Boston Scientific
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EMBLEM™ MRI S-ICD SYSTEM

Subcutaneous Implantable Defibrillator

System Specifications

The EMBLEM MRI S-ICD is the second device in the EMBLEM S-ICD family and builds on previous size, longevity and remote patient management enhancements. Like transvenous ICDs, the EMBLEM MRI S-ICD System utilizes a pulse generator capable of delivering life-saving therapy. Unlike traditional ICDs, the EMBLEM MRI S-ICD System leaves the heart and vasculature untouched, avoiding potential complications associated with transvenous leads.

The EMBLEM MRI S-ICD has been tested and approved for use in the MR environment when the conditions of use are met. It contains a separate MRI mode with a timer that will automatically return the device to programmed settings. AF Monitor™ has also been added. This is a tool designed to assist in the detection of new onset, silent, or the progression of AF through R-R variability. The new SMART Pass filter is designed to reduce cardiac over-sensing and bench testing has demonstrated a >40% reduction in inappropriate therapy.

Pulse Generator Specifications[1,2]

Mechanical Specifications

Model Number	A219
Size (W x H x D)	83.1 x 69.1 x 12.7 mm
Mass	130 g
Volume	59.5 cc (cm^3)
Longevity	7.3 years*
Battery	Boston Scientific Li/MnO_2
Device C-Code	C1722

NEW ImageReady™ MR-Conditional Technology

Compatible Electrodes	3400, 3401
Magnet Strength	1.5T
Specific Absorption Rate (SAR) limits for the entire active scan (Normal Operating Mode)	• Whole body averaged, ≤ 2.0 watts/kilogram (W/kg) • Head, ≤ 3.2 W/kg
There are no anatomical exclusion zones or time restrictions.	

Programmable Parameters

Shock Zone	170 bpm - 250 bpm (steps of 10 bpm)
Conditional Shock Zone	Off, On 170 bpm - 240 bpm (minimum 10 bpm less than Shock Zone)
S-ICD System Therapy	Off, On
Post-shock pacing	Off, On (50 ppm, max 30 sec, demand-based)
Induction capability	1-10 sec (50 Hz/200 mA)
Delivered Energy	80J biphasic (only programmable during manual shock and induction test: 10J - 80J, steps of 5J)
Shocks per episode	Maximum of 5 shocks

Diagnostic Tools

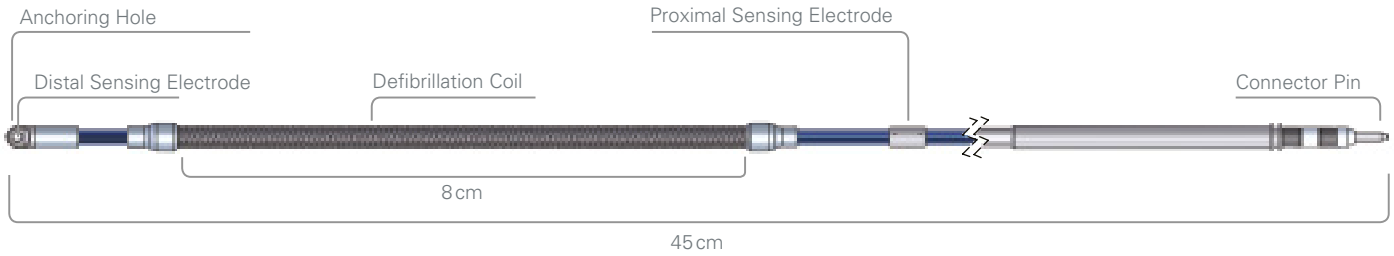
NEW AF Monitor	Information Provided: • Number of days with measured AF in the last 90 days • Estimate of measured AF in the last 90 days (%) Performance: Sensitivity >= 87% Positive Predictive Value >=90%
Episode storage	S-ECG storage for over 40 arrhythmic events (treated & untreated)
Other data	Electrode impedance System status (remaining battery life, patient alerts, etc.) Date and time stamp

NOTE: Longevity projections and the associated energy consumption is based on bench testing only.

1. EMBLEM MRI S-ICD User's Manual 359480-001 EN US 2015-11
2. MRI Technical Guide 359474-001 EN US 2015-11

EMBLEM™ MRI S-ICD SYSTEM

Subcutaneous Electrode Specification



Specifications

Model Number	3401
Type	Tripolar
Length	45 cm
Distal tip size (Diameter)	12 Fr/4 mm
Coil size (Diameter)	9 Fr/3 mm
Electrode shaft size (Diameter)	7 Fr/2.33 mm
Sensing surface area	
Distal	36 mm^2
Proximal	46 mm^2
Sensing location	
Distal	Distal electrode at tip
Proximal	120 mm from tip
Defibrillation surface area	750 mm^2
Defibrillation location	20 - 100 mm from tip
Materials	
Insulation	Polyurethane
Electrodes	MP35N
Conductors	MP35N
Connector pin	MP35N
Suture Sleeve	Silicone
Electrode C-Code	C1896

EMBLEM™ MRI 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 the 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 S-ICD System only. Connection of any S-ICD System components to a non-compatible 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 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 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 co-implanted 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. Do not implant in MRI site Zone III. Use caution when placing a magnet over the S-ICD 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. 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 (and higher). 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. It is strongly recommended that patients are followed on LATITUDE NXT after an MRI scan if they are not already. 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.

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.
For a list of all potential adverse events associated with MRI scanning, refer to the MRI Technical Guide. Rx only.
(Rev A)

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