25Ω intervals and programmed polarity based on the following.

- First shock success was based on the absence of a subsequent shock following the first maximum energy shock. Sub-maximum energy, first shocks that were not followed by a subsequent shock were considered successful. Multiple maximum energy shocks were considered unsuccessful.
- Episode success was based on whether the episode had fewer than the maximum number of shocks delivered within a therapy zone.

Note, BSC defibrillators allow the output of the first two shocks of each therapy zone to be programmed at sub-maximum energy with all other non-programmable shocks set to maximum energy.

Additionally, an analysis was performed to determine the likelihood of a post-shock Code-1005 in a gradually rising LVSI lead. All shocks were included independent of appropriateness, including commanded shocks and shocks during induced episodes. These shocks were classified in the same manner as shock efficacy with polarity determined for each individually delivered shock rather than the programmed polarity for the shock episode. The results of this analysis are described in Figure 1. Published literature (NORDIC, ALTITUDE, SCD-HeFT, etc.)[23,24,25,26] describes a first shock success range of 82.7%-93% and a shock episode success range of 98.4%-100%. It is important to note that the data in Figure 1 did not include adjudication, so comparison to published literature may not be appropriate. The analysis evaluated pre-gradual device-determined episode success for both Initial (RV-) and Reversed (RV+) polarity at 98%. Device-determined shock success data is limited by sample size and resulting confidence intervals. However, the device-determined shock success trend in combination with the likelihood of Code-1005 indicates that shock success diminishes in devices programmed to Initial (RV-) polarity when a preceding 28-day average LVSI is ≥150Ω. Specifically,

- In devices programmed to Initial (RV-) polarity and experiencing a gradual rise in LVSI, a preceding 28-day averaged LVSI ≥150Ω is associated with a 24.9% likelihood for a post-shock Code-1005 and device-determined shock success decreases in absolute and relative terms compared to lower impedance intervals.
- In devices programmed to Reversed (RV+) polarity and experiencing a gradual rise in LVSI, the Code-1005 and overall device-determined success rate is less favorable when compared to Initial (RV-) polarity with the likelihood of a Code-1005 in particular 4.5 times higher.

The average time to detect calcification of an ePTFE lead through a pattern of gradual rise LVSI is up to eight (8) or more years. Less than a third of ePTFE leads that have exhibited a gradual rise in LVSI will exceed 150Ω five (5) years later, see Figure 7.

Appendix A

Post-Shock Effects on LVSI in Suspected Calcified Defibrillation Leads

A temporary reduction in LVSI after delivery of a shock has been observed clinically. Histological analysis and shock testing of ePTFE leads suggest that shocks may fissure the calcified encapsulant temporarily lowering impedance. However, histopathologic analysis also suggests that the inherent biological healing response can re-calcify those fissures/fractures. Longitudinal data on post-shock averaged LVSI displayed in Figure 5 indicates that LVSI returns to pre-shock levels in approximately 50% of cases within six months.

Clinical Impact

Although physical evidence of calcified shock coil(s) was noted with returned leads exhibiting a gradual risk in LVSI, this could not be confirmed as the exclusive cause for the reported gradual rise in LVSI of leads that were not returned. The ability to establish an exclusive association of calcification and gradually rising LVSI is limited by the low number of explanted and returned leads. Although other resources, such as Computed Tomography (CT), are described as potentially useful for lead extraction planning by identifying areas of adhesion to vessel walls and/or areas of calcification[27], these are not routinely performed and are not likely to be used for detection of coil calcification due to artifact from the lead components. Therefore, for the purpose of this investigation, clinical impact was assessed based on the potential for a gradual rise in LVSI using the de-identified US LATITUDE RM dataset.

Harms

The most common harm is early lead replacement and was determined by analyzing de-identified US LATITUDE RM dataset of BSC defibrillators connected to gradually rising LVSI BSC ePTFE leads and BSC non-ePTFE leads (Table 3).

Table 3 Rate of lead replacement due to gradually rising LVSI

Lead Type	Occurrence rate at 10 years
BSC ePTFE Leads	0.42% (1 in 238)
BSC non-ePTFE Leads	0.01% (1 in 10,000)

The most serious harm is death due to non-conversion of a sustained ventricular arrhythmia from a reduced shock energy due to high impedance. The potential for life-threatening harm due to arrhythmic death in ePTFE leads experiencing a gradually rising LVSI is estimated at 0.0021% (1 in 47,500 ePTFE leads at 10 years).

Other patient harms considered include death from attempted lead extraction of defibrillation leads, the remote possibility of arrhythmia induction as a result of an inappropriate shock, and additional procedures of commanded shocks and conversion testing.

Utilizing Approximate 28-day Average LVSI in Lieu of Assessing Gradually Rising LVSI Patterns

The LATITUDE programmer and RM display one year of LVSI data, so identification of leads exhibiting a gradual rise in shock impedance over several years requires historical data that may not be available to HCPs. Utilizing either the most recent 28-day average or preceding 28-day average prior to a recently delivered shock provides a practical approach for HCPs with an acceptable false positive or false negative rate. Determining the 28-day average from the LVSI trends is intended to be an approximation, see Appendix C for further discussion. Figure 6 provides the distribution of the highest 28-day average LVSI for defibrillation leads in the de-identified US LATITUDE dataset at 10 and 15 years of age. Note, not all leads within this dataset remain in-service.

Discussion of Clinical Recommendations to Mitigate Risk

If an ePTFE lead is experiencing a gradually rising LVSI that exceeds 90Ω for a SC or 70Ω for a DC lead, the risk of compromised shock efficacy can be mitigated by programming all shocks to maximum energy and shock polarity to Initial (RV-) in those patients whose devices are not already programmed in this manner. For ePTFE leads with a gradually rising LVSI, there is a 4.5x higher likelihood of generating a FC 1005 in Reversed (RV+) polarity compared to Initial (RV-) polarity. The recommended programmed settings (i.e., Initial (RV-) polarity and maximum energy shocks correspond with nominal out-of-the box settings for BSC defibrillators. Based on review of ePTFE leads with the defibrillators active on LATITUDE RM in US, Table 4 includes the percentage of devices programmed to Initial (RV-) polarity and maximum energy shocks in all programmed shock therapy zones.

Table 4 Percentage of defibrillators active in US LATITUDE RM database programmed to Initial (RV-) and maximum energy shocks

Parameters	% Programmed
Initial (RV-) Polarity	81.1%
All Shocks Programmed to Maximum	81.4%
Initial (RV-) Polarity and All Shocks Programmed to Maximum	65.3%

Based on data in Figure 1, ePTFE lead replacement should be a consideration for the following situations:

- ePTFE systems programmed to Initial (RV-) polarity and maximum energy shocks with a 28-day average LVSI that continues increasing to ≥150Ω are at risk of compromised shock efficacy and post-shock Code-1005.
- ePTFE systems that have presented a post-shock Code-1005.

If considering lead replacement, contacting BSC Technical Services is advised; guidance is available for ruling out other causes for impedance abnormalities and to assess if other considerations or programming options are applicable. Addition of a new defibrillation lead is a complex decision influenced by

patient-specific factors (e.g., age, co-morbidities, cardiac condition, SCD risk), as well as the data/information presented herein. Lead extraction often accompanies implantation of a new defibrillation lead. These factors must be balanced against the risks of lead extraction, which increase with implant time and potential calcification. Leads affected by this phenomenon are likely to have long dwell times and possibly varying levels of calcification. Due to the heightened risk associated with extracting such leads, replacement without extraction should be considered through shared decision-making. Deaths have been reported as a result of extraction of leads exhibiting a gradual rise in LVSI.[28] For patients without a pacing indication, system replacement with non-transvenous defibrillation technology may be an alternative.

Conventional troubleshooting of high shock impedance prior to the findings of this investigation included commanded shocks to assess the HVSI. However, given the median recovery of LVSI post shock was less than six months (Figure 5), delivery of commanded shocks is neither effective at permanently mitigating rising impedance risk nor predictive of future impedance. The applicability of these data and recommendations to non-ePTFE defibrillation leads is less certain due to the limited data available.

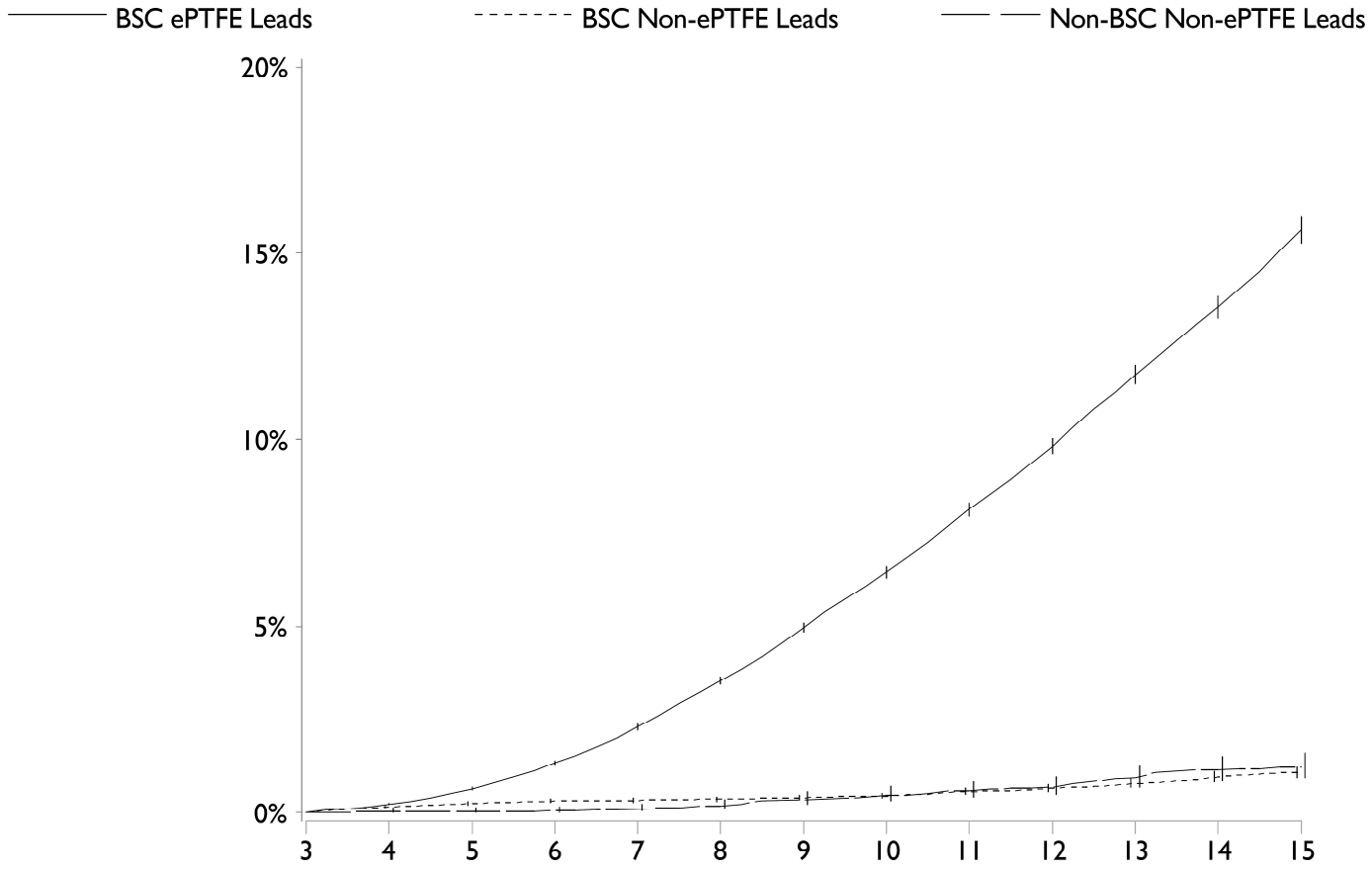
Discussion of Non-uniform Calcification Risk of ePTFE Leads

Unlike other lead-related hazardous conditions (e.g., fracture), which generally present a uniform risk, the risk associated with identification of the onset of gradually increasing LVSI is non-uniform.

- Approximately 1 in 15 (6.4%, Figure 3) 10-year-old ePTFE leads will experience a gradual rise in LVSI.
- Of the ePTFE leads experiencing a gradual rise in LVSI, less than a third of them (30%-SC and 14%-DC, Figure 7) will reach a 28-day average LVSI $\geq$150Ω in 5 years following the detection of a gradual rise and need to be considered for replacement. Based on the observed implant time at which a gradual rise occurs, exceeding a 28-day average LVSI of 150Ω is expected to occur late in the implant duration of these leads.

Thus, once the phenomenon of gradual rise in shock impedance is encountered, neither a continued gradual rise LVSI nor exceeding a 150Ω LVSI is inevitable.

Appendix A



BSC ePTFE Leads	0.0%	0.2%	0.6%	1.3%	2.3%	3.5%	5.0%	6.4%	8.1%	9.8%	11.7%	13.5%	15.6%
BSC Non-ePTFE Leads	0.0%	0.2%	0.2%	0.3%	0.3%	0.4%	0.4%	0.4%	0.6%	0.7%	0.8%	0.9%	1.1%
Non-BSC Non-ePTFE Leads	0.0%	0.0%	0.0%	0.1%	0.1%	0.2%	0.4%	0.5%	0.6%	0.7%	0.9%	1.1%	1.2%

Figure 3 Incidence of gradually rising LVSI in defibrillation leads based on US BSC de-identified LATITUDE and registration data. X-axis: Years Post-Implant; Y-axis: Leads with Gradual Rise (%).

Appendix A

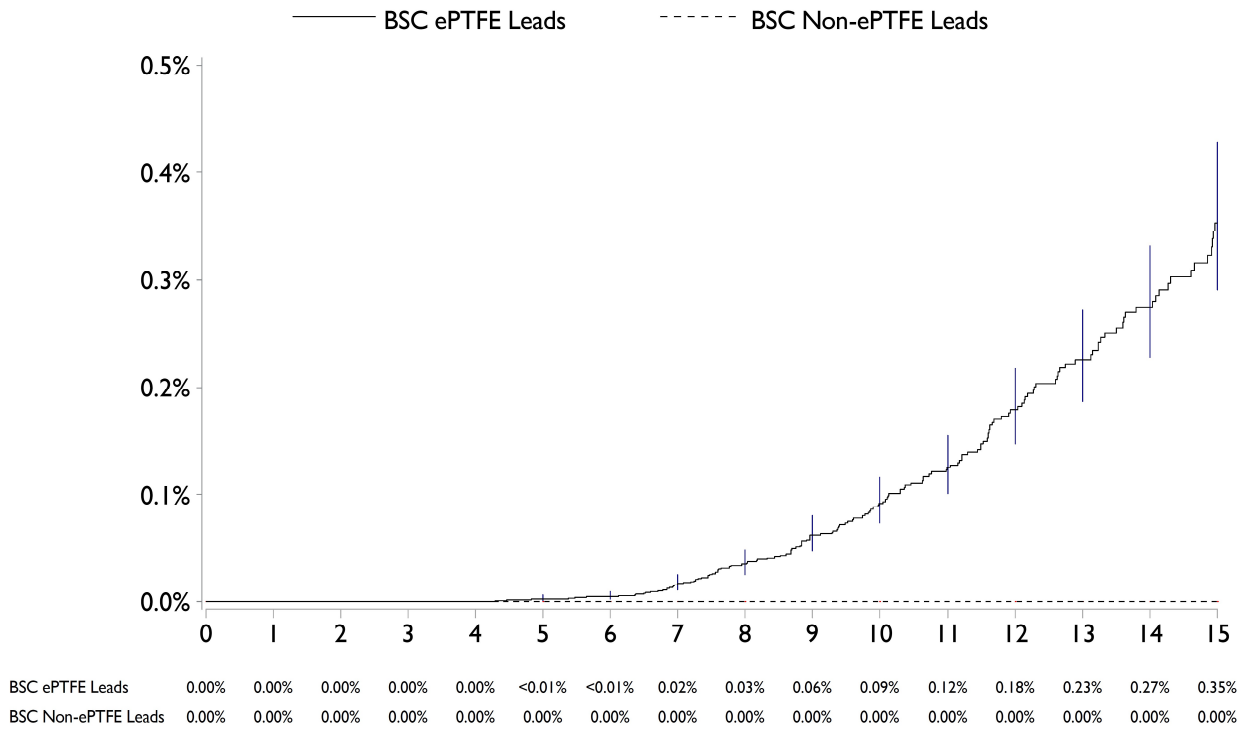


Figure 4 Incidence of a lead having a post-shock Code-1005 after a gradual rise in LVSI. X-axis: Years Post-Implant; Y-axis: Leads with Gradual Rise and Code-1005 (%).

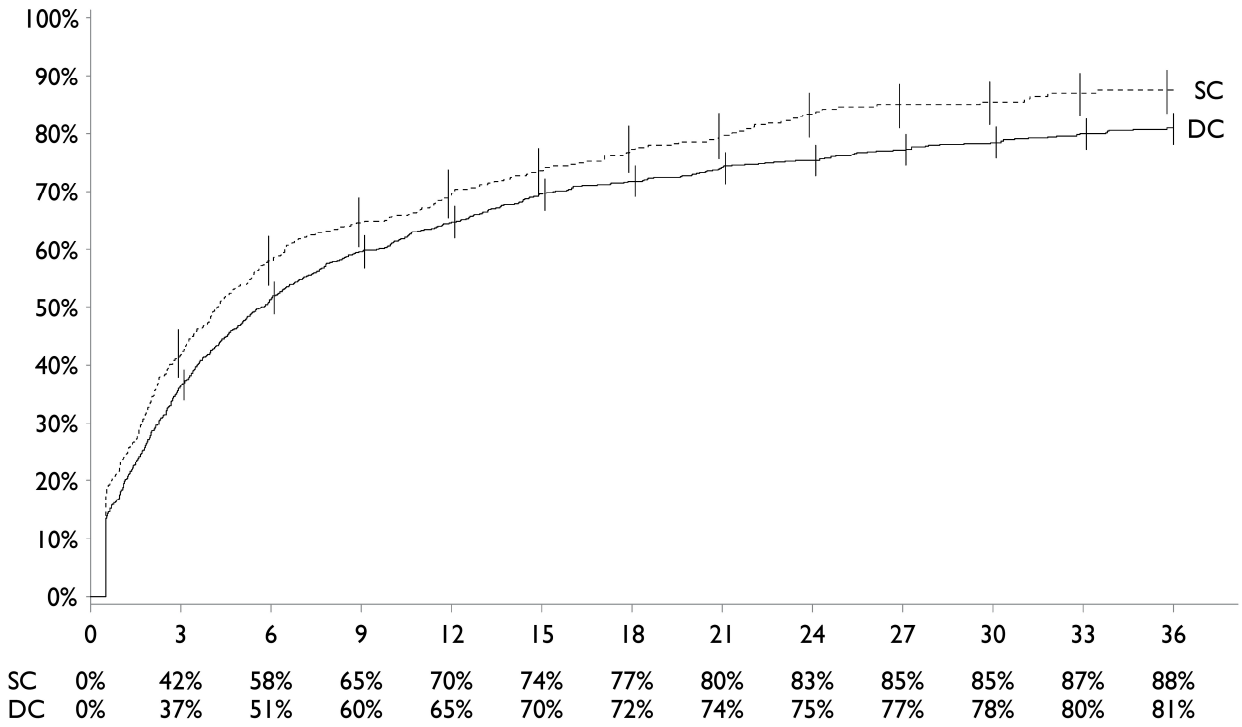
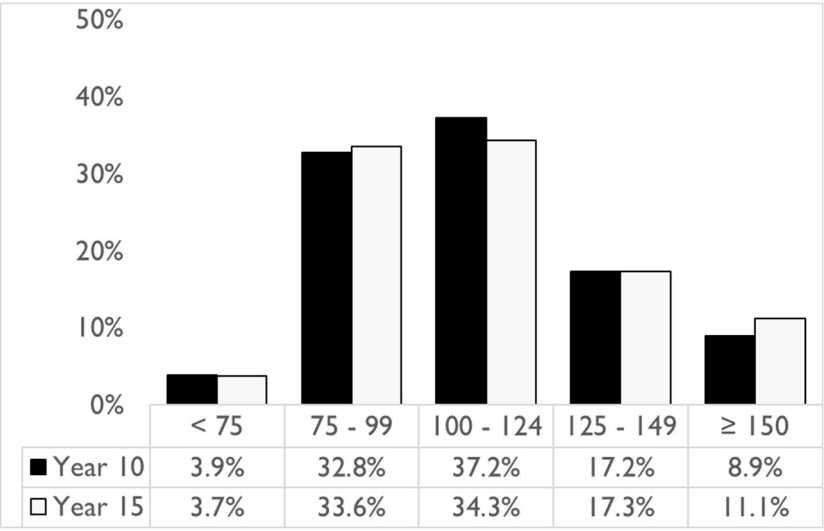


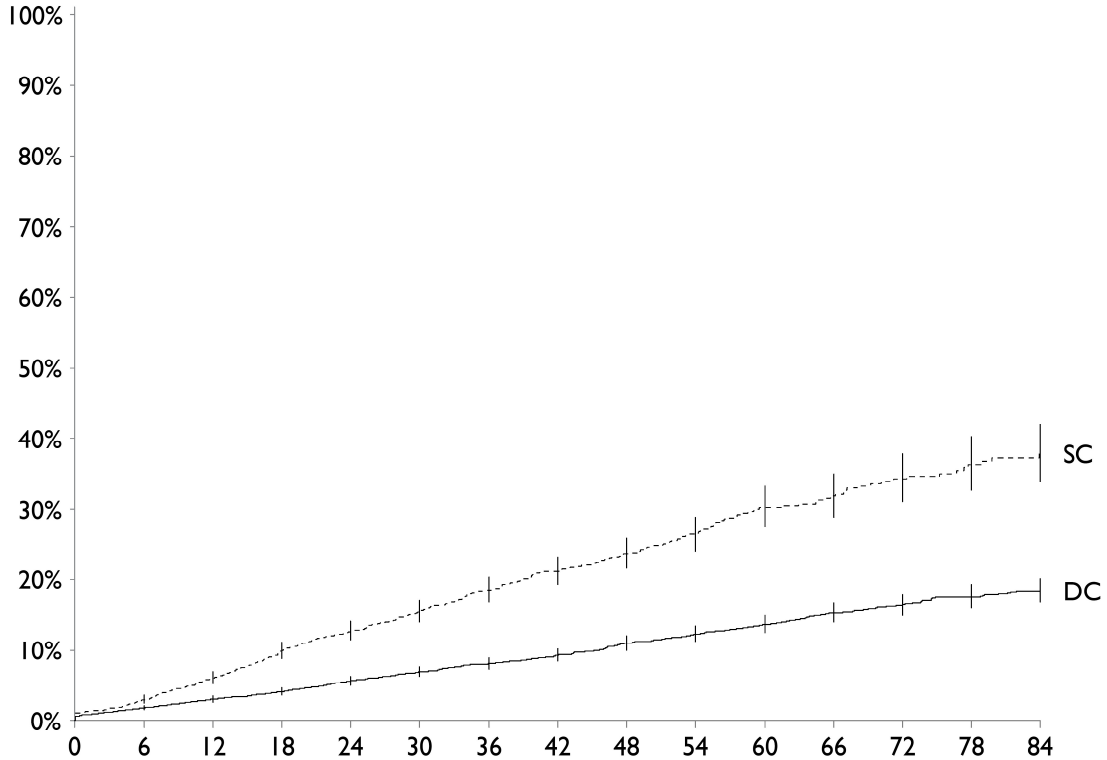
Figure 5 Likelihood of returning to pre-shock LVSI. X-axis: Months Post-Shock; Y-axis: Leads Returned to Pre-Shock LVSI (%).

Appendix A



	< 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.



SC	0%	3%	6%	10%	13%	15%	18%	21%	24%	26%	30%	32%	34%	36%	38%
DC	0%	2%	3%	4%	6%	7%	8%	9%	11%	12%	14%	15%	16%	18%	18%

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 (%).

Management of Potentially Calcified Defibrillation Lead Coil(s) Using 28-Day Averaged LVSI

Appendix B

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

Management of Potentially Calcified Defibrillation Lead Coil(s) Using 28-Day Averaged LVSI

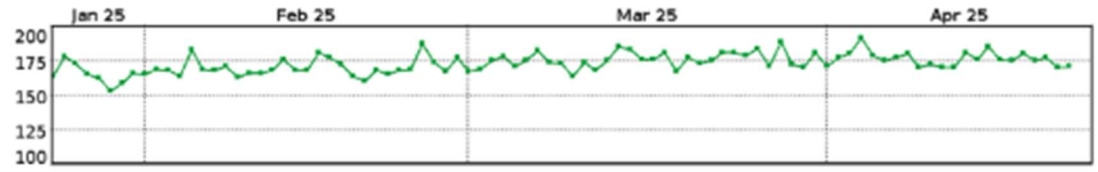
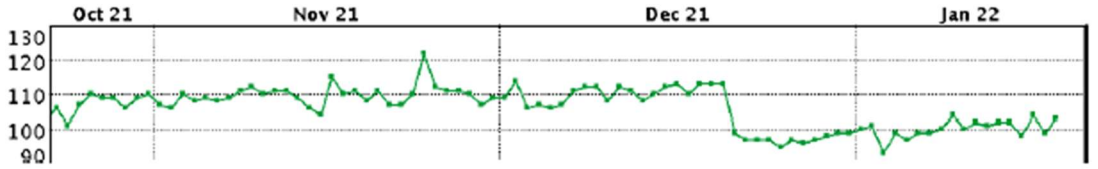
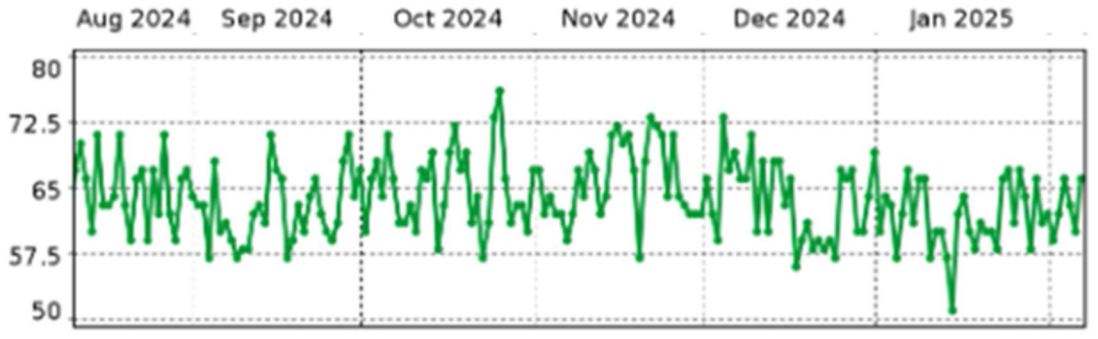
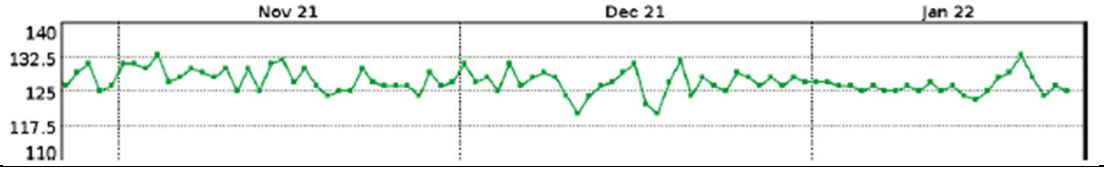
Appendix C

The recommendations state: During routine follow-up, determine the most recent 28-day average LVSI that has not been affected by the delivery of a shock.

The 28-day average LVSI used to inform the recommendations was calculated using US LATITUDE RM data. The shock impedance trends display up to one year of data through the LATITUDE programmer and RM. Review the trend and determine if there are any sudden changes in impedance that are associated with a delivered shock.

1. If there are any sudden changes in impedance, visually estimate the 28-day average LVSI prior to the impedance change.
2. If there is no sudden change in impedance, visually estimate the most recent 28-day average LVSI.

Table 5 Examples of LVSI trends and visually estimated 28-day average impedance

Criteria	Examples
No sudden change in impedance; the most recent 28-day average LVSI is about 180Ω	
Sudden change in impedance mid-Dec; the 28-day average LVSI before this change is about 110Ω	
No sudden change in impedance; the most recent 28-day average LVSI is about 60Ω	
No sudden change in impedance; the most recent 28-day average LVSI is about 127Ω	

Endnotes

[1] 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.

[2] 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. doi: 10.1161/CIRCEP.119.008092. Epub 2020 Jan 27. PMID: 31985260.

[3] 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.

[4] 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.

[5] 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

[6] 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.

[7] Where RV = Right Ventricle and indicates that for a given shock polarity, the RV coil is either positive(+) or negative(-) for the first phase of a biphasic waveform [e.g., Initial (RV-) or Reversed (RV+)].

[8] Boston Scientific ICDs/CRT-D labeling recommends 3-month follow-ups.

[9] The follow-up interval for ICDs/CRT-Ds not monitored remotely is 3-6 months and 1-3 months as the device approaches elective replacement (COR-1/LOE-C) pg e107, section 5.1; Ferrick AM Raj SR, Deneke T, et al. 2023 HRS/EHRA/APHRS/LAHRS expert consensus statement on practical management of the remote device clinic. Heart Rhythm, ISSN: 1547-5271, Vol: 20, Issue: 9, Page: e92-e144. https://doi.org/10.1016/j.hrthm.2023.03.1525.

[10] In patients with CIEDs, RM is recommended as part of the standard of care (COR-1/LOE-A) pg e99. Ferrick AM Raj SR, Deneke T, et al. 2023 HRS/EHRA/APHRS/LAHRS expert consensus statement on practical management of the remote device clinic. Heart Rhythm, ISSN: 1547-5271, Vol: 20, Issue: 9, Page: e92-e144. https://doi.org/10.1016/j.hrthm.2023.03.1525.

[11] Moss AJ. MADIT-I and MADIT-II. J Cardiovasc Electrophysiol. 2003 Sep;14(9 Suppl):S96-8. doi: 10.1046/j.1540-8167.14.s9.5.x. PMID: 12950528.

[12] GORE is a trademark of W.L. Gore and associates

[13] Sprint Fidelis is a trademark of Medtronic, the recall was initiated in Oct 2007, and designated a Class 1 recall by the FDA (recall ID 45403) https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?start_search=1&event_id=45403

[14] Riata is a trademark of Abbott (St. Jude), the recall was initiated in Nov 2011, and designated a Class 1 recall by the FDA (recall ID 60571) https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?start_search=1&event_id=60571

[15] Boston Scientific 2025 First Edition Product Performance Report for all RELIANCE active fixation leads with published 10-year cumulative survival probability data available online at www.BostonScientific.com/ppr.

[16] Boston Scientific's Product Performance Report is available online at www.BostonScientific.com/ppr

[17] Swerdlow CD, et al. doi: 10.1161/CIRCEP.119.008092. Epub 2020 Jan 27. PMID: 31985260.

[18] Swerdlow CD, et al. doi: 10.1016/j.hrthm.2021.09.027. Epub 2021 Sep 28. PMID: 34597770.

[19] Mond HG, Helland JR, Stokes K, Bornzin GA, McVenes R. The electrode-tissue interface: the revolutionary role of steroid-elution. Pacing Clin Electrophysiol. 2014 Sep;37(9):1232-49. doi: 10.1111/pace.12461. Epub 2014 Jul 29. PMID: 25130977.

[20] Swerdlow CD, et al. doi: 10.1161/CIRCEP.119.008092. Epub 2020 Jan 27. PMID: 31985260.

[21] Swerdlow CD, et al. doi: 10.1016/j.hrthm.2021.09.027. Epub 2021 Sep 28. PMID: 34597770.

[22] The US is the largest dataset with registered defibrillators and leads that include implant and out of service dates.

[23] Bänsch D, Bonnemeier H, Brandt J, Bode F, Svendsen JH, Táborský M, Kuster S, Blomström-Lundqvist C, Felk A, Hauser T, Suling A, Wegscheider K; NORDIC ICD Trial Investigators. Intra-operative defibrillation testing and clinical shock efficacy in patients with implantable cardioverter-defibrillators: the NORDIC ICD randomized clinical trial. Eur Heart J. 2015 Oct 1;36(37):2500-7. doi: 10.1093/eurheartj/ehv292. Epub 2015 Jun 25. PMID: 26112885; PMCID: PMC4589656.

[24] Cha YM, Hayes DL, Asirvatham SJ, Powell BD, Cesario DA, Cao M, Gilliam FR 3rd, Jones PW, Jiang S, Saxon LA. Impact of shock energy and ventricular rhythm on the success of first shock therapy: the ALTITUDE first shock study. Heart Rhythm. 2013 May;10(5):702-8. https://doi.org/10.1016/j.hrthm.2013.01.019

[25] Blatt JA, Poole JE, Johnson GW, Callans DJ, Raitt MH, Reddy RK, Marchlinski FE, Yee R, Guarnieri T, Talajic M, Wilber DJ, Anderson J, Chung K, Wong WS, Mark DB, Lee KL, Bardy GH; SCD-HeFT Investigators. No benefit from defibrillation threshold testing in the SCD-HeFT (Sudden Cardiac Death in Heart Failure Trial). J Am Coll Cardiol. 2008 Aug 12;52(7):551-6. doi: 10.1016/j.jacc.2008.04.051. PMID: 18687249.

[26] Swerdlow CD, Russo AM, Degroot PJ. The dilemma of ICD implant testing. Pacing Clin Electrophysiol. 2007 May;30(5):675-700. doi: 10.1111/j.1540-8159.2007.00730.x. PMID: 17461879.

[27] Svennberg E, Jacobs K, McVeigh E, Pretorius V, Birgersdotter-Green U. Computed Tomography-Guided Risk Assessment in Percutaneous Lead Extraction. JACC Clin Electrophysiol. 2019 Dec;5(12):1439-1446. doi: 10.1016/j.jacep.2019.09.007. Epub 2019 Nov 27. PMID: 31857044; PMCID: PMC7718020.

[28] Narayanan et al. https://doi.org/10.1016/j.hrthm.2023.03.1497.

CUSTOMER ACKNOWLEDGEMENT FORM
PRODUCT NAME: Reliance ICD Leads

Instructions: **This form must be completed and returned in all cases even if you do not have any affected product.**
Immediately complete form and Scan/e-mail to: **OR** **Fax to #:**

Account #:	**Customer Name:**

Contact Name:
Address:
City: **State:** **Province:** **Postal Code:**
Country:

PLEASE COMPLETE, SIGN AND RETURN THIS FORM AS A CONFIRMATION THAT YOU RECEIVED THIS NOTICE FROM BOSTON SCIENTIFIC (even if you do not have any of the referenced product on the enclosed product listing in your current inventory).

My signature below acknowledges receipt of the Boston Scientific Notice regarding 97391810-FA RELIANCE ePTFE Gradual Rise in Shock Impedance Advisory Field Action

Section to be filled out by Customer:

1. Please Indicate:
Are you a Distributor?

☐ Yes, and we have notified all customers that have been shipped/sold affected product
☐ No

2. Sign and Date to acknowledge this Field Action Notification (must be completed):

Print Name:_____Signature:_____Date:_____