

SUMMARY

A Model 6860 or Model 4520 magnet may be used with a Boston Scientific S-ICD to temporarily inhibit tachy therapy.

This article provides the necessary steps to inhibit tachy therapy using a magnet with Boston Scientific S-ICDs.

Products Referenced

Model 1010 SQ-RX™ Pulse Generator
Model A209 EMBLEM™ Pulse Generator
Model 6860 Magnet, Model 4520 Magnet

Products referenced are unregistered or registered trademarks of Boston Scientific Corporation or its affiliates. All other trademarks are the property of their respective owners.

Products referenced herein may not be approved in all geographies. Information is for the use in countries with applicable Health Authority product registrations.

For comprehensive information on device operation, reference the full instructions for use found at: www.bostonscientific-labeling.com.

CAUTION: Federal (U.S.) law restricts this device to sale by or on the order of a physician.

All graphics produced by Boston Scientific Corporation, unless otherwise noted.

CRT-D: Cardiac Resynchronization Therapy Defibrillator
CRT-P: Cardiac Resynchronization Therapy Pacemaker
ICD: Implantable Cardioverter Defibrillator
S-ICD: Subcutaneous Implantable Defibrillator

Contact Information

www.bostonscientific.com

Americas

Technical Services

LATITUDE™ Customer Support

1.800.CARDIAC (227.3422)

+1.651.582.4000

Patient Services

1.866.484.3268

Europe, Middle East, Africa

Technical Services

+32 2 416 7222

inttechservice@bsci.com

LATITUDE Customer Support

latitude.europe@bsci.com

Japan

Technical Services

japantechservice@bsci.com

LATITUDE Customer Support

japan.latitude@bsci.com

Asia Pacific

Technical Services

+61 2 8063 8299

aptechservice@bsci.com

LATITUDE Customer Support

latitude.asiapacific@bsci.com

© 2015 by Boston Scientific Corporation or its affiliates. All Rights Reserved.

Using a Magnet to Temporarily Inhibit S-ICD Therapy

If an S-ICD System programmer is not available, a Model 6860 magnet or Model 4520 magnet may be used to prevent arrhythmia detection and/or shock delivery by an S-ICD System pulse generator. Therapy will only be temporarily inhibited (disabled) during magnet application; a magnet cannot be used to program therapy off.

Instructions for Magnet Use

1. APPLY/POSITION THE MAGNET

For the Model 1010 SQ-RX™ S-ICD, apply a magnet flat against the skin directly over the implanted device (Figure 1).



Figure 1. Magnet placement for SQ-RX

For the Model A209 EMBLEM™ S-ICD, apply the magnet flat against the skin over the device header or over the lower edge of the device (Figure 2).



Figure 2. Magnet placement for EMBLEM

2. LISTEN FOR BEEPING TONES

If the magnet is correctly placed over the device, beeping tones (r-wave synchronous) will be heard approximately one second after the magnet is applied. Arrhythmia detection is now suspended and shock therapy is inhibited.

When using the magnet for a patient with a deep implant placement, the exact location of the pulse generator may not be evident, and other magnet positions may need to be tested near the general pulse generator location. Considering the following tips when attempting to apply the magnet:

- Beeping may be difficult to hear and a stethoscope should be used if necessary.
- Two or more magnets may be used in a stacked configuration to increase the likelihood of eliciting beeping tones and associated inhibition of therapy.
- If beeping tones cannot be detected, it may be necessary to use the programmer to suspend therapy in these patients.

WARNING: In patients with a deep implant placement (greater distance between the magnet and the pulse generator) magnet application may fail to elicit the magnet response. In this case the magnet cannot be used to inhibit therapy.

3. HOLD THE MAGNET IN PLACE

Therapy remains inhibited for as long as the magnet remains correctly positioned. While the magnet is held correctly in place, r-wave synchronous beeping tones will continue for 60 seconds. After 60 seconds, the beeping stops, but therapy continues to be inhibited unless the magnet has been moved.

NOTE: *If it is necessary to reconfirm that therapy is still being inhibited after beeping has stopped, remove and replace the magnet to reactivate the beeping tones. This step can be repeated as necessary. When long duration therapy suspension is desired, it is recommended to modify pulse generator behavior with the programmer rather than the magnet.*

4. REMOVE THE MAGNET

When the magnet is removed, arrhythmia detection resumes and therapy delivery is no longer inhibited.

IMPORTANT: If the beeping tones do not stop upon magnet removal, please call Technical Services for additional guidance.

Additional Magnet Response Notes:

- If the pulse generator mode is in Shelf Mode, a single beep sounds when the magnet is detected.
- A commanded Manual or Rescue Shock from a programmer will override the use of the magnet if the magnet was in place prior to the initiation of the command. However, if the magnet is applied after the initial programmer command, the Manual or Rescue Shock will be terminated.
- Magnet application will also terminate post-shock pacing therapy and prohibit arrhythmia induction testing.
- If the magnet is applied during an episode, the episode will not be stored in device memory.
- Magnet application does not affect wireless communication between the device and the programmer.
- Patients should be advised to contact their physician immediately whenever they hear beeping tones coming from their device.

Emblem™ S-ICD System from Boston Scientific CRM

Indications for Use

The S-ICD System is intended to provide defibrillation therapy for the treatment of life-threatening ventricular tachyarrhythmias in patients who do not have symptomatic bradycardia, incessant ventricular tachycardia, or spontaneous, frequently recurring ventricular tachycardia that is reliably terminated with anti-tachycardia pacing.

Contraindications

Unipolar pacing and impedance-based features are contraindicated for use with the S-ICD System.

Warnings

Read this manual thoroughly before using the S-ICD System to avoid damage to the pulse generator and/or subcutaneous electrode. Such damage can result in patient injury or death. For single patient use only. Do not reuse, reprocess, or resterilize. All Boston Scientific S-ICD implantable components are designed for use with the Boston Scientific or Cameron Health S-ICD System only. Connection of any S-ICD System components to a noncompatible component will result in failure to deliver life-saving defibrillation therapy. Always have external defibrillation equipment and medical personnel skilled in CPR available during implant and follow-up testing. Using multiple pulse generators could cause pulse generator interaction, resulting in patient injury or a lack of therapy delivery. Test each system individually and in combination to help prevent undesirable interactions. Concomitant use of the S-ICD System and implanted electromechanical devices (for example a ventricular assist device, VAD; or implantable insulin pump or drug pump) can result in interactions that could compromise the function of the S-ICD, the co-implanted device, or both. Electromagnetic (EMI) or therapy delivery from the coimplanted device can interfere with S-ICD sensing and/or rate assessment, resulting in inappropriate therapy or failure to deliver therapy when needed. In addition, a shock from the S-ICD pulse generator could damage the coimplanted device and compromise its functionality. To help prevent undesirable interactions, test the S-ICD system when used in combination with the co-implanted device, and consider the potential effect of a shock on the coimplanted device. Handle the components of the S-ICD System with care at all times and maintain proper sterile technique. Do not modify, cut, kink, crush, stretch or otherwise damage any component of the S-ICD System. Use caution handling the subcutaneous electrode connector. Do not directly contact the connector with any surgical instruments such as forceps, hemostats, or clamps. Use appropriate anchoring techniques as described in the implant procedure to prevent S-ICD System dislodgement and/or migration. Use caution when placing a magnet over the S-ICD pulse generator because it suspends arrhythmia detection and therapy response. In patients with a deep implant placement (greater distance between the magnet and the pulse generator) magnet application may fail to elicit the magnet response. Do not expose a patient with an implanted S-ICD System to diathermy. Do not expose a patient to MRI scanning. Advise patients to seek medical guidance before entering environments that could adversely affect the operation of the active implantable medical device, including areas protected by a warning notice that prevents entry by patients who have a pulse generator. The pulse generator may be more susceptible to low frequency electromagnetic interference at induced signals greater than 80 uV. The S-ICD System has not been evaluated for pediatric use.

Precautions

For specific information on precautions, refer to the following sections of the product labeling: clinical considerations, sterilization and storage, implantation, device programming, environmental and medical therapy hazards, hospital and medical environments, home and occupational environments, follow-up testing, explant and disposal and supplemental precautionary information. Advise patients to avoid sources of EMI because EMI may cause the pulse generator to deliver inappropriate therapy or inhibit appropriate therapy.

Potential Adverse Events

Potential adverse events related to implantation of the S-ICD System may include, but are not limited to, the following: Acceleration/induction of atrial or ventricular arrhythmia, adverse reaction to induction testing, allergic/adverse reaction to system or medication, bleeding, conductor fracture, cyst formation, death, delayed therapy delivery, discomfort or prolonged healing of incision, electrode deformation and/or breakage, electrode insulation failure, erosion/extrusion, failure to deliver therapy, fever, hematoma/seroma, hemothorax, improper electrode connection to the device, inability to communicate with the device, inability to defibrillate or pace, inappropriate post shock pacing, inappropriate shock delivery, infection, keloid formation, migration or dislodgement, muscle/nerve stimulation, nerve damage, pneumothorax, post-shock/post-pace discomfort, premature battery depletion, random component failures, stroke, subcutaneous emphysema, surgical revision or replacement of the system, syncope, tissue redness, irritation, numbness or necrosis. Patients who receive an S-ICD System may develop psychological disorders that include, but are not limited to, the following: depression/anxiety, fear of device malfunction, fear of shocks, phantom shocks.

Refer to the product labeling for specific indications, contraindications, warnings/precautions and adverse events. Rx only. (Rev. A)

S-ICD™ System from Boston Scientific CRM Indications for Use

The S-ICD™ System is intended to provide defibrillation therapy for the treatment of life-threatening ventricular tachyarrhythmias in patients who do not have symptomatic bradycardia, incessant ventricular tachycardia, or spontaneous, frequently recurring ventricular tachycardia that is reliably terminated with anti-tachycardia pacing.

Contraindications

Unipolar pacemakers are contraindicated for use with the S-ICD System.

Warnings and Cautions

The S-ICD System contains sterile products for single use only. Do not resterilize. Handle the components of the S-ICD System with care at all times and maintain proper sterile technique. All Cameron Health implantable components are designed for use with the Cameron Health S-ICD System only. Connection of any S-ICD System components to any other ICD system will result in failure to deliver lifesaving defibrillation therapy.

General

- External defibrillation equipment should be available for immediate use during the implantation procedure and follow-up.
- Placing a magnet over the SQ-RX Pulse Generator suspends arrhythmia detection and therapy response. Removing the magnet resumes arrhythmia detection and therapy response.
- Battery depletion will eventually cause the SQ-RX Pulse Generator to stop functioning. Defibrillation and excessive numbers of charging cycles shorten the battery longevity.
- The S-ICD System has not been evaluated for pediatric use.
- The S-ICD System does not provide long-term bradycardia pacing, Cardiac Resynchronization Therapy (CRT) or Anti-Tachycardia Pacing (ATP).

Potential Adverse Events related to implantation of the S-ICD System may include, but are not limited to, the following:

Acceleration/induction of atrial or ventricular arrhythmia; Adverse reaction to induction testing; Allergic/adverse reaction to system or medication; Bleeding; Conductor fracture; Cyst formation; Death; Delayed therapy delivery; Discomfort or prolonged healing of incision; Electrode deformation and/or breakage; Electrode insulation failure; Erosion/extrusion; Failure to deliver therapy; Fever; Hematoma; Hemothorax; Improper electrode connection to the device; Inability to communicate with the device; Inability to defibrillate or pace; Inappropriate post-shock pacing; Inappropriate shock delivery; Infection; Keloid formation; Migration or dislodgement; Muscle stimulation; Nerve damage; Pneumothorax; Post-shock/post-pace discomfort; Premature battery depletion; Random component failures; Stroke; Subcutaneous emphysema; Surgical revision or replacement of the system; Syncope; Tissue redness, irritation, numbness or necrosis.

Refer to the product labeling for specific indications, contraindications, warnings/precautions and adverse events. Rx only. (Rev. D)