EMBLEM™ MRI
S-ICD System

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

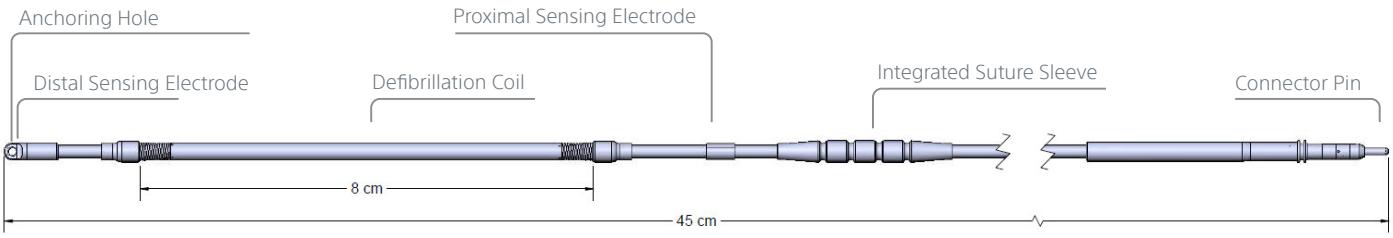
Diagnostic Tools

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.

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 electro-mechanical 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. • 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 non-compatible component has not been tested and could 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. If not terminated in a timely fashion, an induced ventricular tachyarrhythmia can result in the patient's death. • 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. Refer to „S-ICD System and Pacemaker Interaction" on page 73 for more information. • Attention is required to placement of the arm ipsilateral to the device implant to avoid injury of the ulnar nerve and brachial plexus while the patient is in the supine position during device implantation and before VF induction or shock delivery. The patient should be positioned with the arm abducted to an angle of no more than 60° with the hand in a supinated (palm up) position during the implant phase of the procedure. Securing the arm to an arm board is standard practice to maintain positioning of the arm during device implantation. Do not strap the arm too tightly during defibrillation testing. Elevation of the torso through use of a wedge may also add stress to the shoulder joint and should be avoided during defibrillation testing. • Use appropriate anchoring techniques as described in the implant procedure to prevent S-ICD System dislodgement and/or migration. Dislodgement and/or migration of the S-ICD System may result in an inappropriate shock or failure to deliver therapy to the patient. • Use caution when placing a magnet over the S-ICD pulse generator because it suspends arrhythmia detection and therapy response. Removing the magnet resumes 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. In this case the magnet cannot be used to inhibit therapy. • 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. • High shocking electrode impedance may reduce VT/VF conversion success. • When positioning the electrode and pulse generator, avoid excessive tension on the electrode, particularly if the electrode body extends over the pulse generator. This could cause structural damage, abrasion, and/or conductor discontinuity. • Although pliable, the electrode is not designed to tolerate excessive flexing, tight radius bending, kinking, or twisting. This could cause structural damage, conductor discontinuity, electrode migration, and/or dislodgement. • Electrode fracture, abrasion, under-insertion of the electrode connector into the pulse generator connector port, or a loose setscrew connection may result in compromised sensing, loss of therapy, or inappropriate therapy. • Following any sensing parameter adjustment or any modification of the subcutaneous electrode, always verify appropriate sensing. • Determine if the device and programmed parameters are appropriate for patients with SVTs because SVTs can initiate unwanted device therapy. • During a device software update, tachycardia therapy is suspended. Always monitor the patient and have external defibrillation equipment available during interrogation. • 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) as defined by the American College of Radiology Guidance Document on MR Safe Practices. • During MRI Protection Mode the Tachycardia therapy is suspended. • MRI scanning after ERI status has been reached may lead to premature battery depletion, a shortened device replacement window, or sudden loss of therapy. • The Beeper may no longer be usable following an MRI scan. • The pulse generator may be more susceptible to low frequency electromagnetic interference at induced signals greater than 80 uV. • Immersion in saltwater and similar conductive fluid environments (i.e. ocean, saltwater pools) may divert some defibrillation shock energy away from the patient's heart into the surrounding conductive fluid (as evidenced by a lower-than-normal shock impedance). This may reduce VT/VF conversion success, especially in patients with low BMI.

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. • 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 antitachycardia pacing (ATP). • When implanting the S-ICD system in a patient with sternal wires, ensure that there is no contact between the sternal wires and the distal and proximal sense electrodes (for example, by using fluoroscopy). Compromised sensing can occur if metal-to-metal contact occurs between a sense electrode and a sternal wire. If necessary, re-tunnel the electrode to ensure sufficient separation between the sense electrodes and the sternal wires. • Implanting a replacement device in a subcutaneous pocket that previously housed a larger device may result in pocket air entrapment, migration, erosion, or insufficient grounding between the device and tissue. Irrigating the pocket with sterile saline solution decreases the possibility of pocket air entrapment and insufficient grounding. Suturing the device in place reduces the possibility of migration and erosion.
Electromagnetic Interference (EMI) Precautions • Avoid electromagnetic interference (EMI). Advise patients to avoid sources of EMI because EMI may cause the pulse generator to deliver inappropriate therapy or inhibit appropriate therapy. • Moving away from the source of the EMI or turning off the source usually allows the pulse generator to return to normal operation. • Examples of potential EMI sources are: - Electrical power sources - Arc welding or resistance welding equipment (should remain at least 24 inches from the implant) - Robotic jacks - High voltage power distribution lines - Electrical smelting furnaces - Large RF transmitters such as radar - Radio transmitters, including those used to control toys - Electronic surveillance (antitheft) devices - An alternator on a car that is running - Medical treatments and diagnostic tests in which an electrical current is passed through the body, such as TENS, electrocautery, electrolysis/thermolysis, electrodiagnostic testing, electromyography, or nerve conduction studies - Any externally applied device that uses an automatic lead detection alarm system (e.g., an EKG machine) • Home appliances. Home appliances that are in good working order and properly grounded do not usually produce enough EMI to interfere with pulse generator operation. There have been reports of pulse generator disturbances caused by electric hand tools or electric razors used directly over the pulse generator implant site. • Electronic Article Surveillance (EAS) and security systems. Advise patients how to avoid impact to cardiac device function due to antitheft and security gates, tag deactivators, or tag readers that include radio frequency identification (RFID) equipment. These systems may be found at the entrances and exits of stores, at checkout counters, in public libraries, and in point-of-entry access control systems. Patients should avoid lingering near or leaning against antitheft and security gates and tag readers. In addition, patients should avoid leaning against checkout counter-mounted and handheld tag deactivation systems. Antitheft gates, security gates, and entry control systems are unlikely to affect cardiac device function when patients walk through them at a normal pace. If the patient is near an electronic antitheft, security, or entry control system and experiences symptoms, they should promptly move away from nearby equipment and inform their doctor. • Cellular phones. Patients should not carry a cellular phone within 15 cm (6 inches) of the implanted device in order to avoid interaction which may cause the pulse generator to deliver inappropriate therapy or inhibit appropriate therapy. Advise patients to hold cellular phones to the ear opposite the side of the implanted device, and to avoid storing a cellular phone within 15 cm (6 inches) of the implanted device. Examples of storage locations to be avoided include a breast or other shirt pocket, on a belt, or in a handbag held near the implant location. • Static magnetic fields. Advise patients that extended exposure to strong (greater than 10 gauss or 1 mTesla) magnetic fields may suspend arrhythmia detection. Examples of permanent magnet—containing sources to be aware of include: - Industrial motors if held within 60 cm (24 inches) of the pulse generator - MRI scanners - Large stereo speakers if held within 60 cm (24 inches) of the pulse generator - Telephone receivers if held within 1.27 cm (0.5 inches) of the pulse generator - Magnetic wands such as those used for airport security and in the Bingo game - Cellular phones, ear buds, or headphones, if held within 15 cm (6 inches) of the pulse generator - Magnetically attached charging port or cable, such as used in laptops or cellular phones, if held within 15 cm (6 inches) of the pulse generator - Be aware of other body-worn items which may contain magnets, such as wrist bands, jewelry, clothing, nametags, CPAP masks, etc.

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 • Organ injury or perforation • Pneumothorax • Post-shock/post-pace discomfort • Premature battery depletion • Random component failures • Stroke • Subcutaneous emphysema • Surgical revision or replacement of the system • Syncope • Tissue damage • Tissue redness, irritation, numbness or necrosis • Vessel injury or perforation Transient procedural adverse events are expected in some patients. These include, but are not limited to, discomfort, pain and other systemic symptoms that might be related to medications or other interventions performed during implant. 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 "Instructions for Use"and MRI Technical Guide for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.

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