Boston Scientific
Advancing science for life™

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. Data from the head to head PRAETORIAN trial demonstrated non-inferiority and concluded that the S-ICD has comparable performance to transvenous ICDs (P=0.01). Unlike transvenous ICDs, the EMBLEM MRI S-ICD System leaves the heart and vasculature untouched, which results in significantly fewer lead complications (P=0.001) as well as fewer complications overall.[1]

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 SMART Pass filter is designed to reduce cardiac over-sensing and data has demonstrated that the inappropriate shock rate for S-ICD is now lower than transvenous ICDs.[2]

Pulse Generator Specifications[3,4]

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	8.7 years*
Battery	Boston Scientific Li/MnO_2
Device C-Code	C1722

ImageReady™ MR-Conditional Technology

Compatible Electrodes	3010, 3400, 3401, 3501
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

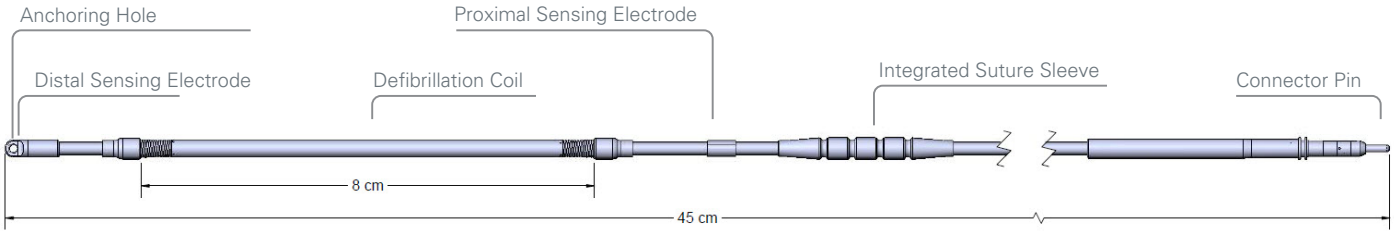
AF Monitor	Information Provided: • Number of days with measured AF in the last 90 days • Estimate of measured AF in the last 90 days (%) Performance: Sensitivity ≥ 87% Positive Predictive Value ≥ 90%
Episode storage	S-ECG storage for over 40 arrhythmic events (treated and untreated)
Other data	Electrode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

*NOTE: Longevity projections and the associated energy consumption is based on analysis of >2900 Emblem patients followed on LATITUDE. June 2017.

1. Knops R. et al., A Randomized Trial of Subcutaneous versus Transvenous Defibrillator Therapy: The PRAETORIAN Trial. Heart Rhythm Society Late Breaking Clinical Trials LBCT-01 2020.
2. Gold M. et al., Understanding Outcomes With The S-ICD In Primary Prevention Patients With Low Ejection Fraction (UNTOUCHED) Trial Primary Results. Heart Rhythm Society Late Breaking Clinical Trials LBCT-02 2020.
3. EMBLEM MRI S-ICD User's Manual 359480-004 EN US 2018-10.
4. MRI Technical Guide 359474-001 EN US 2015-11.

EMBLEM™ MRI S-ICD SYSTEM

Subcutaneous Electrode Specifications



Specifications

Model Number	3501
Type	Tripolar
Length	45 cm
Distal tip size (Diameter)	11.5 Fr/3.84 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	At tip
Proximal	120 mm from tip

Specifications

Defibrillation surface area	750 mm^2
Defibrillation location	20 - 100 mm from tip
Materials	
Insulation	Polycarbonate polyurethane
Electrodes	MP35N
Conductors	MP35N
Connector pin	MP35N
Integrated Suture Sleeve	Radiopaque White Silicone
Slit Suture Sleeve	Silicone
Electrode C-Code	C1896

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.

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CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.

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