Oversensing Associated with Seal Plug Integrity

SUMMARY

Seal plugs that cover the setscrews in the header of an implantable pulse generator, permit torque wrench insertion yet prevent body fluids from entering the header cavity. On occasion, wrench insertion during the implant procedure can temporarily stretch or even damage a seal plug, leading to the creation of an accessory sensing pathway and potentially to inappropriate inhibition of therapy or inappropriate shocks. This article focuses on how to identify sensing of non-cardiac noise associated with integrity of seal plugs.

Products Referenced

All Boston Scientific ICDs and CRT-Ds

Products referenced herein may not be approved in all geographies. For comprehensive information on device operation and indications for use, reference the appropriate product labeling.

CRT-D: Cardiac Resynchronization Therapy Defibrillator
ICD: Implantable Cardioverter Defibrillator

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Seal Plugs

The silicone rubber seal plugs covering setscrews in the header of every Boston Scientific pacemaker and defibrillator are designed to permit torque wrench insertion and setscrew operation, and prevent body fluids from entering the device header. In most cases, minor body fluid infiltration through the seal plug or lead barrel does not disrupt the system's sensing or therapy delivery functions[1]. However, temporary or permanent compromise of the seal can lead to noisy electrograms and/or oversensing. Depending on the circumstance, symptoms may self-correct or the device may require reprogramming or more aggressive, possibly invasive intervention[2].

Seal plugs are pre-slit to facilitate insertion of a torque wrench. At wrench insertion, care should be exercised to locate the pre-slit depression of the seal plug and carefully guide the wrench through the slit to the setscrew cavity beneath. This will open up the seal plug, relieving any potential pressure build-up within the lead port by providing a pathway to release trapped fluid or air during lead insertion. Failure to properly insert the supplied torque wrench in the pre-slit depression of the seal plug may result in damage to the seal plug and compromise its sealing properties, creating the potential for oversensing issues. Upon visual inspection, if a seal plug appears to be damaged at implant or revision, the device should not be implanted.

Acute/temporary oversensing caused by entrapped air and seal plugs that have not completely resealed following wrench insertion

The silicone rubber used for seal plugs has a "shape memory". Inserting a wrench to operate a setscrew stretches the rubber, and seal plugs may require a short time to reseal following removal of the wrench. Until the seal fully closes, infiltration of body fluid from the implant pocket into the device header may create a temporary accessory sensing pathway. If air is trapped in the header during the lead insertion process, it may escape through the seal plug, momentarily displacing body fluid and disrupting the conductive accessory pathway. This momentary disruption causes a change in impedance of the accessory pathway, which generates an artificial (non-physiologic) noise signal capable of inhibiting pacing pulses. Oversensing of this type is sporadic and unlikely to cause either extended inhibition of brady pacing or inappropriate shocks in a defibrillator. This form of oversensing is rarely seen beyond implant and disappears once the seal plug returns to its normal closed position, the entrapped air has dissipated, and pressure equilibrium within the header has been achieved[1, 3, 4, 5].

Figure 1 provides an example of oversensing caused by air escaping through a seal plug following wrench insertion. Depending on which seal plug is compromised, this type of non-physiologic noise may appear on the atrial or ventricular EGM, with no corresponding event appearing on the shock EGM or on the surface electrocardiogram (ECG). The noise signals appear as single events of short duration, similar to intrinsic heart activity. One deflection is created for each escaping air bubble. ***NOTE:*** *These noise signals are different in appearance than other physiologic signals (such as pectoral or diaphragmatic signals), which typically demonstrate more erratic amplitude and frequency characteristics (Figure 2).*

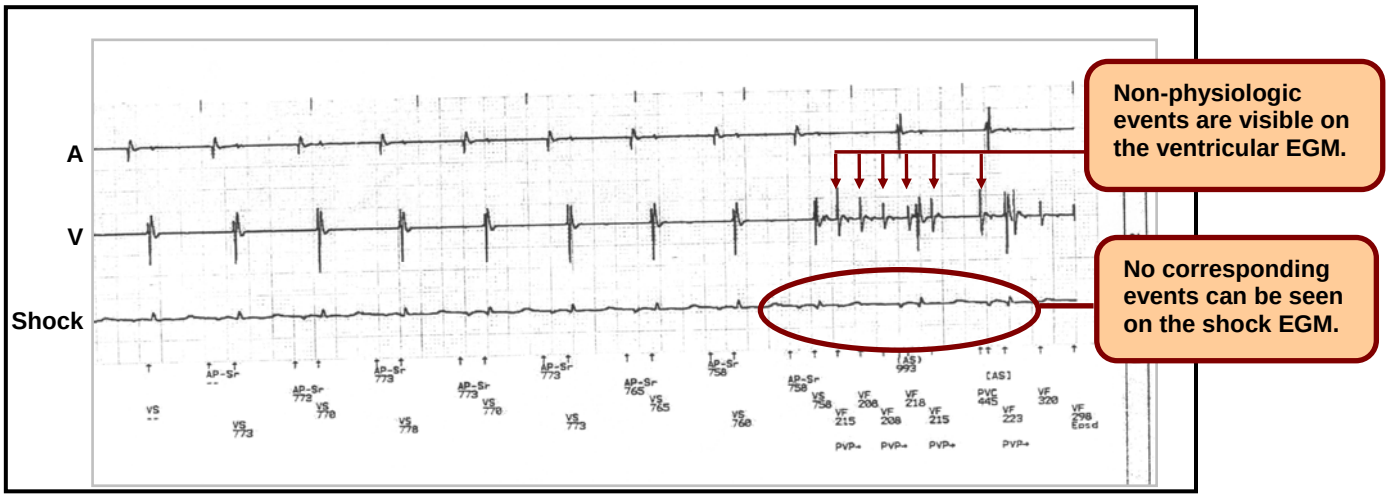

Figure 1. EGM indicating non-physiologic oversensing due to air bubbles escaping header through seal plugs.

If sporadic oversensing of this type is observed, it will typically resolve spontaneously without intervention within 24 hours after initial presentation.

Chronic oversensing caused by seal plug damage

Figure 2 provides an example of oversensing of pectoral myopotentials when a seal plug is damaged (torn) or is missing altogether. The accessory sensing pathway caused by significant seal plug damage may cause chronic oversensing of skeletal/pectoral muscle signals. This type of oversensing is typically visible on stored EGMs viewed at implant or during routine patient follow-up. Signals associated with this type of seal plug damage are typically irregular in frequency and amplitude and occur for more cardiac cycles[6, 7].

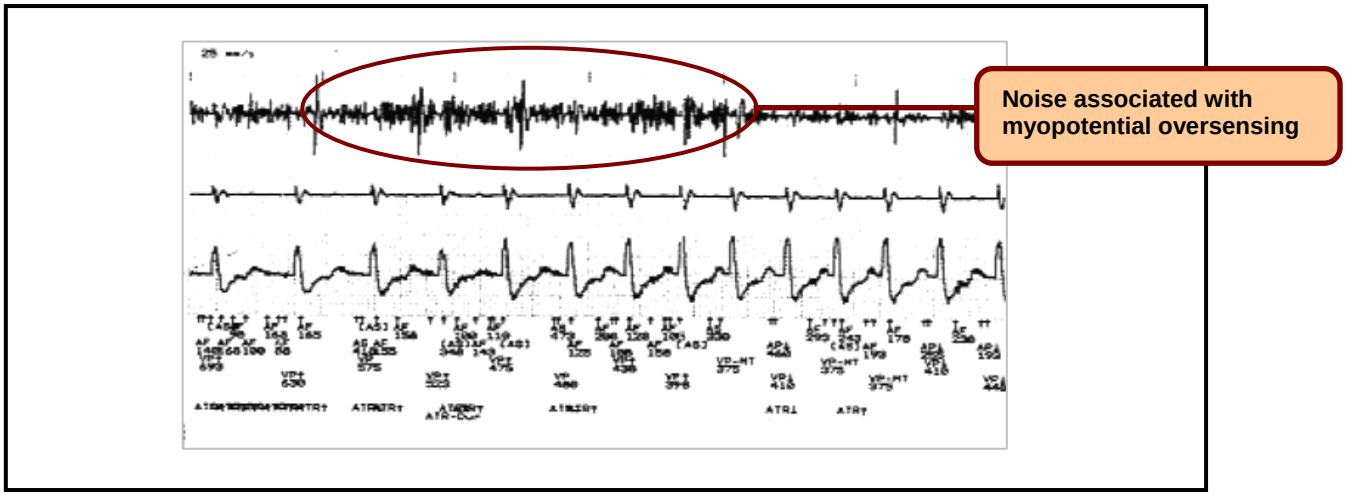

Figure 2. Example of oversensing of pectoral muscle activity due to significant atrial seal plug damage.

Oversensing of pectoral muscle activity facilitated by seal plug damage may cause extended pauses in pacing, asynchronous pacing (noise mode) or unnecessary shocks. Standard troubleshooting procedures should be followed to identify and correct oversensing of this type, keeping in mind that other causes, such as lead insulation abrasion, loose setscrews, sub-optimal lead position and lead conductor fracture can yield similar clinical observations and are other plausible root causes to be considered.

[1]D.D. McManus et. al. Inappropriate shock from non-physiologic noise during implantation of a Boston Scientific COGNIS N119 biventricular implantable cardioverter-defibrillator (CRT-D). *Heart Rhythm*. 2009; Vol. 6, No 7; pages 1066-1068.

[2]B. D. Gunderson et. al. Causes of ventricular oversensing in implantable cardioverter-defibrillators: Implications for diagnosis of lead fracture,. *Heart Rhythm.* 2010; Vol. 7, No. 5: page 632.

[3]J.W. Cheung et. al. Shock-induced ventricular oversensing due to seal plug damage: A potential mechanism of inappropriate device therapies in implantable cardioverter-defibrillators. *Heart Rhythm*. 2005; Vol. 2, No.12; pages 1371-1375.

[4]K.A. Ellenbogen et. al. Oversensing in a newly implanted dual-chamber implantable cardioverter-defibrillator: What is the mechanism?, *Heart Rhythm*. 2005; Vol. 2, No. 7; pages 782-783.

[5]Boston Scientific Corporation: Cardiac Rhythm Management Product Performance Report Q3 2010. St. Paul, MN: Boston Scientific Corporation, 2010; page 110; pattern 43 and 103 “Seal Plug”.

[6]Boston Scientific Corporation: Cardiac Rhythm Management Product Performance Report Q3 2010. St. Paul, MN: Boston Scientific Corporation, 2010; page 109; pattern 91 “Seal Plug”.

[7]S.Serge Barold. Cardiac Pacemakers Step by Step. Blackwell Futura; 2004: pages 188, 195, 310: oversensing symptoms associated with seal pug issues and other lead insulation issues.