S-ICD™ System
Patient Preparation
and Draping
Hair Removal

Remove hair prior to entering the procedural room. The patient should have all hair removed from:

- Suprasternal notch to the umbilicus
- Right mid clavicular line to left posterior axillary line
- Axilla circumferentially to the elbow
Landmarks

1. **Position Patient**
   - The patient will be supine with left arm abducted no more than 60 degrees
   - Secure left arm to arm board
   - Ensure both arms are supported and restrained

2. **Mark Landmarks with a marker at the:**
   - Pocket incision and device placement/location
   - Xiphoid and/or xiphoid incision
   - Suprasternal notch
   - Sternal midline
   - Mid-axillary line

3. **The ideal pulse generator location** is between the 5th and 6th intercostal space at the mid-axillary line. The inferior edge of the device should not be below the diaphragm.

   It is recommended to mark the intended position of the electrode as well. Consider using Langer lines when marking pocket incision location. Landmarking can be done pre-procedural or on the table.

*Note: Utilize fluoroscopy as needed*
1. **Procedural Room Prep**: Surface ECG electrodes, external defibrillator pads, and grounding pad placement

   - **Surface ECG electrodes**
     - Place limb leads outside of the sterile field to record induction and time to therapy
   - **External defibrillator pads**
     - Anterior = Right upper anterior chest
     - Posterior = Left sub-scapular
     - Be mindful of sterile field when placing pads
     - Always verify placement with physician prior to draping
   - **Grounding pad**
     - place per standard of care

2. **Skin Prep**

   - Per standard of care, scrub area liberally with a wide prep
   - Extend from right mid clavicular line to left posterior axillary line, including left shoulder, axilla to the elbow, and from umbilicus to chin
Drape the Patient

1. **Towel off sterile field, ensuring all landmarks and incision marks are exposed**
   - Pocket incision and device placement/location
   - Xiphoid and/or xiphoid incision
   - Suprasternal notch
   - Sternal midline
   - Mid-axillary line

2. **Antimicrobial Impregnated Drape:**
   - Place across operative site and down left lateral side
   - Be careful not to pull skin tightly such that the incision marks are displaced. *Pat in place instead of pulling*

3. **Surgical Drape:**
   - Drape options: 1 piece fenestrated chest drape - Use large enough window without cutting, 4 piece universal drape
   - Once again, place drape making sure all landmarks and incision marks are visible
   - Surgical incisions may need to be re-marked after scrub and drape. Utilize sterile marking pen
   - Continue drape from right of sternal midline to the table on the left side per standard of care
Gender Specific recommendations:

- Consider having female patients wear/bring their bra to the pre-operative prep area
- Mark bra lines with the patient sitting in an upright position to avoid implanting the device directly under bra straps
- Mark preferred location for pocket incision to avoid the submammary area especially for female patients
- Stabilize breast tissue as necessary per standard of care
- Tunneling tool can puncture breast implants
- Consider asking female patients to abandon the use of underwire bras during recovery period as they could create areas of pressure on incisions and lead to infections
Procedure Accessories to consider:

• **Disposables**
  - Sterile wand cover
  - Incision flush solution
  - Marking pens 2+, as needed
  - MD specific skin closure

• **Sutures**
  - Non-absorbable suture (minimum of 6 packs)
  - 1 2-0 non-absorbable suture - minimum 30cm in length to create EIT/electrode loop
  - Suture material per physician preference
  - Recommend minimum of 2 layer closure for all 3 incisions

• **Instruments**
  - Standard Pacemaker/ICD surgical instrument tray
  - Retractors
  - Large Weitlaners
  - Consider utilizing a bariatric tray for larger patients
  - Headlamp for better visualization of the device pocket
  - Long nose needle drivers for anchoring to fascia
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 SICD 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.

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

(Rev. C)