Boston Scientific
Advancing science for life™

EMBLEM™ S-ICD SYSTEM

Subcutaneous Implantable Defibrillator

System Specifications

The EMBLEM S-ICD System has been built upon the excellent clinical performance of the world's first and only S-ICD System[1], providing protection from sudden cardiac arrest (SCA) while leaving the heart and vasculature untouched. Like transvenous ICDs, the S-ICD System utilizes a pulse generator capable of delivering life-saving therapy. Unlike transvenous ICDs, the S-ICD System uses a subcutaneous electrode and analyzes the heart rhythm – rather than individual beats – to effectively sense, discriminate, and convert VT/VF.

For years patients' lives have been extended by implanting transvenous implantable defibrillators. The EMBLEM S-ICD System provides a new solution to protect patients from SCA without touching the heart, which avoids potential complications associated with transvenous leads.

Pulse Generator Specifications*

Mechanical Specifications

Model Number	A209
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
Electrode compatibility	3400/3401
Device C-Code	C1722

Automatic Functions

Sensing configuration	Primary (ring to can), Secondary (tip to can), Alternate (tip to ring) Optimal sensing configuration automatically selected during Auto Setup (manual programming optional)
Gain selection	x1, x2 Optimal gain selection automatically selected during Auto Setup (manual programming optional)
Rhythm discrimination	INSIGHT™ algorithm discriminators automatically activated when the Conditional Shock Zone is programmed
Shock polarity	Standard (coil to can), reverse (can to coil) Automatically selects and stores last successful shock polarity
Adaptive Shock Polarity	Shock polarity alters automatically after failed shock
SMART Charge	Automatically extends initial detection time to allow self termination of non-sustained tachyarrhythmias
Internal warning system	Audible tone alerts patient to elective replacement indicator, electrode impedance out of range, prolonged charge times, failed device integrity check

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

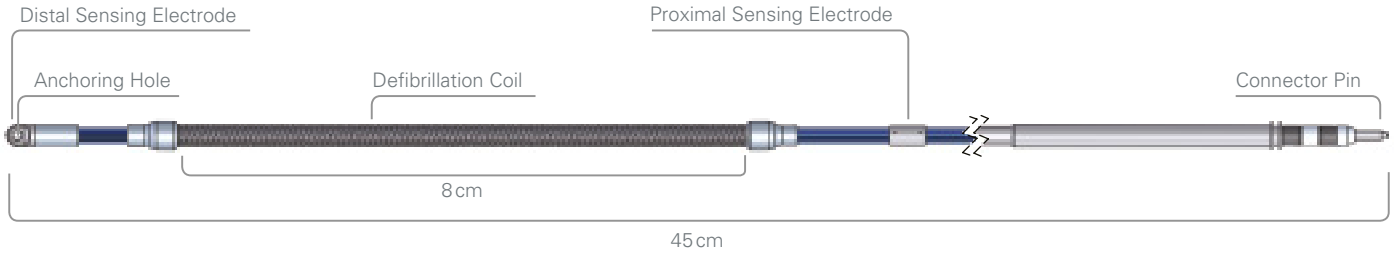
Diagnostics

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

1. As of March 1, 2015
* Pulse generator user's manual, 359279-001, 359278-002
** Based on 3 annual full energy charges

EMBLEM™ 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	46 mm^2
Proximal	36 mm^2
Sensing location	
Distal	Distal electrode 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™ 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 this 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 or Cameron Health S-ICD System only. Connection of any S-ICD System components to a noncompatible 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 coimplanted 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 coimplanted 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 coimplanted 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. Use caution when placing a magnet over the SICD 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. Do not expose a patient to MRI scanning. 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.

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

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