

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	130g
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, 3501
Magnet Strength	1.5T
Specific Absorption Rate (SAR) limits for the entire active scan (Normal Operating Mode)	<ul style="list-style-type: none"> • 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	<p>Information Provided:</p> <ul style="list-style-type: none"> • Number of days with measured AF in the last 90 days • Estimate of measured AF in the last 90 days (%) <p>Performance: Sensitivity ≥ 87 % Positive Predictive Value ≥ 90 %</p>
Episode storage	S-ECG storage for over 40 arrhythmic events (treated & untreated)
Other data	<p>Electrode impedance</p> <p>System status (remaining battery life, patient alerts, etc.)</p> <p>Date and time stamp</p>

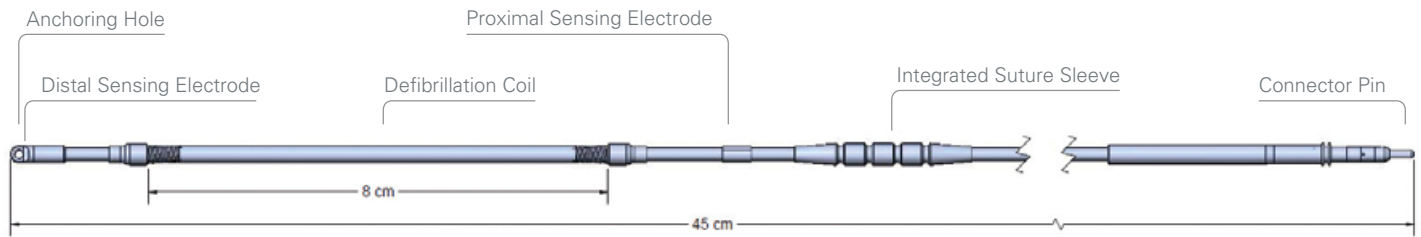
* Longevity projections and the associated energy consumption is based on bench testing only.

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

2. MRI Technical Guide 359474-001 EN US 2015-11

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Subcutaneous Electrode Specification



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
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



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