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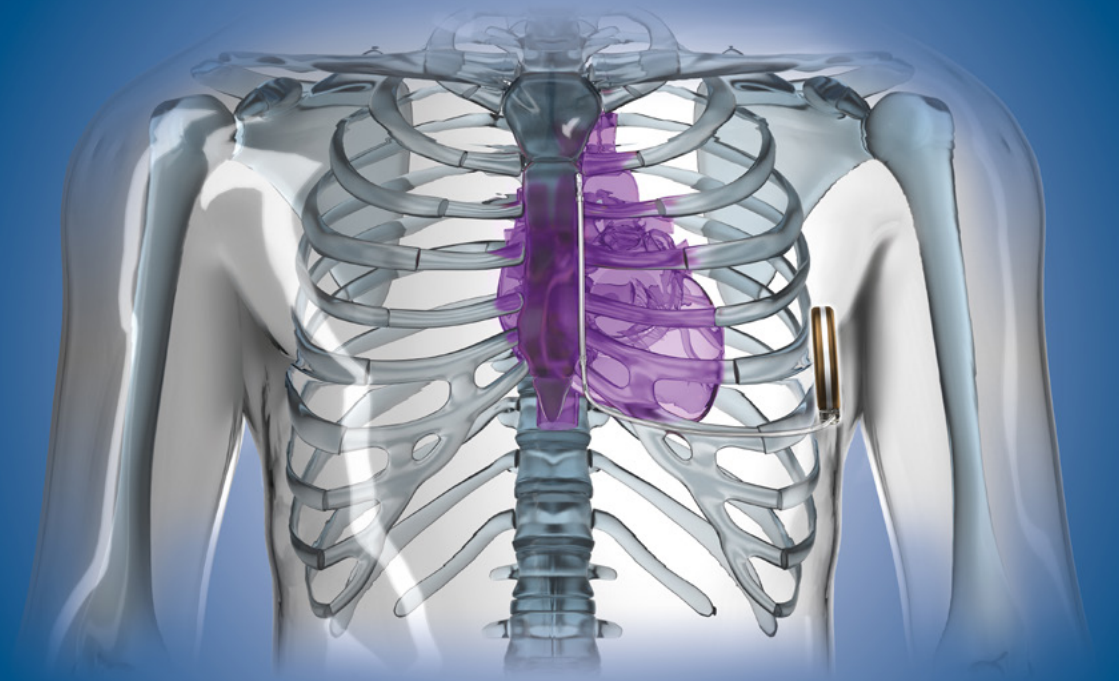
ANAESTHESIA CHAPTER

EMBLEM™ MRI S-ICD SYSTEM

Implant Best Practices

EMEA Version 2



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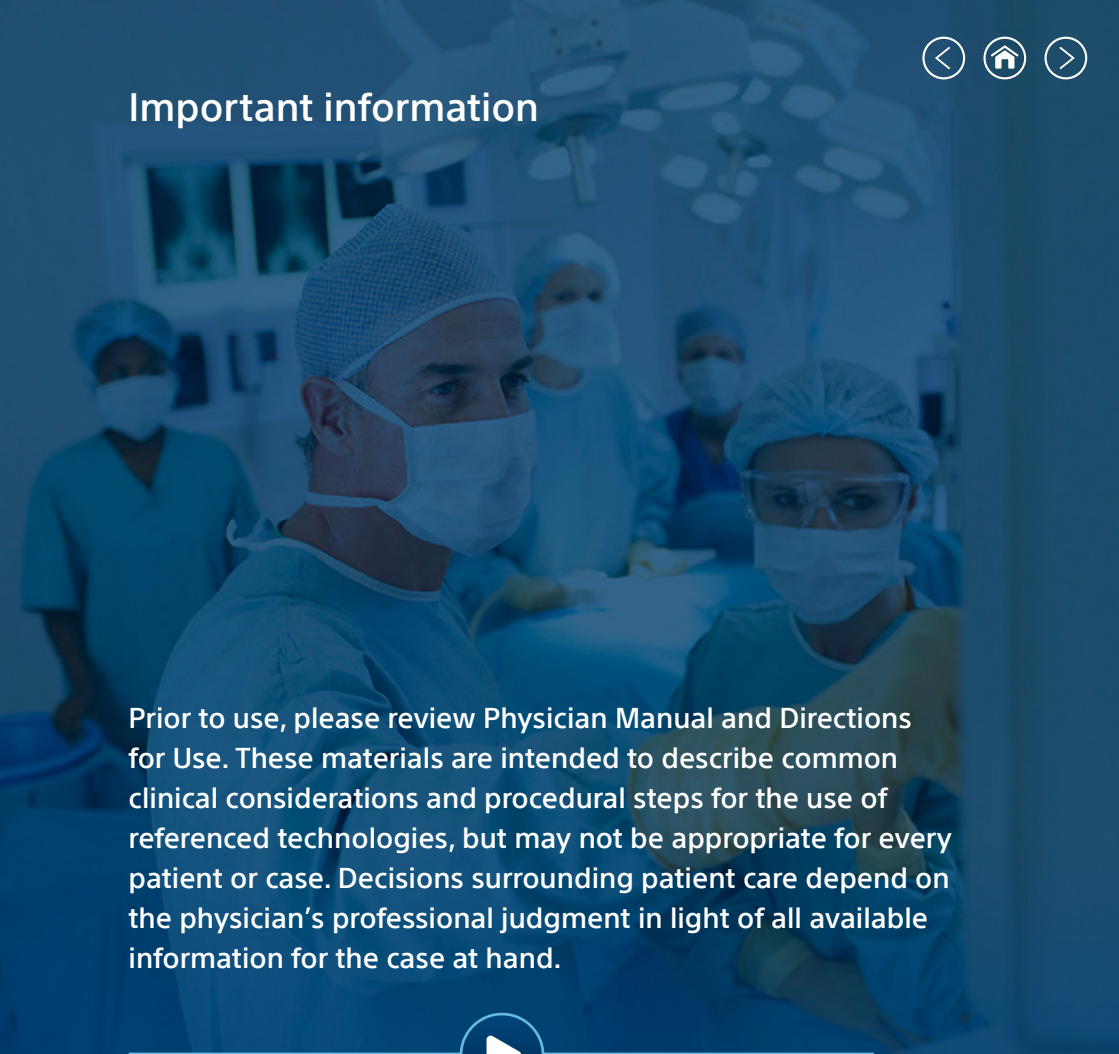
Important information



Prior to use, please review Physician Manual and Directions for Use. These materials are intended to describe common clinical considerations and procedural steps for the use of referenced technologies, but may not be appropriate for every patient or case. Decisions surrounding patient care depend on the physician's professional judgment in light of all available information for the case at hand.

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Boston Scientific extend their thanks to Dr Reinoud Knops, Prof. Jürgen Kuschyk and Dr Andrea Droghetti for their support, and expertise in the development of this document. Also to Dr Daniel Rodríguez Muñoz for providing additional S-ICD implant images, and Dr Michael Essandoh for review of the anaesthesia content.

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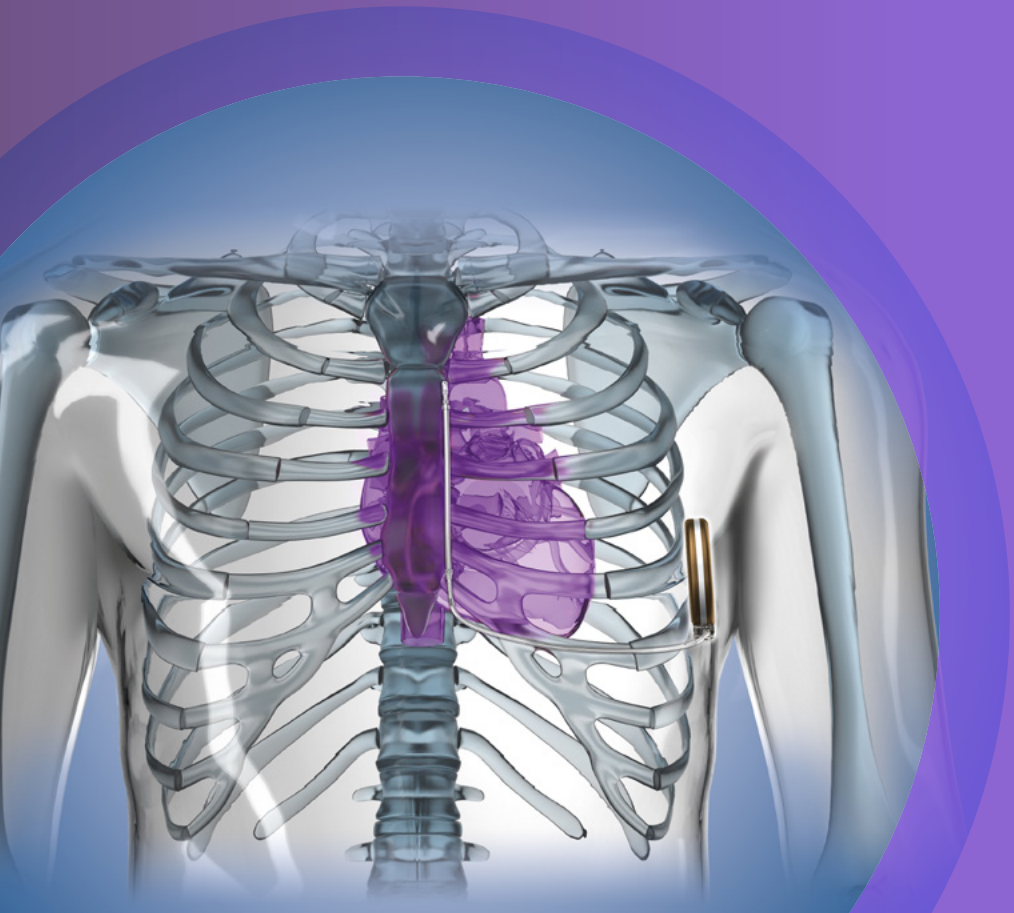
7

Anaesthesia Options when Implanting S-ICD



7 | Anaesthesia Options when implanting S-ICD

7.1 Anaesthesia Management

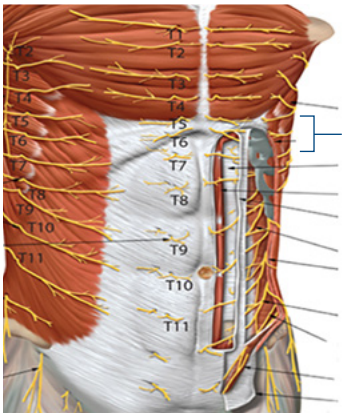
An expert panel recommended several anaesthesia options and best practices that allow implant of the S-ICD without the need for general anaesthesia.[14] In addition to adequate sedation and pain control during the implant itself, these best practices provide superior post-operative pain control and in many instances allow patients to be discharged home the same day of surgery.[14,15]

S-ICD pocket creation requires substantial dissection within the highly innervated intercostal region (T2-T9); this pocket creation, together with tunnelling and defibrillation testing requires sedation and pain control practices that are different to those used for a transvenous ICD implant.

TIP

Partner with the anaesthesia team to determine the best anaesthesia approach to utilise during the learning curve phase (first 5-10 S-ICD implants).[14]

If local anaesthesia options are utilised, it is important for the implanter to communicate with the anaesthesia provider the parts of the implant where there is a need to have deeper sedation: creating the pocket, tunnelling, and defibrillation testing.



General Anaesthesia

If general anaesthesia is employed, consider also using a long acting local anaesthetic, as this has been shown to reduce the need for post-operative opioids.[14,16-18]

Using general anaesthesia may increase costs and case time, and can cause clinically significant bradycardia and hypotension in patients with heart failure, and may prolong post-op recovery.[14]

VIDEOS

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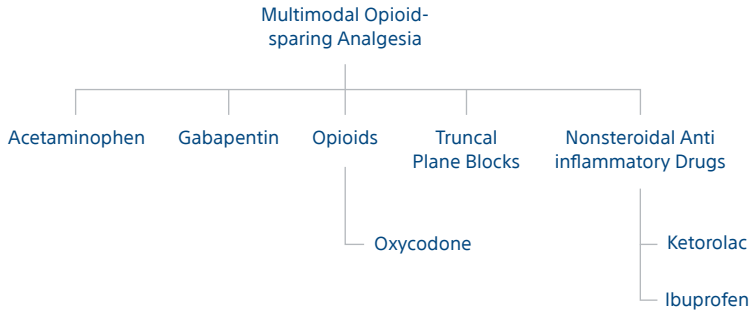
Monitored anaesthesia care (MAC) is a service provided by an anaesthesiologist or nurse anaesthetist (not general anaesthesia).

The benefits of using MAC during the S-ICD implant is that it allows the implanter to completely focus on the technical aspects of the S-ICD implant while the anaesthesia provider controls sedation and pain, and manages haemodynamics during the most stimulating points in the procedure.

This diagram displays a list of options to control post-operative pain. Some of these medications are given preoperatively, such as preoperative acetaminophen or gabapentin. Some medications are given during the implant (e.g. the long acting local anaesthetic bupivacaine), but last longer and help to prevent pain in the postoperative period. Experts believe preventing pain is a more effective approach than treating post-implant pain.[14]

Postoperative Pain Control

Enhanced Recovery for S-ICD Patients



7.2 Monitored Anaesthesia Care (MAC) (continued)

BEST PRACTICES

When utilised with a long acting local anaesthetic, such as bupivacaine, and pre-operative acetaminophen, patients can often go home the same day as the S-ICD implant.[15]

TIP

In place of 1% lidocaine, a long acting local anaesthetic (0.25% bupivacaine) at a maximum dose of 2.5 mg/kg may be used. Irrespective of body weight, the maximum dose of bupivacaine administered should NOT exceed 175 mg. Intralipid 20% should be available for intravenous infusion in the event of local anaesthetic systemic toxicity.[14]

While MAC combined with long-acting local anaesthetic and other pre-operative and post-operative multi-modal therapies is safe and very effective for S-ICD implants, it may not be the ideal anaesthesia protocol for S-ICD implants when anaesthesia services are not available.

VIDEOS

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While NASA may be more convenient to utilise, care must be taken to assure patient safety due to the risks associated with respiratory or cardiovascular complications. Especially when utilising non-reversible sedative, and hypnotic agents, such as Propofol (which has a narrow therapeutic window, and can rapidly progress from sedation to general anaesthesia).

BEST PRACTICES

- The nurse responsible for patient sedation and monitoring should be exempt from additional duties, to ensure rapid recognition and treatment of sedation-related complications.
- Patient selection must be carefully considered.
- The use of reversible sedatives and analgesics such as midazolam and opioids should be considered.
- As with a TV-ICD implant, consider GA or MAC versus NASA when the patient:
  - Is morbidly obese, has obstructive sleep apnea, severe heart failure, severe pulmonary hypertension, and/or has a challenging airway.
  - Has psychiatric illness for which psychoactive drugs are prescribed or opiates for chronic pain, as both scenarios may lead to increased sedation and analgesia requirements.
- It is important that the NASA approach only be considered once the implanter has acquired sufficient S-ICD implant experience, as NASA requires that the sedation be administered by the implanter, or by a nurse under the direct supervision of the implanter.
- The use of a long acting local anaesthetic such as 0.25% bupivacaine in the pocket and preoperative acetaminophen and/or oxycodone is recommended when utilising the NASA approach.[14]

TIP

For implanters who have deep sedation privileges at their institution, the use of small bolus doses of etomidate 0.1 mg/kg is recommended over the use of propofol due to the potential for cardiovascular and respiratory depression with propofol.[14]

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7.4 Truncal Plane Blocks

Truncal Plane Blocks, including the serratus anterior plane block (SAPB) are quick and easy to administer (5 – 10 minutes),[19] and should be administered up to a minimum of 40 minutes before the implant procedure.

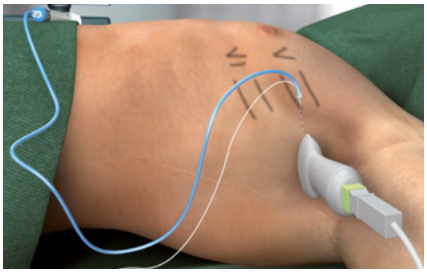
SAPB provides long acting anaesthesia (480 minutes) to the lateral branches of intercostal nerves from the T2 to T9 level with excellent results.[16,17,19-21]

EQUIPMENT NEEDED[21]

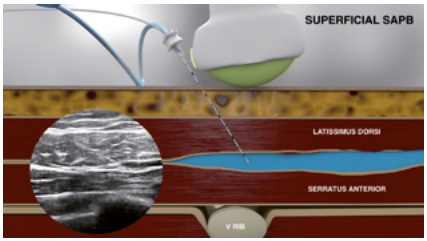
- 50 – 120 mm, 21 – 22 gauge needle
- High-frequency linear ultrasound (US) probe

1. With the patient in a supine position, starting at the clavicle, count the ribs inferiorly and laterally, down to the fifth rib in the midaxillary line. The latissimus dorsi (superficial and posterior), teres major (superior) and serratus muscles (deep and inferior) are then easily identifiable by ultrasound overlying the fifth rib.
2. Infiltrate the skin at the puncture site with local anaesthesia.
3. Insert the needle into the plane under US guidance with the probe in a anteroposterior direction.

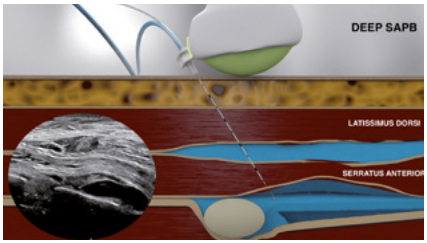
a. Ultrasound-guided SAPB[21]



b. Injection of anaesthesia into the superficial interfascial plane between latissimus dorsi and serratus anterior[21]



c. Injection of anaesthesia between serratus anterior and intercostal muscles[21]



TIP

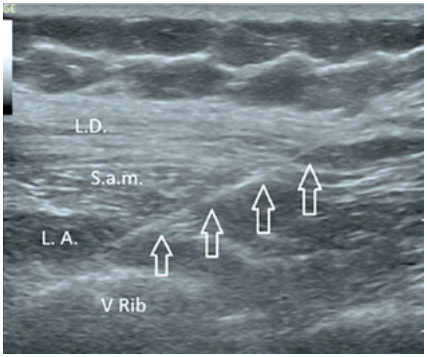
Ensure that the needle is in the same plane as the probe so that it can be visualised.

BEST PRACTICES

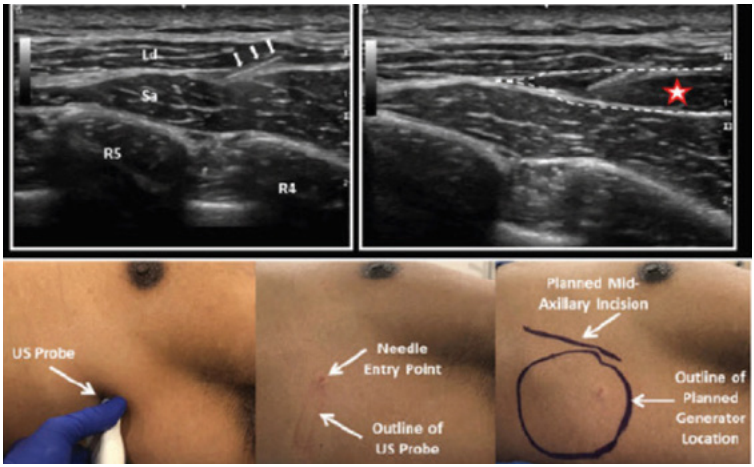
Communication with the patient is important, particularly when using local anaesthesia techniques, as it puts the patient at ease and may improve the overall experience and acceptance of the device.[22]

1. Identify the two areas the anaesthesia is to be delivered:
   - Superficial interfascial plane between the serratus anterior and latissimus dorsi muscle.
   - Deeper block between serratus anterior and ribs plane.
2. Inject saline solution to open the fascia, followed by injection of anaesthetic solution.

Figure 1: Deep serratus anterior plane block[22]



L.A. = local anaesthetic
L.D. = latissimus dorsi
S.a.m. = serratus anterior muscle



Figures 2: Shows serratus anterior plane block demonstrating the injection site on the chest wall and the corresponding ultrasound images of the injection above and below the serratus anterior muscle.[17]

NOTE

Ensure that the anaesthesia is administered between the muscle layers and not directly into the muscle.

TIP

Ensure that sufficient volume (appropriate dose according to the patient weight) of anaesthesia is used to fully permeate the layers.

Implantation of S-ICD using SAPB may also result in less post-operative pain, and reduce post-operative opioid use.[17]

"Discuss the option of plane blocks with your anaesthesia provider and determine if this might be an appropriate option for patients who are not able to tolerate general anaesthesia or MAC, or in obese patients who may require more local anaesthetic."[23]

VIDEOS

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14

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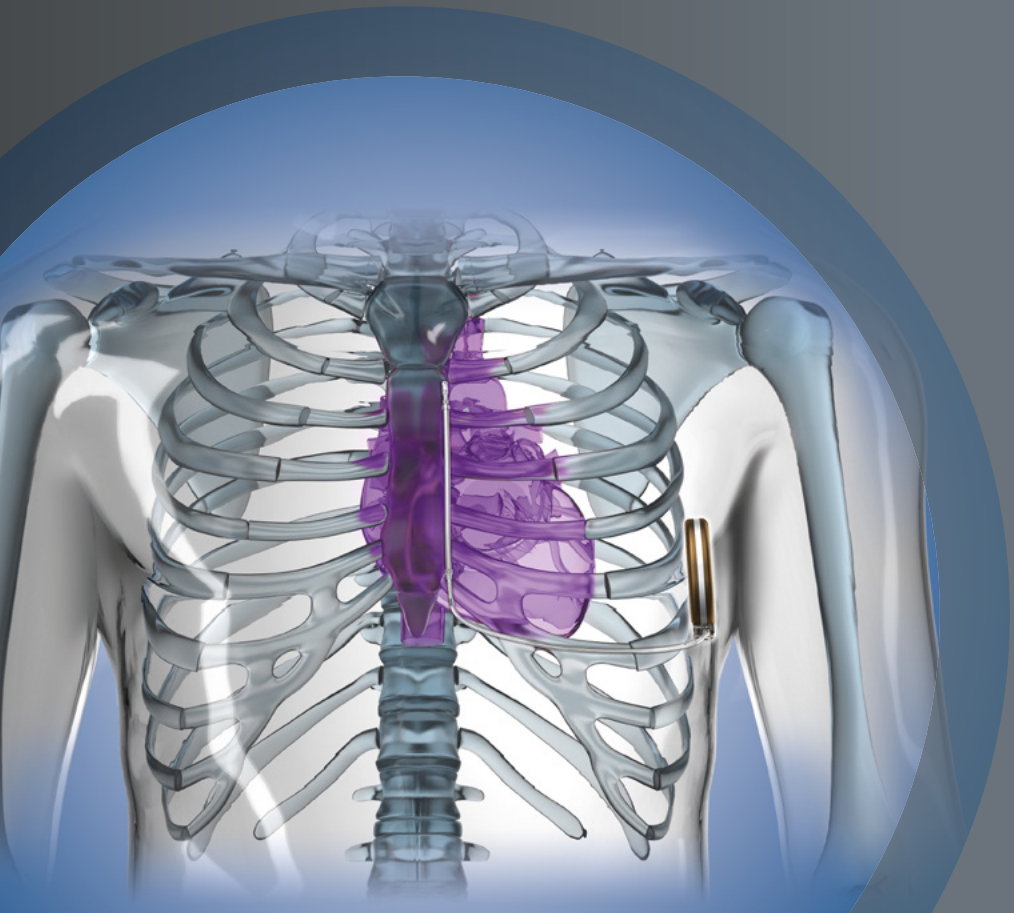

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Emblem™ MRI S-ICD System

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 anti-tachycardia pacing.

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

WARNINGS
Concomitant use of the S-ICD System and implanted electromechanical devices (for example implantable neuromodulation/neurostimulation systems, 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. The S-ICD is intended as lifesaving therapy and should be seen as priority in the decision and evaluation of concomitant system implants over non-lifesaving applications. Electromagnetic (EMI) or therapy delivery from the co-implanted 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 co-implanted device and/or compromise its functionality. Verify sensing configuration, operation modes, surgical considerations and existing placement of all involved devices prior to any co-implant. 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 co-implanted device. Induction testing is recommended to ensure appropriate detection and time to therapy for the S-ICD and appropriate post-shock operation of the co-implanted device. Failure to ensure appropriate detection and time to therapy delivery of the S-ICD system could result in patient injury or death. Following completion of the interaction testing, thorough follow-up evaluation of all co-implanted devices should be performed to ensure that device functions have not been compromised. If operational settings of the co-implanted devices change or if patient conditions changes which may affect S-ICD sensing and therapy performance, re-evaluation of the co-implanted devices may be required. Do not expose a patient with an implanted S-ICD System to diathermy. EMBLEM S-ICD devices are considered MR Conditional. Unless all MRI Conditions of Use are met, MRI scanning of the patient does not meet MR Conditional requirements for the implanted system. The Programmer is MR Unsafe and must remain outside the MRI site Zone III. During MRI Protection Mode the Tachycardia therapy is suspended. MRI scanning after ERI status has been reach may lead to premature batter depletion, a shortened device replacement window, or sudden loss of therapy. The Beeper may no longer be usable following an MRI scan.

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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, supplemental precautionary information.

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.

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. E) 046774 AI

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