

USER'S MANUAL

EMBLEM™ S-ICD

Subcutaneous Electrode Insertion Tool

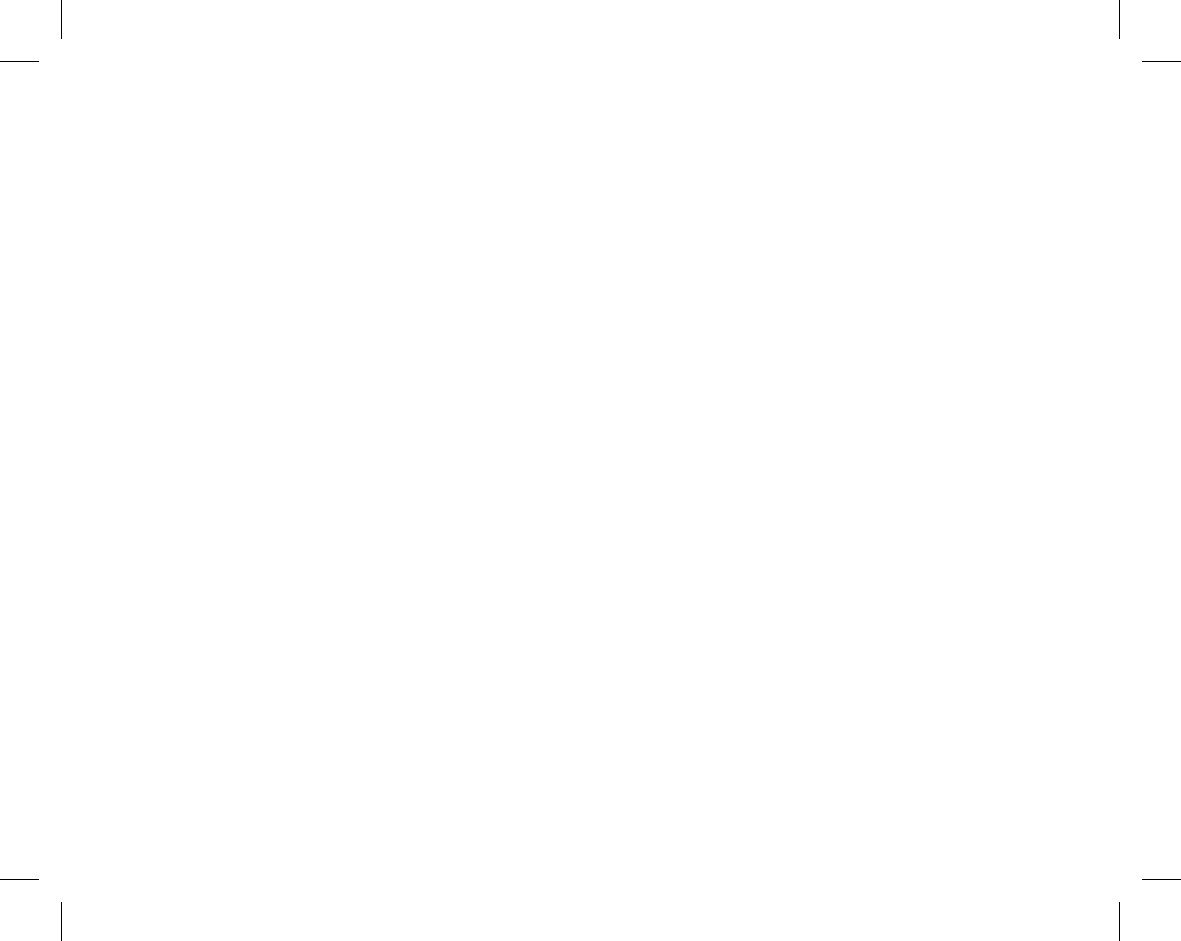
Model 4711

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician trained or experienced in device implant and follow-up procedures.



Table of Contents

Description.....	1
Trademark Information.....	1
Related Information.....	1
Indications for Use.....	1
Contraindications.....	1
Warnings.....	2
Precautions.....	4
Potential Adverse Events.....	5
Pre-Implant Information.....	8
Surgical Preparation.....	8
Items Included in Package.....	8
Implantation.....	8
Overview.....	8
Implant the EMBLEM S-ICD Subcutaneous Electrode.....	13
Connect the Subcutaneous Electrode to the Pulse Generator.....	19
EMBLEM S-ICD Subcutaneous Electrode Insertion Tool Diagram.....	19
EMBLEM S-ICD Subcutaneous Electrode Insertion Tool Specifications.....	20
Definitions of Package Label Symbols.....	20
Warranty Disclaimer.....	22



DESCRIPTION

The EMBLEM S-ICD Subcutaneous Electrode Insertion Tool (the "EIT") is a component of the Boston Scientific S-ICD System, which is prescribed for patients when cardiac arrhythmia management is warranted. The EIT is used to create subcutaneous tunnels to facilitate implantation of the EMBLEM S-ICD Subcutaneous Electrode. The EIT is also compatible with S-ICD Electrode models 3401 and 3501.

TRADEMARK INFORMATION

The following are trademarks of Boston Scientific Corporation or its affiliates: EMBLEM.

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 subcutaneous electrode user's manual.

A summary of the S-ICD System Clinical Investigation, including observed adverse events, can be obtained by contacting Boston Scientific using the information on the back cover.

INTENDED AUDIENCE

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

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 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.

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. Use care when tunneling to avoid injury to the implanter.

- **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 connector. Do not directly contact the connector with any surgical instruments such as forceps, hemostats, or clamps. This could damage the connector. A damaged connector may result in compromised sealing integrity, 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 for Safe MR Practices¹. 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.

1. Kanal E, et al., American Journal of Roentgenology 188:1447-74, 2007

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 electrode insertion tool is sterilized with gamma irradiation and is packaged in a sterile container. When the electrode insertion tool is received, it is sterile provided the container is intact. If the packaging is wet, punctured, opened, or otherwise damaged, return the electrode insertion tool to Boston Scientific.
- **Use by date.** Use the electrode insertion tool 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 use 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.
- **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.

For precautions related to hospital or other medical environments, refer to the applicable S-ICD pulse generator user's manual.

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
- 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

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

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 items are included with the subcutaneous electrode insertion tool:

- Product literature

IMPLANTATION

Overview

This section presents the information necessary for implanting the EMBLEM S-ICD Subcutaneous Electrode (Model 3401 or 3501) using the EMBLEM S-ICD Subcutaneous Electrode Insertion Tool (the "EIT").

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 for Safe MR Practices². 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.*

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 parallel to the sternum, in close proximity to or in contact with the deep fascia, below adipose tissue, approximately 1-2 cm from the sternal midline (Figure 1 Placement of the S-ICD System (Model 3501 Electrode shown) on page 10 and Figure 2 Subcutaneous Tissue Layers on page 11).

2. Kanal E, et al., American Journal of Roentgenology 188:1447-74, 2007

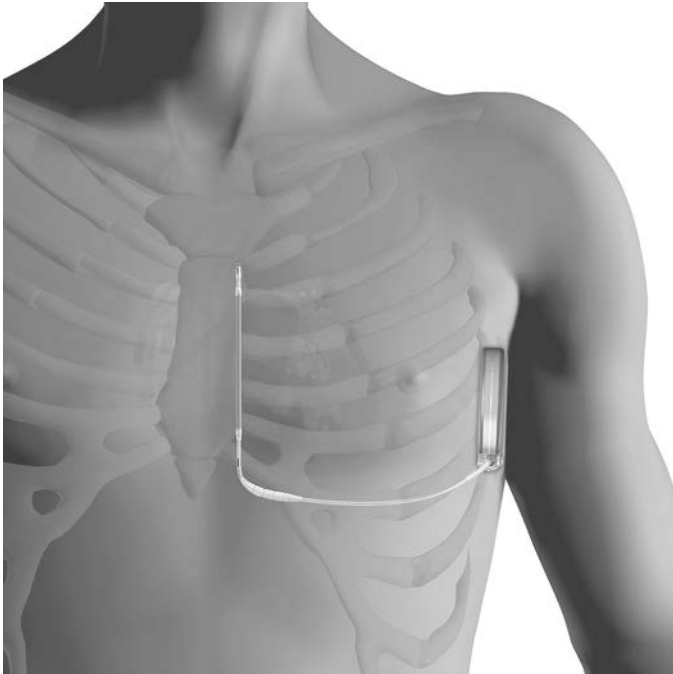
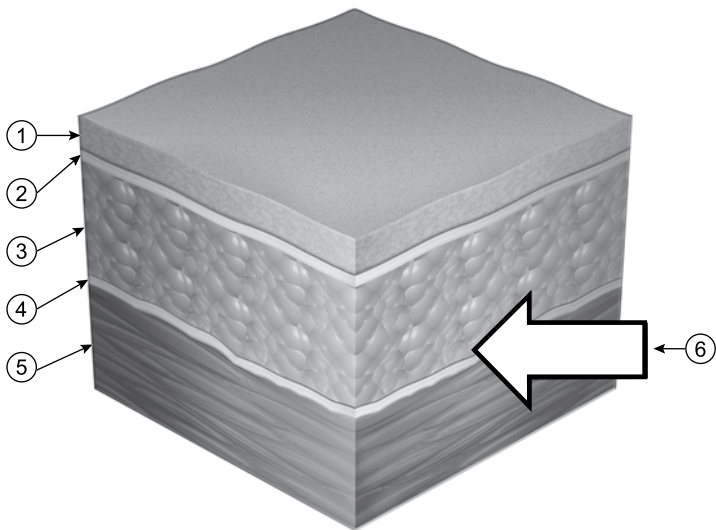


Figure 1. Placement of the S-ICD System (Model 3501 Electrode shown)



[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 2. 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 position both the electrode and device directly on the fascia without underlying adipose tissue. High shocking electrode impedance may be associated with adipose tissue under the coil of the electrode, which may require repositioning of the electrode so that it is on the fascia.

In order to maximize the heart mass between the pulse generator and electrode, while maintaining acceptable sensing parameters, transthoracic defibrillation is achieved through the positioning of an anterior electrode and a device in the mid-axillary line or posterior axillary line.

In case of failure to convert VT/VF without adequate safety margin, either during defibrillation testing or later spontaneous ambulatory episode(s), the physician should review the position of both the electrode and device by use of anatomical landmarks or X-ray/fluoroscopy. A more posterior device location may reduce the defibrillation threshold.

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.

A pocket for the pulse generator must be created prior to implanting the subcutaneous electrode. The pocket incision is utilized during the electrode implant. Refer to the applicable S-ICD pulse generator user's manual for information on creating the device pocket.

Implant the EMBLEM S-ICD Subcutaneous Electrode

The following detailed instructions describe one of several surgical approaches that can be used to appropriately implant and position the electrode. Alternate surgical approaches could be considered if system placement requirements can be achieved. The physician determines which tools and surgical technique are used to implant and position the electrode based on the patient's anatomical features.

In addition to the incisions described below, the pocket incision is utilized when implanting the electrode.

Lateral Tunnel

1. Make a small, 2 cm horizontal incision at the xiphoid process (xiphoid incision). The size and orientation may vary at the physician's discretion based on the patient's body habitus.

NOTE: *If desired, in order to facilitate attachment of the suture sleeve to the fascia following electrode placement, two suture ties to the fascia can be placed at the xiphoid incision prior to continuing.*

NOTE: *Ensure that the sutures are securely fastened to fascia by gently tugging on the sutures.*

2. Insert the distal tip of the EIT at the xiphoid incision and tunnel laterally until the distal tip emerges at the pocket incision.

CAUTION: 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.

3. Using conventional suture material, tie the anchoring hole at the distal end of the subcutaneous electrode to the suture hole at the distal end of the EIT, creating a long 15-16 cm loop (Figure 3 Connecting the Electrode to the EIT on page 14).

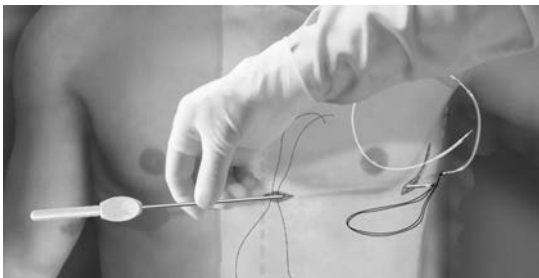


Figure 3. Connecting the Electrode to the EIT

4. With the subcutaneous electrode attached, carefully pull the EIT back through the tunnel to the xiphoid incision until the proximal sensing electrode emerges.
5. **If using S-ICD Subcutaneous Electrode Model 3501**, a suture sleeve is permanently affixed (integrated) to the electrode body.

OPTIONAL: If the accessory slit suture sleeve is needed in addition to the integrated suture sleeve, attach it to the electrode body as follows: Place the suture sleeve over the electrode shaft, making sure not to cover the integrated suture sleeve, sensing electrodes, or defibrillation coil. Using the preformed grooves, bind the suture sleeve to the subcutaneous electrode shaft using 2-0 silk or similar non-absorbable suture material. After the suture sleeve is attached to the electrode body, check that it is stable by grasping the suture sleeve with fingers and trying to slide it along the subcutaneous electrode body in either direction.

If using S-ICD Subcutaneous Electrode Model 3401, place a suture sleeve over the subcutaneous electrode shaft 1 cm below the proximal sensing electrode. Using the preformed grooves, bind the suture

sleeve to the subcutaneous electrode shaft using 2-0 silk or similar non-absorbable suture material, making sure not to cover the proximal sensing electrode. After the suture sleeve is attached to the electrode body, check that it is stable by grasping the suture sleeve with fingers and trying to slide it along the subcutaneous electrode body in either direction.

NOTE: *The subcutaneous electrode may be anchored to the fascia either before or after creating the superior tunnel at the physician's discretion. For instructions on anchoring at the xiphoid incision, see step 12.*

Superior Tunnel

6. Identify the intended position of the superior incision, at a point approximately 14 cm superior to the xiphoid incision (Figure 4 Tunneling to Superior Incision on page 16). The length of the superior tunnel must accommodate the portion of the subcutaneous electrode from the proximal sensing electrode to the distal tip of the electrode body. If the exposed portion of the electrode body is placed on the skin to make this measurement, take tissue depth into account to avoid underestimating the necessary length of the tunnel.
7. Make the superior incision. Pre-place one or two fascial sutures in superior incision. Use a non-absorbable suture material of appropriate size for long-term retention. Apply gentle traction to ensure adequate tissue fixation. Retain the needle on the suture for later use in passing through the electrode anchoring hole.
8. Insert the distal tip of the EIT into the xiphoid incision between the adipose and fascial plane and tunnel subcutaneously towards the superior incision, staying below adipose tissue and as close to the deep fascia as possible (Figure 4 Tunneling to Superior Incision on page 16).

CAUTION: 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.

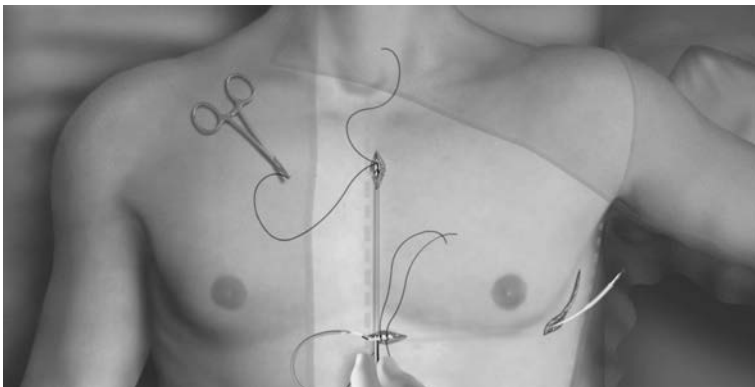


Figure 4. Tunneling to Superior Incision

9. Once the distal tip of the EIT emerges from the superior incision, disconnect and retain the suture loop from the distal tip of the EIT. Secure the ends of the suture with a surgical clamp. Remove the EIT.
10. Using the secured suture loop at the superior incision, carefully pull the suture and subcutaneous electrode through the tunnel until the anchoring hole emerges. The subcutaneous electrode should be parallel to the sternal midline with the defibrillation coil beneath any adipose tissue and in close proximity to the deep fascia.
11. Cut and discard the suture material.

Anchoring the Electrode at the Xiphoid Incision

12. At the xiphoid incision, anchor the subcutaneous electrode to the fascia using 2-0 silk or similar non-absorbable suture material.

If using S-ICD Subcutaneous Electrode Model 3501, use at least two of the four suture grooves when anchoring the electrode to the fascia. The integrated suture sleeve may be anchored in a horizontal, vertical, or curved orientation.

If using S-ICD Subcutaneous Electrode Model 3401, the suture sleeve(s) may be anchored in a horizontal, vertical, or angled orientation.

WARNING: 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.

CAUTION: Do not suture directly over the subcutaneous electrode body, as this may cause structural damage. Use the suture sleeve to prevent subcutaneous electrode movement.

CAUTION: Suture only those areas indicated in the implant instructions.

NOTE: *Ensure that the suture is securely fastened to fascia by gently tugging on the suture prior to tying to the suture sleeve and subcutaneous electrode.*

13. At the superior incision, secure the anchoring hole at the distal end of the electrode to the fascia using the pre-placed sutures from step 6 (Figure 5 Anchoring the Distal Tip of the Subcutaneous Electrode on page 18).



Figure 5. Anchoring the Distal Tip of the Subcutaneous Electrode

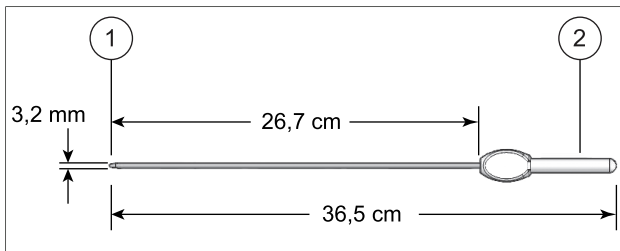
NOTE: *Ensure that the suture is securely fastened to fascia by gently tugging on the suture prior to tying to the subcutaneous electrode anchoring hole.*

14. Gently tug the subcutaneous electrode at the superior incision to ensure the anchoring hole is secured to the fascia.
15. To dispose of the EIT, return the used product to the original package, then dispose in a biohazard container.
16. To avoid air entrapment and ensure good tissue contact with the implanted subcutaneous electrode, flush all incisions with sterile saline solution and apply firm pressure along the electrode to expel any residual air out through the incisions prior to closing. Consider using fluoroscopy to check the electrode position prior to closure.

Connect the Subcutaneous Electrode to the Pulse Generator

For information on connecting the subcutaneous electrode to the pulse generator, as well as information about setup of the pulse generator and defibrillation testing, refer to the applicable S-ICD pulse generator user's manual. Additional information on post-implant follow-up and explant of the system can also be found in the applicable S-ICD pulse generator user's manual.

EMBLEM S-ICD SUBCUTANEOUS ELECTRODE INSERTION TOOL DIAGRAM



[1] Distal Tip, [2] Handle

Figure 6. Model 4711 dimensions

EMBLEM S-ICD SUBCUTANEOUS ELECTRODE INSERTION TOOL SPECIFICATIONS

Table 1. Specifications

Component	Specification
Electrode insertion tool materials	Acrylonitrile-butadiene-styrene (ABS), stainless steel
Transportation, Handling, and Storage Temperature Range	-18°C to +55°C (0°F to +131°F)

DEFINITIONS OF PACKAGE LABEL SYMBOLS

The following symbols may be used on packaging and labeling.

Table 2. Packaging Symbols



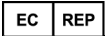
Symbol	Description
	Sterilized by gamma irradiation
	Date of manufacture
	Authorized Representative in the European Community

Table 2. Packaging Symbols (continued)











Symbol	Description
	Use by
	Lot number
	Reference number
	Temperature limitation
	Open here
	Consult instructions for use on this website: www.bostonscientific-elabeling.com

Table 2. Packaging Symbols (continued)

Symbol	Description
	Do not resterilize
	Do not reuse
	Do not use if package is damaged
	Manufacturer

WARRANTY DISCLAIMER

Except as otherwise provided herein, Boston Scientific disclaims all express and implied warranties for this product, including without limitation any implied warranties of merchantability or fitness for a particular purpose. Boston Scientific's obligations under any warranty provided herein shall be limited strictly to replacement of the product. Buyer assumes all risk of loss or damages arising from use of this product.



Boston Scientific

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

www.bostonscientific.com

1.800.CARDIAC (227.3422)
+1.651.582.4000

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