EMBLEM™ S-ICD System
Physician Training

Anatomic Considerations
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EMBLEM™ S-ICD System Brief Summary
After completing this module, you should be able to:

- Discuss the appropriate depth for EMBLEM™ S-ICD System implant.
- Describe how to protect the axillary nerves during EMBLEM S-ICD System implant.
- Refer to anatomic landmarks to:
  - Plan EMBLEM S-ICD System positioning
  - Determine incision locations for the electrode and pulse generator.
- Discuss the intermuscular approach to EMBLEM S-ICD System implant.
- Discuss how to adjust the implant procedure to accommodate anatomic anomalies.
The layers of the skin and fascia are the epidermis, dermis, superficial fascia, and deep fascia. The EMBLEM™ S-ICD System is implanted between the superficial and deep fascial layers.

- The **epidermis** consists of closely joined epithelial cells. The **dermis** is a layer of dense connective tissue composed of interlacing collagen and elastin fibers.

- The **superficial fascia** (subcutaneous tissue) is composed of loose connective tissue with an abundance of blood vessels and **adipose (fat) cells**. The **deep fascia** consists of dense connective tissue that surrounds and isolates individual muscles. The **fascial layers are easily separated by blunt dissection.**

- Adipose tissue has five to ten times more electrical resistance than cardiac tissue.* Thus, it is important to place the EMBLEM S-ICD System **below adipose tissue.**


The EMBLEM S-ICD System is implanted below adipose tissue (superficial fascia) and against the deep fascia and muscle.

Fluoroscopy may be helpful when making incisions in overweight patients. A metal instrument such as a scalpel helps assess the depth of an incision.
The **thoracic wall** consists of skin, fascia, muscles, and thoracic cage. The thoracic wall protects the thoracic and upper abdominal organs.

- The **thoracic cage** is formed by the ribs, spine, sternum, and their attachments. The **sternum** is a long flat bone in the middle of the rib cage. The **manubrium** is the broad upper part of the sternum.

- The **xiphoid process** is the sword-like projection that connects to the sternum at the **xiphisternal joint**. The xiphoid process is the surface landmark for midline surgical incisions. *It is the primary landmark for positioning the EMBLEM™ S-ICD System.*

- The **thoracic muscles** elevate and depress the rib cage during respiration. The **pectoralis major** is a thick muscle that attaches to the sternum and extends to the front of the armpit (axilla). It forms the bulk of the chest wall in males and lies under the breast in females. The **pectoralis minor** is a thin muscle that lies below the pectoralis major.

- The **serratus anterior** covers the side of the rib cage.

**KEY CONCEPT**

The xiphoid process is the primary landmark for positioning the EMBLEM S-ICD System.

**NOTES**

Skin tension lines (Langer’s lines) correspond to the direction of collagen fibers in the dermis. Surgical incisions that run parallel to skin tension lines heal well because the lines of force pull the cut surfaces together. Incisions that run across tension lines split collagen fibers, take longer to heal, and may result in more scarring.
The axilla is a pyramid-shaped space at the junction of the thoracic wall and upper arm. It provides a passage for blood vessels and nerves traveling to the arm.

- The **brachial plexus** arises from the cervical spine, extends into the axilla, and branches into the arm and hand. Excessive stretching or compression of the brachial plexus can cause abnormal sensations, such as tingling, burning, or pain. Severe injury can permanently impair arm or hand movement.

- Careful patient prep protects the brachial plexus. Attention to detail when placing the pulse generator protects the long thoracic nerve.

- The **long thoracic nerve** passes behind the brachial plexus and runs along the outer surface of the serratus anterior. Damage to this nerve may result in pain, loss of shoulder movement, or scapular winging. Because of its long, fairly superficial course, the long thoracic nerve may be visualized in the pulse generator (PG) pocket. *Careful PG placement protects the nerve from injury.*

**KEY CONCEPT**

Careful patient prep protects the brachial plexus. Attention to detail when placing the pulse generator protects the long thoracic nerve.
Anatomic Considerations

Clinicians use **imaginary planes** to visualize and describe the position of anatomic structures.

- The **median plane** passes vertically through the center of the body, dividing it into **right and left sides**. **Parasagittal planes** are **parallel to the median plane**.
- **Coronal planes** pass vertically through the body, dividing it into front (anterior) and back (posterior) sections.
- **Transverse (axial) planes** pass horizontally through the body, dividing it into upper (superior) and lower (inferior) sections.

Directional terms, arranged as opposites, are used to compare the relative position of two anatomic structures. **Examples:**

- **Medial** (middle); **lateral** (away from the middle)
- **Distal** (farther from a reference point); **proximal** (closer to a reference point)

KEY CONCEPT

The median, parasagittal, coronal, and transverse planes provide points of reference for visualizing and describing anatomic structures.

NOTES

In practice, radiographic images do not lie precisely in a particular plane, but are slightly oblique.
Anatomic Landmarks

The images show the normal position of the heart in the thoracic cavity and the **anatomic landmarks** used to position the EMBLEM™ S-ICD System.

- The **heart** lies between the right and left lungs, posterior to the sternum. About 2/3 of its mass is left of midline. The right side of the heart projects toward the sternum (anterior location); the left side toward the spine (posterior location).

- The **left ventricular (LV) apex** rests on the thoracic diaphragm, superior to the xiphoid process. It is posterior to the 5th intercostal space, about nine cm from the median plane.

- The **thoracic diaphragm** is a dome-shaped sheet of muscle that separates the thoracic cavity from the abdominal cavity. Because of its size, shape, and location, it serves as an important anatomic landmark.

- The EMBLEM S-ICD System is positioned **superior** to the xiphoid process and diaphragm (Figure B).
  - The PG is placed between the 5th and 6th intercostal spaces on the left midaxillary line.
  - The **proximal** electrode is on the same plane as the PG. The sensing ring is 1 cm left of the xiphisternal joint.
  - The **distal** electrode is placed along the sternum, one cm left of the midline.

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**KEY CONCEPT**

The position of the EMBLEM S-ICD System is dictated by the position of the heart in the thoracic cavity. The goal is to ensure there is enough ventricular mass between the PG and electrode for appropriate sensing and shock delivery.

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**NOTES**

Figure A: Anterior view

Figure B: Implanted EMBLEM S-ICD System
Axillary lines of reference are used to position the pulse generator (PG).

- The **midaxillary line** starts at the deepest part of the armpit. The **anterior axillary line** runs along the axillary fold near the thoracic wall; the **posterior axillary line** along the axillary fold near the back.

- **When properly positioned, the EMBLEM™ S-ICD System pulse generator straddles the left midaxillary line.** This position ensures there is sufficient heart tissue between the PG and electrode for appropriate sensing and shocking (not too anterior; not too posterior).

**Note:** The initial PG pocket incision is made near the anterior axillary line.

**KEY CONCEPT**

When properly positioned, the PG straddles the left midaxillary line.

**NOTES**

Recall that a vertical orientation of the PG is typically more comfortable for the patient.
Implant Variations

**A intermuscular approach** may be used to reduce device protrusion and prevent device erosion in low BMI (body mass index) patients.

- The **lattisimus dorsi** is a broad back muscle that originates along the spine and extends to the midaxillary line (Figure A). Along with the pectoralis major, the lattisimus dorsi lifts the trunk to the arms.

- Figure B shows a **intermuscular implant**. The pulse generator is placed between the *anterior* lattissimus dorsi and serratus anterior. *When correctly positioned, the PG straddles the midaxillary line.*

**Note:** Placing the entire PG under the lattissimus dorsi would compromise sensing as the device would be too posterior.
Pectus excavatum is a congenital anomaly caused by excessive growth of connective tissue between the ribs and sternum. It causes the sternum and anterior ribs to sink inward.

- The images in Figure A show how pectus excavatum can displace the heart’s normal position within the thoracic cavity. The x-ray image in Figure B shows an obliterated right heart border, an indication of pectus excavatum.
- The degree of deformity in pectus excavatum varies from person to person. A pre-implant CT scan and chest x-ray help identify anatomic landmarks and plan placement of the EMBLEM S-ICD System pulse generator and electrode. Fluoroscopy ensures good visualization when tunneling along the fascial plane.

Pectus excavatum can displace the heart’s normal position. Pre-implant images help identify landmarks and plan EMBLEM S-ICD System placement.

NOTES

Pectus excavatum occurs in 1 of 400 children with a 3:1 male to female ratio. It usually presents in the first year of life and worsens as the child grows. If heart and lung function are compromised, surgical repair may be considered when the child reaches puberty.¹
**Pectus carinatum** is a congenital anomaly caused by the outward growth of connective tissue between the ribs and sternum. It causes the sternum to push forward, giving the chest a bird-like appearance.*

- Pectus carinatum may be asymmetric, with one side of the chest affected more than the other. In some cases, pectus carinatum occurs on one side of the chest and pectus excavatum on the other. Some patients develop a rigid chest wall.
- Pre-implant x-ray images help identify anatomic landmarks and plan placement of the EMBLEM S-ICD System. Fluoroscopy helps ensure good visualization when tunneling along the fascial plane.

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**KEY CONCEPT**

Pectus carinatum may be asymmetric or combined with pectus excavatum. Pre-implant images help identify landmarks and plan EMBLEM S-ICD System placement.

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**NOTES**

Pectus carinatum occurs in 1 of 1,500 children with a 4:1 male to female ratio. It usually presents in childhood and worsens during puberty. The standard treatment is bracing of the thoracic wall. If bracing is ineffective, surgical repair may be considered.²
**Dextrocardia** is a congenital anomaly in which the heart is situated right of midline and the apex points to the right. The great vessels are also reversed.

- **Isolated dextrocardia** is the reversed positioning of the heart and great vessels (Figure B). **Dextrocardia with situs inversus** is the reversed positioning of all thoracic and abdominal organs. Other defects may be present.

- Dextrocardia requires reversed positioning of the EMBLEM™ S-ICD System. The distal electrode is placed 1 cm right of the sternal midline and the pulse generator (PG) at the right midaxillary line. Pre-implant MRI images and clear labeling of the right and left sides helps identify anatomic landmarks. X-ray images help plan PG and electrode placement.

**KEY CONCEPT**

Dextrocardia requires reversed positioning of the EMBLEM S-ICD System. Pre-implant images and left-right labelling help identify landmarks and plan EMBLEM S-ICD System placement.

**NOTES**

Dextrocardia occurs in 1 of 10,000 children. Diagnosis may be delayed if cardiovascular function is normal.³
The patient’s heart is enlarged posteriorly, so the PG is placed slightly posterior to ensure there is enough ventricular mass between the PG and electrode.

The electrode is too high for this low BMI patient. The PG is too posterior and rotated off plane, so it may be uncomfortable.

This distal electrode is too lateral. The PG is too anterior and placed slightly too superior for optimal sensing.

This PG is too inferior. In the optimum position, the PG is superior to the xiphoid process.

For more implant images, refer to the Image Atlas.
Reference: Anatomic Considerations

1. Iglesias J. *Chest Wall Deformities: Pectus Carinatum and Excavatum*. Available at: www.cookchildrens.org/pediatric surgery. Accessed May 1, 2015,

2. UCSF Pediatric Surgery. *Pectus Carinatum*. Available at: www.pedsurg.ucsf.edu Accessed May 1, 2015,

EMBLEM™ S-ICD Brief Summary

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 SICD 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.
EMBLEM™ S-ICD System Brief Summary

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)