Subcutaneous Implantable Cardioverter Defibrillator (S-ICD) Electrode Fracture: Follow-up, Troubleshooting and Evaluation

Running Title: S-ICD electrode fracture

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Structured Abstract:

Introduction: The subcutaneous-ICD (S-ICD) and its electrode were developed to avoid long-term complications of transvenous leads in the vasculature.

Methods: We report a case of unexpected, inappropriate S-ICD shocks due to oversensing of high amplitude, non-physiologic, electrical noise artifacts that were not preceded by high impedance alerts or sensing electrogram noise detections.

Results: Following explant, high-magnification, X-ray imaging of the S-ICD electrode demonstrated partial fracture of the distal sensing conductor located near a short radius bend in the electrode at the electrode-header interface.

Conclusions: Clinicians should be aware of a potential for fatigue failure fracture of the S-ICD electrode. Recommendations for systematic S-ICD follow-up and troubleshooting are discussed.

Key Words: Subcutaneous ICD, Electrode Fracture, Oversensing; Inappropriate ICD therapy.

Introduction:

The subcutaneous-ICD (S-ICD) and its totally subcutaneous electrode were designed to avoid implantation of defibrillator leads within the heart and vasculature (1). Clinical development and subsequent approval of the S-ICD (Europe and United States in 2009 and 2012, respectively) provides an alternative to transvenous ICD systems for termination of life-threatening, ventricular arrhythmias. S-ICD preserves the central venous circulation, reduces significant long-term complications of endocardial leads and eliminates risks associated with transvenous lead extraction (2). More than a decade of S-ICD clinical experience suggests that its subcutaneous electrode is highly reliable. However, data on the long-term durability and survival of the S-ICD electrode are limited (3, 4).

We report a case of unexpected S-ICD electrode fracture resulting in inappropriate S-ICD shocks almost two years after implantation that was not preceded by high impedance alerts or sensing electrogram noise detections. In light of this case and the manufacturer's recent S-ICD electrode advisory (5), we discuss potential electrode failure mechanisms, review follow-up of the S-ICD and highlight systematic troubleshooting of suspected S-ICD electrode failures.

Case:

A 68-year-old male presented on September 10, 2020 with complaint of shocks from his S-ICD. He had hypertrophic cardiomyopathy with a left ventricular apical aneurysm. On October 29, 2018, he underwent S-ICD implantation (Boston Scientific generator: Model A219 EMBLEM; subcutaneous electrode 3501) at another center. Beginning in January 2019, he received in-office and remote monitoring at our center. The S-ICD was programmed with tachyarrhythmia and conditional shock zones of 220 and 170 bpm, respectively. Sensing configuration was alternate vector (distal to proximal ring electrodes) and SMART Pass was on.

The atrial fibrillation (AF) monitor detected asymptomatic episodes of paroxysmal AF in November 2019 and February and July 2020. Electrode high impedance alerts were not recorded and audible beep tones were not reported. During device interrogations, presenting sensing electrograms were appropriate and noise was not seen. Subsequent to his implant, untreated episodes were not recorded and his S-ICD had not delivered a shock until September 10, 2020. At 12:02 AM, after getting up from sleep, the patient received an unexpected S-ICD shock. He returned to bed, but received another shock at 4:07 AM. He did not have any preceding symptoms of palpitations, dizziness or syncope with either shock. A remote device alert for S-ICD shocks was received. The transmission demonstrated high amplitude, non-physiologic sensing electrogram noise artifacts, which were oversensed and resulted in inappropriate shock therapy on both episodes. Electrograms recorded from one episode are shown in Figure 1. Measured shock impedances were within normal limits (87 and 79 ohms). The patient was advised to proceed to his local emergency room, and subsequently, was transferred to our center.

Sensing electrogram noise could not be reproduced with maneuvers in primary, secondary or alternate vectors. He denied twiddling, S-ICD migration or exposure to electromagnetic interference (EMI). A chest x-ray was unremarkable for any gross abnormalities of the S-ICD or electrode. However, an acute bend was noted in the S-ICD electrode about 2-3 cm from where it exited the device header (Figure 2A, B). A decision was made to explant the S-ICD. After opening the device pocket, an acute bend in the S-ICD electrode was observed near the device header in a location similar to that on x-ray (Figure 2C). There were no obvious defects noted involving the electrode or device. The electrode was fully inserted into the header. To assist explantation, the electrode was cut approximately 20 cm from the terminal pin. The entire S-ICD system was removed and provided to the manufacturer for return product analysis.

The patient underwent uneventful dual-chamber, transvenous ICD implantation.

During the manufacturer's analysis, the generator was interrogated and benchtop testing revealed normal sensing in all three vectors. The device was exposed to simulated heart load conditions with testing of defibrillation and sensing functions. The device operated appropriately according to its performance specifications with no out-of-range measurements or interruptions in therapy output. A setscrew mark was noted in the correct location on the terminal pin of the S-ICD electrode indicating appropriate electrode insertion in the device header. Resistance testing on the two electrode segments confirmed that each segment was electrically continuous. High-magnification, X-ray imaging identified a fracture in several filars of the distal sensing cable (utilized for secondary and alternate sensing) approximately 25 mm from the terminal pin (Supplemental Figures). In the location of the filar fractures, a bend was noted in the terminal pin area with an indentation and surface abrasion of the terminal boot insulation corresponding to where the electrode exited the device header. Proximal sensing conductor (utilized for primary and alternate sensing) and high voltage cable were confirmed intact without fractures.

Discussion:

This case demonstrates a fracture of the S-ICD electrode that produced oversensing of non-physiologic, electrical noise artifacts and resulted in inappropriate shocks that occurred without prior warning almost two years after implant. The partial electrode fracture involved the distal sensing conductor cable at the electrode-device header interface. An abrupt bend in the electrode in the device pocket was noted and laboratory analysis revealed an indent in the terminal insulation boot and filar fractures near this site.

Our case along with several isolated case reports of S-ICD electrode failure published since 2019 demonstrate that even though the electrode is not implanted in the vasculature, it is

not “indestructible” in the body, but is subject to rare but clinically important failures (6-9). Interestingly, fractures in several cases were severe enough to cause complete or near-complete physical separation of the electrode into two pieces. One fracture was similar to ours occurring near the electrode-header interface in the pocket (7). In the other cases, the fracture was just distal to the proximal sense ring, which is a specific site recently identified in a safety advisory by the manufacturer, as prone to S-ICD electrode (Emblem model 3501) body fracture (5, 8-9).

Among published cases of S-ICD electrode failure, a common failure mode is a location at or near a fixation site (i.e. in the axilla near the electrode-header interface or in the xiphoid near the proximal ring suture position) that is facilitated by an electrode bend close to these fixed sites (6-9). Repeated movements may lead to excessive electrode bending at these fixed sites that can result in cyclic, fatigue stress fractures of conductor cables and appear to be the root-cause failure mechanism. The microscopic conductor filar cracks seen in this case would be expected to grow as continued stress is applied repeatedly to the electrode with eventual physical disruption and potential for fatigue failure without warning prior to an inappropriate shock. The manufacturer specifically advises against bending the electrode near the electrode-header interface and inserting the electrode connector straight into the pulse generator header.

S-ICD electrodes clearly are less prone to fracture and do not have the same complication risks compared with transvenous ICD leads (2, 10). Notably, the flexibility of the S-ICD electrode permits it to easily bend or curve during implantation. This design feature may contribute to stress on the metal conductor components. The Fidelis transvenous ICD lead (Medtronic) suffered a high conductor failure rate due to fractures (~20% after 10 years) related to its extreme flexibility (10). Fidelis fractures most commonly occur just proximal to the defibrillator ring electrode where adhesive was applied outside the lead to prevent fluid ingress.

This lead design created a hinge point prone to flexion fatigue failure during cardiac motion. During S-ICD electrode manufacturing, adhesive likewise is applied just distal to the proximal sense ring in close proximity again to the location of reported electrode fractures. In Fidelis, lead fractures also are near the anchoring sleeve close to the electrode-header interface likely related to electrode stress with shoulder motion (10). This may be a similar mechanism for conductor failure in our case close to an abrupt bend in the electrode near the header, a location prone to hinge point overstress. Thus, a short radius, S-ICD electrode curve close to a fixation site may result in mechanical stress on the electrode body creating a potential for fatigue failure. Whether the low S-ICD electrode failure rate will increase in frequency with longer follow-up and recognition (as was seen with Fidelis) remains to be seen (5).

Now that electrode failures including fractures have been identified as a potential S-ICD clinical issue, an important question is how these devices should be managed to appropriately identify and troubleshoot subcutaneous electrode failures? (Figure 3) Delivery of inappropriate shocks is a possible adverse consequence of these failures and importantly needs to be promptly recognized by clinicians during remote transmissions or in-office interrogations based on observation of non-physiologic mechanical artifacts on sensing electrograms. Also, importantly an unrecognized fracture of the high-voltage conductors has the potential to prevent delivery of ICD therapy, regardless of the programmed sensing configuration. In a cross-sectional view of the subcutaneous electrode, the shock coil is straddled by the two sensing conductors. This suggests that oversensing events are more likely to occur prior to disruption of the high voltage defibrillation coil, but electrode reliability after partial fracture as seen in our case remains uncertain. Any oversensing events with non-physiological artifacts causing an inappropriate shock should prompt further investigation with X-ray imaging and consideration of S-ICD

electrode replacement. Short-term reprogramming of a different sensing vector may be considered with consistent remote monitoring. In the absence of inappropriate shocks, the two primary means for detection of S-ICD electrode failure is via a high impedance alert condition or non-physiologic mechanical artifacts on sensing electrograms. Absence of bradycardia pacing alters the evaluation of suspected electrode failures in the S-ICD from the recommended troubleshooting approach in transvenous ICDs (11).

The S-ICD performs weekly electrode integrity tests using sub-threshold pulses to measure high voltage impedance. Impedance values >400 ohms result in activation of alert tones that are potentially audible. However, relying on these impedance checks may not be a reliable screening tool alone to rule out electrode fractures and there are important caveats to be aware of. When the primary sensing configuration (proximal sense ring to S-ICD can) is programmed, a distal sensing electrode fracture beyond the proximal ring (as described in the manufacturer's advisory) will not be identified via weekly impedance checks (unless the high voltage cable is fractured) because the sensing vector does not include the distal sense tip. Furthermore, as seen in our case, weekly impedance checks are an insensitive indicator to rule out intermittent or partial conductor fractures (12). Finally, a single out of range impedance may or may not indicate a clinical problem and alone lacks sufficient specificity to advise replacement (12).

Electrode impedance also is measured with shocks and a high shock impedance >200 ohms activates an alert. If the primary sensing vector is programmed, an unrecognized distal conductor fracture could result in inability to effectively deliver shocks and a subsequent high impedance shock alert. Therefore, a high shock impedance alert requires urgent evaluation for electrode fracture, but also could be due to a loose setscrew, electrode under-insertion within the header or fibrous encapsulation of the S-ICD electrode (11-12).

In contrast to impedance, which is measured intermittently, device sensing is performed continuously. Therefore, oversensing recorded on subcutaneous electrograms with normal impedances, as in our case, will likely be the most common indicator of S-ICD conductor failure similar to transvenous ICD lead failures (12). Careful analysis of electrograms during follow-up in all three sensing configurations is critical to ensure system integrity. Because there may be no early warning of a distal conductor fracture, reprogramming to alternate or secondary sensing vectors may be considered in S-ICDs programmed to the primary vector, if there is adequate sensing performance in other configurations. Analysis of electrograms should be performed on stored episodes and real-time electrograms during provocative maneuvers looking for non-physiologic artifacts, flat-lined electrograms or other subtle changes (e.g. identical electrograms on primary and secondary vectors). Scrutiny of untreated episodes as well as episodes labelled as AF may be instructive to screen for electrode failure. Electrogram characteristics of electrode failure oversensing however, must be distinguished from competing causes of oversensing in S-ICD including myopotentials, T-waves, AF-waves, EMI, air-entrapment, electrode dislodgement or migration. Header connection problems due to a loose setscrew may be indistinguishable from electrode fracture on the basis of electrogram characteristics alone (11).

Conclusions

In summary, this case of partial electrode fracture of the S-ICD distal conductor near the electrode-header interface along with the S-ICD advisory of fractures distal to the proximal sense ring demonstrate the potential for S-ICD electrode failures during long-term follow-up. Recommendations for S-ICD evaluation and troubleshooting emphasize analysis and scrutiny of sensed electrograms for non-physiologic signals and impedance alerts to identify compromised electrode integrity that should prompt consideration of S-ICD electrode replacement.

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Figure –1. S-ICD interrogation strip demonstrating oversensed high amplitude, non-physiologic noise artifact leading to inappropriate ICD therapy (S=Sense; N=Noise; T=Tachy Detection; •=Discard; C=Charge Start; E=Charge End).

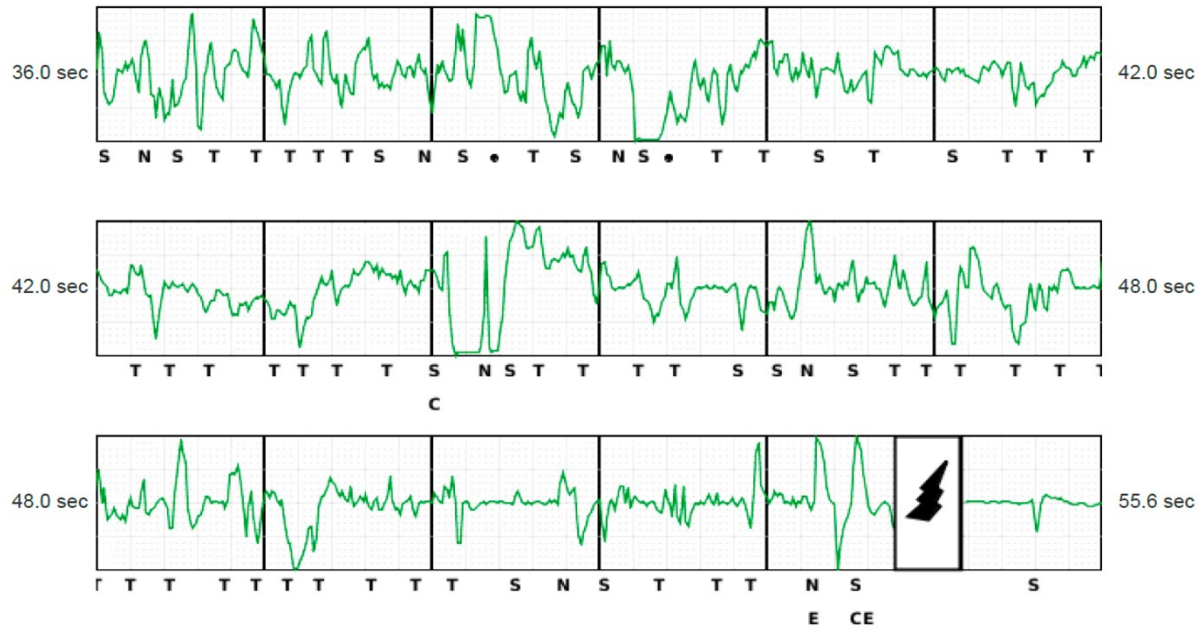
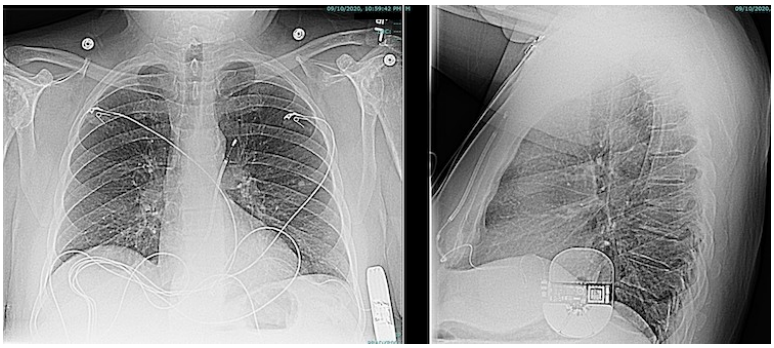
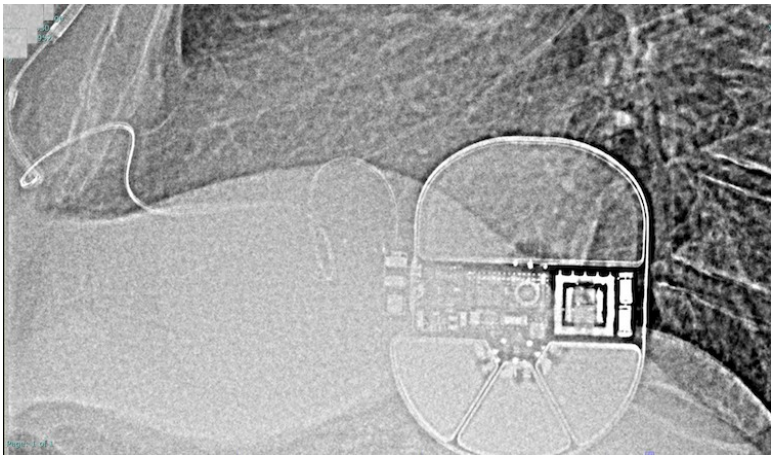


Figure 2. A. Chest X-Ray showing S-ICD. B. High-magnification, X-Ray showing electrode-header interface with a bend in the S-ICD electrode. C. S-ICD generator and electrode after removal from the pocket.





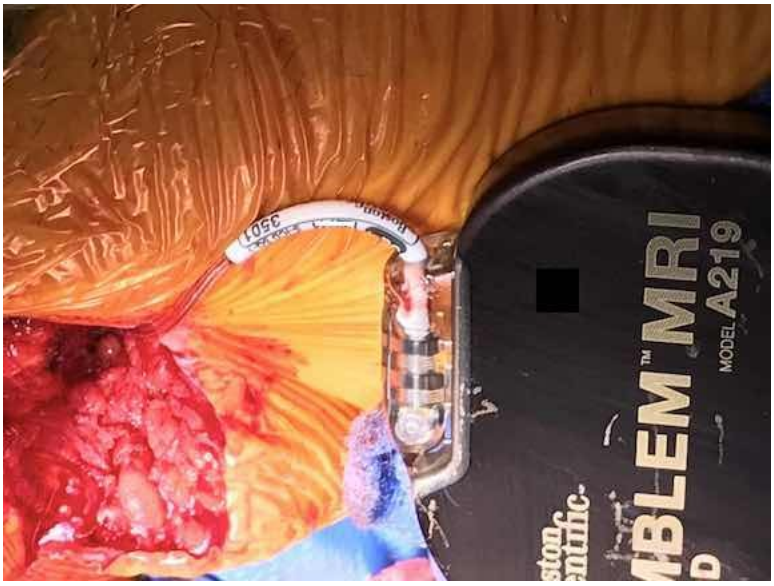
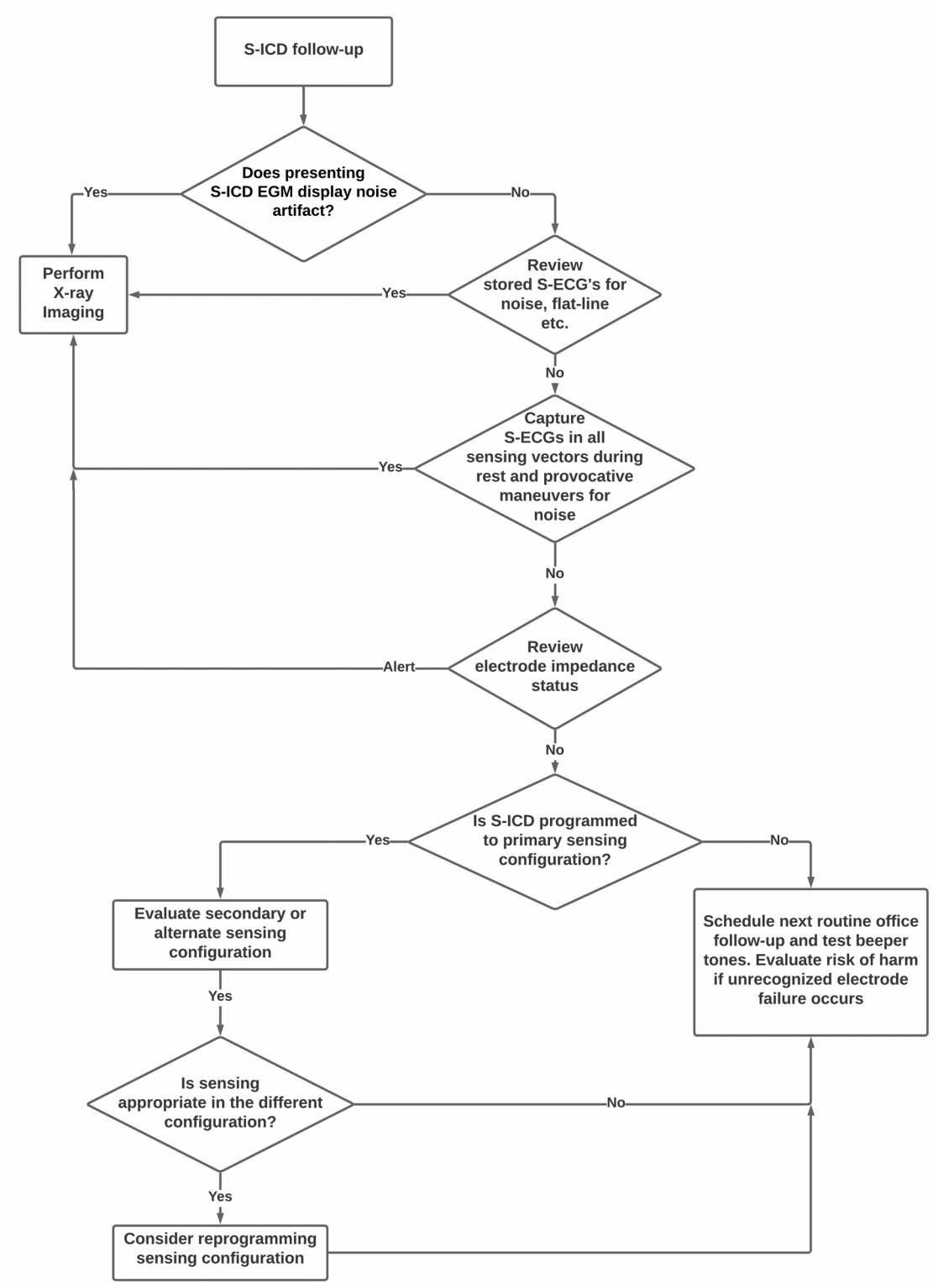


Figure 3. Approach to S-ICD Follow-up and Troubleshooting.


S-ICD follow-up
Does presenting S-ICD EGM display noise artifact?
Yes
No
Perform X-ray Imaging
Review stored S-ECG's for noise, flat-line etc.
Yes
No
Capture S-ECGs in all sensing vectors during rest and provocative maneuvers for noise
Yes
No
Review electrode impedance status
Alert
No
Is S-ICD programmed to primary sensing configuration?
Yes
No
Evaluate secondary or alternate sensing configuration
Schedule next routine office follow-up and test beeper tones. Evaluate risk of harm if unrecognized electrode failure occurs
Yes
Is sensing appropriate in the different configuration?
No
Yes
Consider reprogramming sensing configuration

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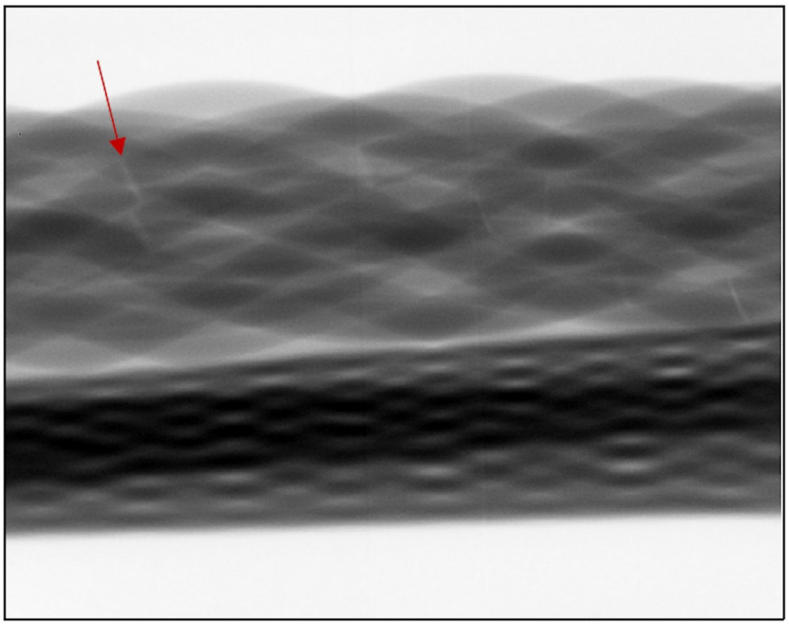
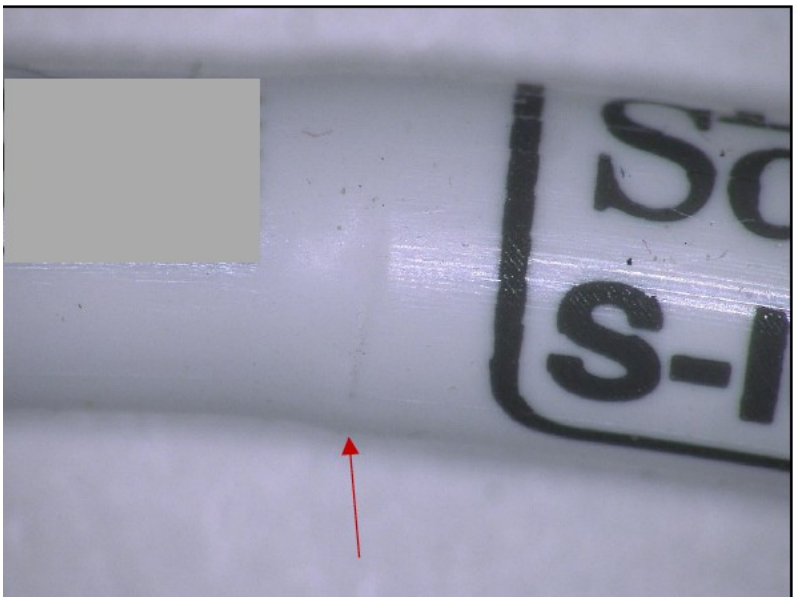
Supplemental Figures.

A. Magnified X-ray of the S-ICD electrode revealing multiple fractured filars of the distal sensing cable. The red arrow signifies the location of one of the fractured filars.



B. Image of the S-ICD electrode) at its terminal boot. The red arrow signifies the location of the indent/crease and surface abrasion of the terminal boot insulation.



C. Image of the S-ICD electrode (placed over a model A219 S-ICD device in alignment with the

expected final position after its insertion in the header). The red arrow signifies the location approximately 25 mm from the terminal pin where the electrode exits the device header.