Boston Scientific

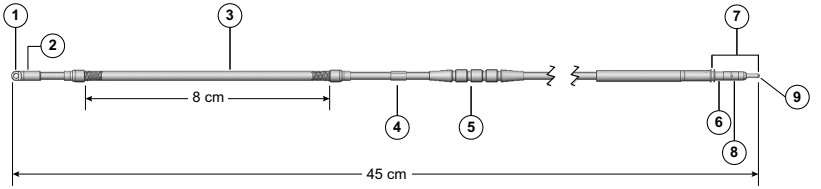
USER'S MANUAL

EMBLEM™ S-ICD

Subcutaneous Electrode

REF 3501

Table of Contents



[1] Anchoring Hole, [2] Distal Sensing Electrode, [3] Defibrillation Coil, [4] Proximal Sensing Electrode, [5] Integrated Suture Sleeve, [6] Terminal electrode connection for proximal sensing electrode, [7] SQ-1 S-ICD connector (non-standard), [8] Terminal electrode connection for defibrillation coil, [9] Terminal Pin (electrode connection for distal sensing electrode)

INFORMATION FOR USE

Description

The EMBLEM S-ICD subcutaneous electrode (the "subcutaneous electrode") is a component of the Boston Scientific S-ICD System, which is prescribed for patients when cardiac arrhythmia management is warranted. The S-ICD System detects cardiac activity and provides defibrillation therapy. The subcutaneous electrode is typically implanted with the distal portion positioned parallel to the left sternal border and the proximal end connected to an EMBLEM S-ICD System pulse generator via an SQ-1 S-ICD connector[1]. The subcutaneous electrode is also compatible with the Cameron Health Model 1010 SQ-RX pulse generator.

The subcutaneous electrode includes one high voltage shock electrode coil for the purpose of providing defibrillation energy. The shock electrode is constructed using multifilars of metallic wire formed into a defibrillation coil 8 centimeters in length. Defibrillation is delivered between the coil on the subcutaneous electrode and the electrically conductive pulse generator case.

The subcutaneous electrode also includes proximal and distal sensing ring electrodes. These sense electrodes are constructed using metallic tubing mechanically affixed to the body of the subcutaneous electrode. Sensing occurs between the two electrically conductive rings on the subcutaneous electrode or between either of the rings on the subcutaneous electrode and the electrically conductive pulse generator case.

Related Information

Instructions in this manual should be used in conjunction with other resource material, including the applicable S-ICD pulse generator user's manual and electrode implant tools user's manual.

Refer to the ImageReady MR Conditional S-ICD System MRI Technical Guide (hereafter referred to as the MRI Technical Guide) for information about MRI scanning.

Summary of Safety and Clinical Performance

For customers in the European Union, use the device name found in the labeling to search for the device's Summary of Safety and Clinical Performance, which is available on the European database on medical devices (Eudamed) website:

https://ec.europa.eu/tools/eudamed

Intended Audience

This literature is intended for use by professionals trained or experienced in device implant and/or follow-up procedures.

Clinical Benefits of the Device

The EMBLEM S-ICD System is intended to provide ventricular defibrillation for the treatment of life-threatening ventricular tachyarrhythmias in patients who do not require bradycardia pacing, anti-tachycardia pacing, or have incessant ventricular tachycardia. The

1. SQ-1 is a non-standard connector unique to the S-ICD System

EMBLEM S-ICD System also provides optional, on-demand post-shock bradycardia pacing at a non-programmable rate of 50 ppm for up to 30 seconds to provide heart rate support after defibrillation therapy. Patient benefit from system implantation may vary based on the underlying medical condition and likelihood of requiring ventricular defibrillation.

MR Conditional System Information

A Boston Scientific/Cameron Health subcutaneous electrode can be used as part of the ImageReady S-ICD System when connected to a Boston Scientific MR Conditional S-ICD pulse generator. Patients with an MR Conditional S-ICD System may be eligible to undergo MRI scans if performed when all Conditions of Use, as defined in the MRI Technical Guide, are met. Components required for MR Conditional status include specific models of Boston Scientific S-ICD pulse generators, electrodes, and accessories; the Programmer; and Programmer Software Application. For the model numbers of MR Conditional S-ICD pulse generator and components, as well as a complete description of the ImageReady S-ICD System, refer to the MRI Technical Guide.

Refer to the MRI Technical Guide for a comprehensive list of Warnings, Precautions, and Conditions of Use that are applicable to MRI scanning of patients implanted with an ImageReady S-ICD System.

Implant-related MRI Conditions of Use

The following subset of the MRI Conditions of Use pertains to implantation and is included as a guide to ensure implantation of a complete ImageReady S-ICD System. For a full list of Conditions of Use, and potential adverse events applicable when the Conditions of Use are met or not met, refer to the MRI Technical Guide. All items on the full list of Conditions of Use must be met in order for an MRI scan to be considered MR Conditional.

- Patient is implanted with an ImageReady S-ICD System
- No other active or abandoned implanted devices, components, or accessories present such as lead adaptors, extenders, leads, or pulse generators
- Patient is judged to be clinically capable of tolerating no Tachycardia protection for the entire duration in which the pulse generator is in MRI Protection Mode
- At least six (6) weeks have elapsed since implantation and/or any electrode revision or surgical modification of the ImageReady S-ICD System
- No evidence of a fractured electrode or compromised pulse generator-electrode system integrity

NOTE: *Other implanted devices or patient conditions may cause a patient to be ineligible for an MRI scan, independent of the status of the patient's ImageReady S-ICD System.*

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 antitachycardia pacing.

Contraindications

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

WARNINGS

NOTE: *Before using the S-ICD System, read and follow all warnings and precautions provided in the applicable S-ICD pulse generator user's manual.*

General

- **Labeling knowledge.** 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 / single procedure use only.** Do not reuse, reprocess, or resterilize. Reuse, reprocessing, or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness, or death. Reuse, reprocessing, or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness, or death of the patient.
- **Component compatibility.** 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 non-compatible component has not been tested and could result in failure to deliver life-saving defibrillation therapy.
- **Backup defibrillation protection.** Always have external defibrillation equipment and medical personnel skilled in CPR available during implant and follow-up testing. If not terminated in a timely fashion, an induced ventricular tachyarrhythmia can result in the patient's death.

Clinical considerations

- **Myopotentials.** The S-ICD System may sense myopotentials which may result in over/under sensing.

Handling

- **Proper handling.** Handle the components of the S-ICD System with care at all times and maintain proper sterile technique. Failure to do so may lead to injury, illness, or death of the patient.
- **Do not damage components.** Do not modify, cut, kink, crush, stretch, or otherwise damage any component of the S-ICD System. Impairment to the S-ICD System may result in an inappropriate shock or failure to deliver therapy to the patient.
- **Handling the subcutaneous electrode.** Use caution handling the subcutaneous electrode. Do not directly contact the shocking coil, sensing electrodes, electrode body, or connector with any surgical instruments such as forceps, hemostats, or clamps. This could damage the electrode, possibly leading to compromised sensing, loss of therapy, or inappropriate therapy.

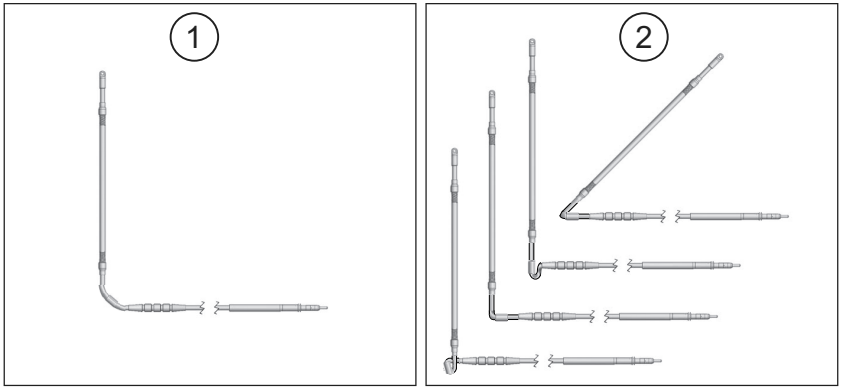
Implantation

- **Arm positioning.** Attention is required to placement of the arm ipsilateral to the device implant to avoid injury of the ulnar nerve and brachial plexus while the patient is in the supine position during device implantation and before VF induction or shock delivery. The patient should be positioned with the arm abducted to an angle of no more than 60° with the hand in a supinated (palm up) position during the implant

phase of the procedure. Securing the arm to an arm board is standard practice to maintain positioning of the arm during device implantation. Do not strap the arm too tightly during defibrillation testing. Elevation of the torso through use of a wedge may also add stress to the shoulder joint and should be avoided during defibrillation testing.

- **System migration.** Use appropriate anchoring techniques as described in the implant procedure to prevent S-ICD System dislodgement and/or migration. Dislodgement and/or migration of the S-ICD System may result in an inappropriate shock or failure to deliver therapy to the patient.
- **Do not implant in MRI site Zone III.** Implant of the system cannot be performed in an MRI site Zone III (and higher) as defined by the American College of Radiology Guidance Document on MR Safe Practices[2]. Some of the accessories used with pulse generators and electrodes, including the torque wrench and electrode implant tools, are not MR Conditional and should not be brought into the MRI scanner room, the control room, or the MRI site Zone III or IV areas.
- **High shocking electrode impedance.** High shocking electrode impedance may reduce VT/VF conversion success.
- **Using the tunneling tool.** Handle the tunneling tool with care. Always be aware of the location of the tool tip relative to patient anatomy. The tunneling tool is not intended to be used for intrathoracic access. Entering the thoracic cavity or advancing the tool under the ribs or sternum could lead to unintended tissue damage including organ or vessel perforation, or inadvertent lead placement in the mediastinum or thoracic cavity with its attendant risk.
- **Excessive tension.** When positioning the electrode and pulse generator, avoid excessive tension on the electrode, particularly if the electrode body extends over the pulse generator. This could cause structural damage, abrasion, and/or conductor discontinuity.
- **Excessive flexing.** Although pliable, the electrode is not designed to tolerate excessive flexing, tight radius bending, kinking, or twisting. This could cause structural damage, conductor discontinuity, electrode migration, and/or dislodgement. See the following figure for guidance on correct electrode placement.

2. Kanal E, Barkovich AJ, Bell C, et al. ACR guidance document on MR safe practices: 2013. J. Magn. Reson. Imaging 2013;37:501-530.



[1] Correct placement [2] Incorrect placement

Figure 1. Correct electrode placement to avoid excessive flexing

- **Electrode/connection malfunction.** Electrode fracture, abrasion, under-insertion of the electrode connector into the pulse generator connector port, or a loose setscrew connection may result in compromised sensing, loss of therapy, or inappropriate therapy.

Post-Implant

- **Diathermy.** Do not expose a patient with an implanted S-ICD System to diathermy. The interaction of diathermy therapy with an implanted S-ICD pulse generator or electrode can damage the pulse generator and cause patient injury.
- **Magnetic Resonance Imaging (MRI) exposure.** Unless all of the MRI Conditions of Use (as described in the MRI Technical Guide) are met, MRI scanning of the patient does not meet MR Conditional requirements for the implanted system, and significant harm to or death of the patient and/or damage to the implanted system may result.

  Refer to the MRI Technical Guide for potential adverse events applicable when Conditions of Use are met or not met, as well as for a complete list of MRI-related Warnings and Precautions.

- **Saltwater Environments.** Immersion in saltwater and similar conductive fluid environments (i.e. ocean, saltwater pools) may divert some defibrillation shock energy away from the patient's heart into the surrounding conductive fluid (as evidenced by a lower-than-normal shock impedance). This may reduce VT/VF conversion success, especially in patients with low BMI.

PRECAUTIONS

Clinical Considerations

- **Pediatric use.** The S-ICD System has not been evaluated for pediatric use.
- **Available therapies.** The S-ICD System does not provide long-term bradycardia pacing, cardiac resynchronization therapy (CRT), or antitachycardia pacing (ATP).

Sterilization and Storage

- **If package is damaged.** The blister trays and contents are sterilized with ethylene oxide gas before final packaging. When the pulse generator and/or subcutaneous electrode is received, it is sterile provided the container is intact. If the packaging is wet, punctured, opened, or otherwise damaged, return the pulse generator and/or subcutaneous electrode to Boston Scientific.
- **Use by date.** Implant the pulse generator and/or subcutaneous electrode before or on the USE BY date on the package label because this date reflects a validated shelf life. For example, if the date is January 1, do not implant on or after January 2.
- **Storage temperature.** The recommended storage temperature range is -18°C to +55° C (0°F to +131°F).

Implantation

- **Creating the subcutaneous tunnels.** Use Boston Scientific tools and accessories designed for use in implanting the subcutaneous electrode to create the subcutaneous tunnels when implanting and positioning the subcutaneous electrode. Avoid tunneling close to any other subcutaneously implanted medical devices or components, for example, an implantable insulin pump, drug pump, sternal wiring from previous sternotomy, or ventricular assist device.
- **Superior tunnel length.** Ensure the superior tunnel is long enough to accommodate the portion of the electrode from the distal tip to the suture sleeve without buckling or curving of the defibrillation coil. Buckling or curvature of the defibrillation coil within the superior tunnel could lead to compromised sensing and/or therapy delivery. After insertion of the electrode into the superior tunnel, X-ray or fluoroscopy may be used to confirm that no buckling or curvature is observed.
- **Suture location.** Suture only those areas indicated in the implant instructions.
- **Do not suture directly over subcutaneous electrode body.** Do not suture directly over the subcutaneous electrode body, as this may cause structural damage. Use the suture sleeve to prevent subcutaneous electrode movement.
- **Do not bend the subcutaneous electrode near the electrode-header interface.** Insert the subcutaneous electrode connector straight into the pulse generator header port. Do not bend the subcutaneous electrode near the subcutaneous electrode-header interface. Improper insertion can cause insulation or connector damage.
- **Sternal wires.** When implanting the S-ICD system in a patient with sternal wires, ensure that there is no contact between the sternal wires and the distal and proximal sense electrodes (for example, by using fluoroscopy). Compromised sensing can occur if metal-to-metal contact occurs between a sense electrode and a sternal wire. If necessary, re-tunnel the electrode to ensure sufficient separation between the sense electrodes and the sternal wires.

Hospital and Medical Environments

- **External defibrillation.** External defibrillation or cardioversion can damage the pulse generator or subcutaneous electrode. To help prevent damage to implanted system components, consider the following:

- Avoid placing a pad (or paddle) directly over the pulse generator or subcutaneous electrode. Position the pads (or paddles) as far from the implanted system components as possible.
- Set energy output of external defibrillation equipment as low as clinically acceptable.
- Following external cardioversion or defibrillation, verify pulse generator function (see the appropriate S-ICD pulse generator manual for suggested post-therapy follow-up actions).

- **Cardiopulmonary resuscitation.** Cardiopulmonary resuscitation (CPR) may temporarily interfere with sensing which may cause delay of therapy, inhibition of or inappropriate therapy.
- **Electrocautery and radio frequency (RF) ablation.** Electrocautery and RF ablation may induce ventricular arrhythmias and/or fibrillation, may cause inappropriate shocks and inhibition of post-shock pacing, and may produce unexpected behavior in the Programmer display or operation. Additionally, exercise caution when performing any other type of cardiac ablation procedure in patients with implanted devices. If electrocautery or RF ablation is medically necessary, observe the following to minimize risk to the patient and device:
  - Have external defibrillation equipment available.
  - Program the pulse generator to Therapy Off mode.
  - Avoid direct contact between the electrocautery equipment or ablation catheters and the pulse generator and subcutaneous electrode.
  - Keep the path of the electrical current as far away as possible from the pulse generator and subcutaneous electrode.
  - If RF ablation and/or electrocautery is performed on tissue near the pulse generator or subcutaneous electrode, verify pulse generator function (see the appropriate S-ICD pulse generator manual for suggested post-therapy follow-up actions).
  - For electrocautery, use a bipolar electrocautery system where possible and use short, intermittent, and irregular bursts at the lowest feasible energy levels.
  - Maintain a distance of at least 30 centimeters (12 inches) between Electrocautery and RF Ablation equipment and the Programmer and telemetry wand. Similarly, maintain this same distance between the Programmer and telemetry wand and the patient during these procedures.

  When the procedure is finished, return the pulse generator to Therapy On mode.

Explant and Disposal

- **Handling at explant.** Before explanting, complete the following actions to prevent unwanted shocks, overwriting of important therapy history data, and audible tones:
  - Program the pulse generator to Therapy Off mode.
  - Disable the beeper, if available.
- **Handling at time of disposal.** Clean and disinfect implanted components using standard biohazard handling techniques.

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
- Injury to or pain in upper extremity, including clavicle, shoulder, and arm
- Keloid formation
- Migration or dislodgement
- Muscle/nerve stimulation
- Nerve damage
- Organ injury or perforation
- Pneumothorax
- Post-shock/post-pace discomfort
- Premature battery depletion
- Random component failures
- Stroke
- Subcutaneous emphysema

- Surgical revision or replacement of the system
- Syncope
- Tissue damage
- Tissue redness, irritation, numbness or necrosis
- Vessel injury or perforation

Transient procedural adverse events are expected in some patients. These include, but are not limited to, discomfort, pain and other systemic symptoms that might be related to medications or other interventions performed during implant.

For a list of potential adverse events associated with MRI scanning, refer to the MRI Technical Guide.

If any adverse events occur, invasive corrective action and/or S-ICD System modification or removal may be required.

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

Any serious incident that occurs in relation to this device should be reported to Boston Scientific and the relevant local regulatory authority.

Warranty Information

A limited warranty certificate for the subcutaneous electrode is available at www.bostonscientific.com. For a copy, contact Boston Scientific using the information on the back cover.

European Union Importer

EU Importer: Boston Scientific International B.V., Vestastraat 6, 6468 EX Kerkrade, Nederland

Patient Counseling Information

The following topics should be discussed with the patient:

- Advise the patient to tell their healthcare professionals, such as their doctor, dentist, or technician, that they have an implanted medical device.
- Discuss pertinent warnings including:

  "Magnetic Resonance Imaging (MRI) exposure" on page 5.

  "Diathermy" on page 5.
- Discuss pertinent precautions including:

  "External defibrillation" on page 6.

  "Electrocautery and radio frequency (RF) ablation" on page 7.

- Discuss any potential adverse events that may occur ("Potential Adverse Events" on page 8).
- Advise the patient to report any serious incident that occurs in relation to their device to Boston Scientific and relevant local regulatory authority.
- Advise the patient to carry their Implant Card at all times and to present it before entering protected environments such as for MRI scanning.
- Inform the patient that the expected lifetime of the subcutaneous electrode is typically a minimum of 10 years based on test data and that a healthcare professional will monitor the long-term performance of the subcutaneous electrode and will determine if and when it may need to be replaced.
- Inform the patient that the subcutaneous electrode contains certain materials and substances that come in contact with the body ("Patient-contacting Materials" on page 18).
- Inform the patient that there is information regarding their subcutaneous electrode from Boston Scientific and direct them to the website noted on the back of the Implant Card for a copy of the information.

  NOTE: *Availability of Patient Information on the website varies by region.*

PRE-IMPLANT INFORMATION

Surgical Preparation

Consider the following prior to the implantation procedure:

The S-ICD System is designed to be positioned using anatomical landmarks. However, it is recommended to review a pre-implant chest X-ray in order to confirm that a patient does not have notably atypical anatomy (e.g., dextrocardia). Consider marking the intended position of the implanted system components and/or incisions prior to the procedure, utilizing anatomical landmarks or fluoroscopy as a guide. Additionally, if deviations from the implant instructions are required to accommodate for physical body size or habitus, it is recommended that a pre-implant chest X-ray has been reviewed.

WARNING: Attention is required to placement of the arm ipsilateral to the device implant to avoid injury of the ulnar nerve and brachial plexus while the patient is in the supine position during device implantation and before VF induction or shock delivery. The patient should be positioned with the arm abducted to an angle of no more than 60° with the hand in a supinated (palm up) position during the implant phase of the procedure. Securing the arm to an arm board is standard practice to maintain positioning of the arm during device implantation. Do not strap the arm too tightly during defibrillation testing. Elevation of the torso through use of a wedge may also add stress to the shoulder joint and should be avoided during defibrillation testing.

Items Included in Package

Store in a clean, dry area. The following pre-sterilized items are included with the subcutaneous electrode:

- Slit suture sleeve

Additionally, product literature is included.

Accessories

Separately packaged accessories are available in addition to those packaged with the electrode. The following accessories are used for implanting the electrode, but are not packaged with the electrode:

- EMBLEM S-ICD Electrode Delivery System (Model 4712)
- EMBLEM S-ICD Subcutaneous Electrode Insertion Tool (Model 4711)
- Slit Suture Sleeve; additional slit suture sleeves that are compatible with the electrode are available as an accessory (Model 4760)

NOTE: *Lead Cap (Model 7007) may also be used.*

IMPLANTATION

Overview

NOTE: *Implantation instructions for the subcutaneous electrode are included in the user's manual for the electrode implant tools that will be used (see* "Accessories" on page 11*). For example, if the electrode will be implanted using the EMBLEM S-ICD Electrode Delivery System (Model 4712), refer to the EMBLEM S-ICD Electrode Delivery System User's Manual for implant instructions.*

This section contains an overview of information needed for implanting the S-ICD system, including the subcutaneous electrode.

WARNING: 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 non-compatible component has not been tested and could result in failure to deliver life-saving defibrillation therapy.

WARNING: Implant of the system cannot be performed in an MRI site Zone III (and higher) as defined by the American College of Radiology Guidance Document on MR Safe Practices[3]. Some of the accessories used with pulse generators and electrodes, including the torque wrench and electrode implant tools, are not MR Conditional and should not be brought into the MRI scanner room, the control room, or the MRI site Zone III or IV areas.

NOTE: *If the electrode terminal will not be connected to a pulse generator at the time of electrode implantation, you must cap the electrode terminal before closing the pocket incision. The lead cap is designed specifically for this purpose. Place a suture around the lead cap to keep it in place.*

NOTE: *Use of a Boston Scientific/Cameron Health electrode is required for an implanted system to be considered MR Conditional. Refer to the MRI Technical Guide for model numbers of system components needed to satisfy the Conditions of Use.*

The pulse generator and subcutaneous electrode are typically implanted subcutaneously in the left thoracic region. The electrode implant tools are used to create the subcutaneous tunnels in which the electrode is inserted. The defibrillation coil must be positioned

3. Kanal E, Barkovich AJ, Bell C, et al. ACR guidance document on MR safe practices: 2013. J. Magn. Reson. Imaging 2013;37:501-530.

parallel to the sternum, in close proximity to or in contact with the deep fascia, below adipose tissue, approximately 1-2 centimeters from the sternal midline (Figure 2 Placement of the S-ICD System (Model 3501 Electrode shown) on page 12 and Figure 3 Subcutaneous Tissue Layers on page 13).

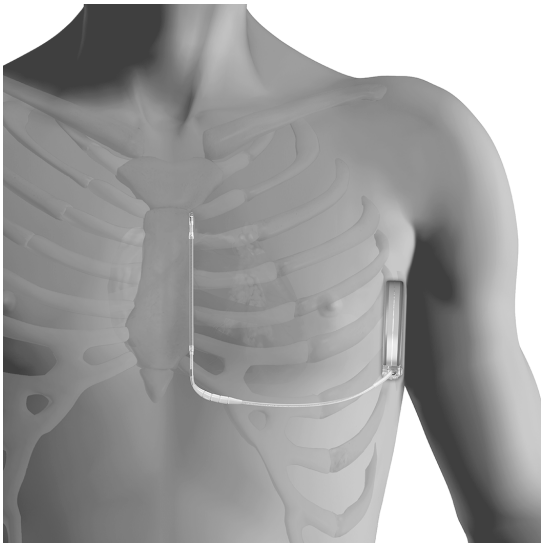
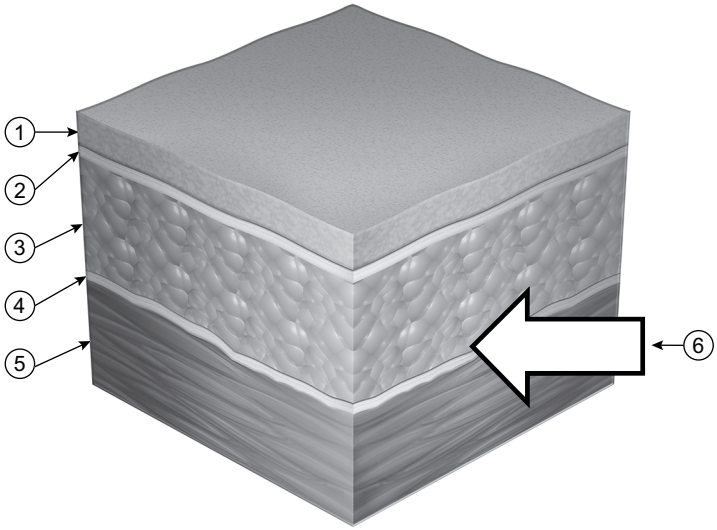


Figure 2. Placement of the S-ICD System (Model 3501 Electrode shown)



[1] Skin, [2] Hypodermal layer, [3] Adipose tissue, [4] Deep fascia, [5] Sub-fascial tissue (muscle or bone), [6] Correct location for subcutaneous tunnels and the S-ICD Subcutaneous Electrode

Figure 3. Subcutaneous Tissue Layers

Placement of the pulse generator and electrode can be achieved using various techniques. To ensure optimal placement of the subcutaneous electrode at the fascial plane, physician preference and patient assessment should be considered when choosing the implant method.

Care should be taken to place both the pulse generator and electrode directly on the fascia without underlying adipose tissue. Adipose tissue can add significant impedance to the high voltage shock current pathway.

To achieve high conversion success rates for VT/VF, the system placement should maximize the heart mass between the pulse generator and electrode. This creates the best vector for the defibrillation current while maintaining acceptable sensing parameters. To accomplish this, the electrode should be positioned parallel to the sternum, between the mid to parasternal line on the fascia, with minimal adipose tissue under the electrode shocking coil and sensing contact areas. The pulse generator should also be on the fascia with minimal underlying adipose tissue, and on the mid-axillary line or posterior axillary line. Intermuscular placement of the pulse generator helps achieve posterior position and good electrical contact with surrounding tissue. Ensure that neither the electrode nor the pulse generator are placed inferior relative to the heart mass.

After system placement, if failure to convert VT/VF with an adequate safety margin occurs either during defibrillation testing or later spontaneous ambulatory episode(s), the physician should review the position of both the electrode and pulse generator by use of anatomical landmarks or X-ray/ fluoroscopy. Additionally, the shocking electrode impedance should be evaluated.

WARNING: High shocking electrode impedance may reduce VT/VF conversion success.

High shocking electrode impedance may be related to lack of good tissue contact, inadequate pulse generator to electrode mechanical connection, or certain patient conditions, and may be associated with, but are not limited to:

- Adipose tissue under the pulse generator, or more typically, under the shocking coil of the electrode.
- Air entrapment proximal to the incision(s) (sternal tunnel or pulse generator pocket).
- Marginal electrode insertion or connection within the pulse generator header.
- Debris within the pulse generator header bore.
- Larger body habitus.
- Significant pulse generator or electrode migration (an ambulatory consideration). For example, if the pulse generator or electrode migrates away from the fascia.

Low shocking electrode impedance may be associated with, but are not limited to:

- Smaller body habitus.
- Patient conditions such as pleural effusion, which decreases the impedance of the shocking current pathway.
- Significant pulse generator or electrode migration (an ambulatory consideration). For example, during Twiddler's Syndrome, the electrode can become dislodged and drawn into the pulse generator pocket so that both shocking surfaces are very close to each other.

Depending on patient body habitus and anatomy, the physician may choose to position the device between the serratus anterior muscle and the latissimus dorsi muscle. Device fixation to the musculature is needed to secure its position, ensure performance, and to minimize wound complications.

Good tissue contact with the electrode and pulse generator is important to optimize sensing and therapy delivery. Use standard surgical techniques to obtain good tissue contact. For example, keep the tissue moist and flushed with sterile saline, expel any residual air out through the incisions prior to closing and, when closing the skin, take care not to introduce air into the subcutaneous tissue.

Refer to the user's manual for the electrode implant tools that will be used to implant the subcutaneous electrode for implantation instructions, including creating the subcutaneous tunnels, inserting the electrode, anchoring the electrode, and checking the electrode position prior to closing.

POST-IMPLANT

Implant Card for Patient

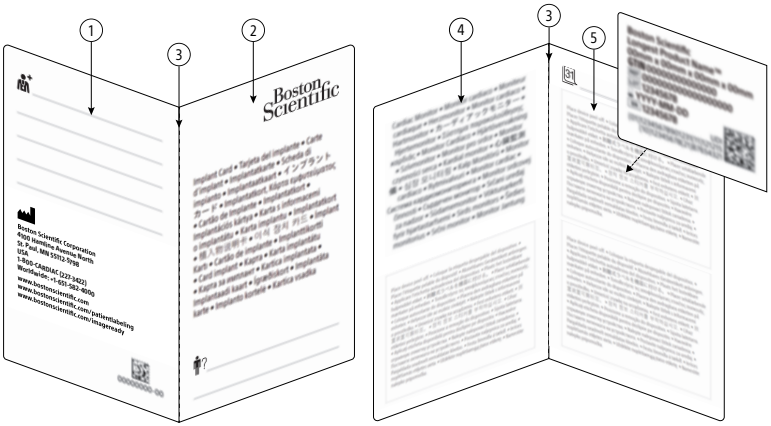
An Implant Card and peel-off labels are supplied in the packaging with this device. The Implant Card (Figure 4 Implant Card for Patient on page 15) must be filled out and provided to the patient receiving the implanted device. Complete the Implant Card as follows:

1. Remove one of the peel-off labels that matches the dimensions of the designated location on the Implant Card and place it on the Implant Card. The card may include space for more than one peel-off label.

2. Write the following information in the spaces provided using permanent ink:

	Name of Patient
	Date of implant
	Name and contact information of healthcare institution or clinician

3. Fold the Implant Card and place it in the sleeve provided.
4. Give the Implant Card to the patient and counsel the patient as described in "Patient Counseling Information" on page 9.



[1] Back page; [2] Front page; [3] Fold; [4] Inside left page; [5] Inside right page

Figure 4. Implant Card for Patient

Post Implant Follow-Up Procedures

It is recommended that device functions be evaluated with periodic follow-up testing by trained personnel to enable review of device performance and associated patient health status throughout the life of the device. Refer to the appropriate pulse generator literature for more information.

WARNING: Always have external defibrillation equipment and medical personnel skilled in CPR available during implant and follow-up testing. If not terminated in a timely fashion, an induced ventricular tachyarrhythmia can result in the patient's death.

Explantation and Disposal

Contact Boston Scientific when any of the following occur:

- When a product is removed from service.
- In the event of patient death (regardless of cause), along with an autopsy report, if performed.

- For other observation or complication reasons.

  CAUTION: Before explanting, complete the following actions to prevent unwanted shocks, overwriting of important therapy history data, and audible tones:

  - Program the pulse generator to Therapy Off mode.
  - Disable the beeper, if available.

Consider the following items when explanting and returning the pulse generator and/or subcutaneous electrode:

- Interrogate the pulse generator and print all reports.
- Disconnect the subcutaneous electrode from the pulse generator.
- If subcutaneous electrode is not explanted and terminal will not be connected to a pulse generator, cap the electrode terminal before closing the pocket incision. The lead cap is designed specifically for this purpose. Place a suture around the lead cap to keep it in place.
- If subcutaneous electrode is explanted, attempt to remove it intact, and return it regardless of condition. Do not remove the subcutaneous electrode with hemostats or any other clamping tool that may damage it. Resort to tools only if manual manipulation cannot free the subcutaneous electrode.
- Wash, but do not submerge, the pulse generator and subcutaneous electrode to remove body fluids and debris using a disinfectant solution. Do not allow fluids to enter the pulse generator's connector port.

  CAUTION: Clean and disinfect implanted components using standard biohazard handling techniques.

Return all explanted components to Boston Scientific regardless of condition. For a Returned Product Kit, contact Boston Scientific using the information on the back cover.

NOTE: *Examination of explanted pulse generators and subcutaneous electrodes by* Boston Scientific *can provide information for continued improvement in system reliability and warranty considerations.*

For all components that are not returned to Boston Scientific, to minimize risk of infection or microbial hazards after use, dispose of product and packaging as follows:

- After use, all explanted components are considered biohazardous. Other components may also contain biohazardous substances.
- Components that contain biohazardous substances should be disposed in a biohazard container that is labeled with the biological hazard symbol and taken to a designated facility for biohazardous waste for proper treatment in accordance with hospital, administrative, and/or local government policy.
- Biohazardous substances should be treated with an appropriate thermal or chemical process.

  NOTE: *Untreated biohazardous substances should not be disposed of in the municipal waste system.*

  NOTE: *Disposal of explanted pulse generators and/or subcutaneous electrodes is subject to applicable laws and regulations.*

WARNING: Do not reuse, reprocess, or resterilize. Reuse, reprocessing, or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness, or death. Reuse, reprocessing, or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness, or death of the patient.

SPECIFICATIONS

EMBLEM S-ICD Subcutaneous Electrode Specifications

Table 1. Electrode Specifications

Specification	Value
Connector	SQ-1 S-ICD connector (non-standard)
Length	45 cm
Distal Tip Size	3.84 mm
Coil Size	9 Fr
Electrode Shaft Size	7 Fr
Distal Sensing Surface Area	36 mm^2
Proximal Sensing Surface Area	46 mm^2
Sensing Location	Distal electrode at tip Proximal electrode 120 mm from tip
Defibrillation Surface Area	750 mm^2
Defibrillation Location	20 mm from tip
Insulation Material	Polycarbonate polyurethane
Electrode Material, Sensing Conductors and Connector Pins	MP35N™[a]
Slit Suture Sleeve Material	Silicone
Integrated Suture Sleeve Material	Radiopaque White Silicone
Storage Temperature Range	-18°C to +55°C (0°F to +131°F)
Maximum outer diameter at SQ-1 S-ICD connector seals	4.0 mm
Defibrillation coil diameter	3.0 mm
Lead shock impedance	25-200 Ω[b]
Maximum Lead Conductor Resistance	

Table 1. Electrode Specifications (continued)

Specification	Value
From high voltage terminal ring connection to defibrillation coil	1 Ω
From low voltage terminal pin to distal sensing electrode ring	50 Ω
From low voltage distal terminal sensing electrode connection to proximal sensing electrode ring	50 Ω
Expected Device Lifetime (nominal based on test data)	10 years

a. MP35N is a trademark of SPS Technologies, Inc.
b. post-shock pacing uses the same vector as shocking

Table 2. Patient-contacting Materials

Material	Approximate Percentage (%) of Total Exposed Surface Area
(Total nominal surface area of electrode lead ≈ 55 cm^2)	
Polycarbonate polyurethane	40%
Metal alloy (MP35N™ [a] [b])	35%
Silicone	25%
TiO_2 (Titanium Dioxide), $BaSO_4$ (Barium sulfate), polyester polyurethane	Additives and/or Trace amounts[c]

a. Contains Cobalt; CAS No. 7440–48–4; EN No. 231–158–0. Defined as a CMR1B according to the European Commission in a concentration above 0.1% weight by weight.
NOTE: *Current scientific evidence supports that metal alloys containing cobalt used in medical devices do not cause an increased risk of cancer or adverse reproductive effects.*
b. MP35N is a trademark of SPS Technologies, Inc.
c. Trace amounts make up less than 5% (combined) of the total surface area.

Definitions of Package Label Symbols

The following symbols may be used on packaging and labeling.

Table 3. Packaging Symbols

Symbol	Description
STERILE EO	Sterilized using ethylene oxide
	Date of manufacture
EC REP	Authorized Representative in the European Community

Table 3. Packaging Symbols (continued)

Symbol	Description
	Use by
	Serial number
	Reference number
	Temperature limitation
	Open here
	Consult instructions for use on this website: www.bostonscientific-elabeling.com
	Contents
	Do not resterilize
	Single use. Do not re-use
	Do not use if package is damaged and consult instructions for use
	Manufacturer
	MR Conditional
SQ-1 	Non-standard connector cavity
	Australian Sponsor Address
	Person identification
	Health care center or doctor
	Date

Table 3. Packaging Symbols (continued)

Symbol	Description
MD	Medical device under EU Legislation
	Double sterile barrier system
UDI	Unique Device Identifier
	Contains hazardous substances

Boston Scientific Corporation
4100 Hamline Avenue North
St. Paul, MN 55112-5798 USA

EC REP

Guidant Europe NV/SA; Boston Scientific
Green Square, Lambroekstraat 5D
1831 Diegem, Belgium

AUS

Boston Scientific (Australia) Pty Ltd
PO Box 332
Botany NSW 1455 Australia
Free Phone 1 800 676 133
Free Fax 1 800 836 666

www.bostonscientific.com

1.800.CARDIAC (227.3422)

+1.651.582.4000

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