PROPONENT™ MRI Pacing System*

ImageReady™ MR Conditional Pacing System

Models L209, L210, L211

- Provides an ImageReady™ MR Conditional pacing system* at 3T and 1.5T, full body, with no time limitations, with automatic MRI timeout feature to optimize workflow in the MR environment**
- Atrial Arrythmia Report provides a comprehensive and proactive approach for comorbidity management
- RF telemetry for wireless transmission of information and efficiency in the operating room and follow-up setting
- LATITUDE™ NXT Remote Patient Management enabled, offering the opportunity for wireless (RF) remote patient monitoring and follow-up
- PaceSafe™ RV and RA, providing dynamic adjustment of pacing outputs to ensure capture, to maximize efficiency and ease of use
- RightRate™ – MV sensor technology and the only MV sensor clinically proven to restore chronotropic competence[1]
- RYTHMIQ™, designed to minimize unnecessary RV pacing without clinically significant pauses, therefore reducing the risk of HF development
- Enhanced features and diagnostics including Respiratory Rate Trend, designed to provide you with greater insight into your patient's disease progression based on the patient's own respiration
- POST function to facilitate patient follow up with a fully automatic device and lead check
- EASYVIEW™ header with port identifiers designed to make the implant experience more efficient

*Please refer to MRI Technical Guide.
**L209 is not ImageReady™ MR Conditional pacing system.

Mechanical Specifications

Model	Type	Size (cm) (W x H x D)	Mass (g)	Volume (cc)	Connector Type (RA RV LV)
L209 (non-MRI model)	VDDR	4.45 x 5.02 x 0.75	24.8	13.7	RA: IS1 – RV: IS1
L210	SR	4.45 x 4.81 x 0.75	23.6	13.2	RA/RV: IS1
L211	DR	4.45 x 5.02 x 0.75	24.8	13.7	RA: IS1 – RV: IS1

Projected Longevity

Pacing		SR	DR	VDDR
50%	RA/RV 2.5V	10.4	9.3	10.0
100%	RA/RV 2.5V	9.7	8.2	9.4

Additional Longevity Information

- Settings: pacing pulse width 0.4ms, Impedance 750Ω, LRL 60bpm, Sensor On, EGM Onset On. These calculations also assume that the pulse generator spends 6 months in Storage mode during shipping and storage, the ZIP™ telemetry use for 1 hour at implant time and for 40 minutes annually for in-clinic follow-up checks. For longevity calculations based on different settings please contact Boston Scientific technical services or your local representative.
- Power Supply SR,DR and VDDR models: lithium-carbon monofluoride cell; Boston Scientific; 402290.

PROPONENT™ MRI Pacing System

ImageReady™ MR Conditional Pacing System

Models L209, L210, L211

Pacing Therapy

Brady Modes	Normal:DDD(R)-DDI(R)-VDD(R)-VVI(R)-AAI(R)-DOO-VOO-AOO-Off Temporary: DDD-DDI-VDD-VVI-AAI-DOO-VOO-AOO-Off
AT/AF Management	ATR Mode Switch, Ventricular Rate Regulation (VRR), Atrial Flutter Response (AFR), Atrial Pacing Preference (APP), ProACt, Rate Smoothing
Automaticity	Automatic Gain Control (AGC) for sensitivity Right Atrial Automatic Threshold (RAAT) Right Ventricular Automatic Capture (RVAC)
Rate Adaptive Pacing	Accelerometer, RightRate™ (Minute Ventilation) or blended sensors with sensor trending function
RV Pacing Reduction	AV Search +, RYTHMIQ™, AV Delay to 400 ms, Rate Hysteresis
Rate Management	Sudden Brady Response (SBR), PMT Termination, PVARP after PVC, Dynamic PVARP
Pace/Sense Configuration	Unipolar, Bipolar, Bipolar/Unipolar, Unipolar/Bipolar, Unipolar/Off, Bipolar/Off, Lead Safety Switch

Patient Diagnostics

Arrhythmia Logbook	Event Summary, Stored Electrograms with Annotation Markers (Intervals and approximately 14 minutes all multi channel EGM, always with 10 seconds Onset and event storage prioritization). Implant activation of all available EGMs. On screen measurements of all stored signal, amplitudes and timing. Snapshot Function (up to 12 seconds trace of ECG/EGM display stored)
Histograms & Counters	Ventricular Tachy Counter, Brady Counter, Hystograms, Intrinsic Promotion (Rate Hysteresis % successful and AVSH+ % successful)
HF Therapy / Diagnostics	Respiratory Rate Trend, AT/AF Burden, Activity Level, A & V Arrhythmias, Weight and Blood Pressure*
Atrial Arrythmia Report	AT/AF% and Total Time in AT/AF, AT/AF Burden Trend, RV Rate during AT/AF Trend, Pacing Percent Trend, Heart Rate Trend, Activity Level and Respiratory Rate Trends, RV Rate during AT/AF Histogram. Timeline history of interrogations, programming, and counter resets for one year. Longest AT/AF, Fastest RVS rate in AT/AF, and most recent episode.
DAILY TREND for last 365 Days	Events, Activity Level, AT/AF Burden, Pacing Percent, Respiratory Rate Trend, Heart Rate, Lead Impedance and Amplitude, RAAT Trend, RVAC Trend

*Weight and Blood Pressure are only available via Latitude.

ImageReady™

MRI Lead Selection	Pulse Generator MR-conditional with all FINELINE™II Sterox, FINELINE™II Sterox EZ and INGEVITY™ Pacing Lead Models
MRI Conditions	Full body scan at 1.5T (≤SAR 2W/Kg) for all FINELINE™II models** Full body scan at 3T and 1.5T (≤SAR 4W/Kg) for all INGEVITY™ MRI models**
MRI Mode	Pacing Mode: AOO,VOO,DOO,Off Protection Time Out: Off, 12,24,48 hours

* ImageReady™ is not available for VDDR model.

**Please refer to the Pacing System MRI Technical Guide as the system is designated as MR Conditional in accordance with specified conditions.

Implant/In Clinic Follow Up

Implant Communication Mode	Programmable values: Enable use of ZIP™ telemetry (MICS) (Requires initial use of wand for device ID) or use wand for all telemetry Nominal: Enable use of ZIP™ telemetry (Requires initial use of wand for device ID)
In Clinic Follow Up	Snapshot Function up to 12 seconds trace of ECG/EGM display stored POST (Post-Operative System Test): provides an automatic device/lead check at a pre-determined time post-implant to help document proper system functionality without requiring manual system testing
Indications-Based Programming (IBP)	Tool that provides specific programming recommendations based on the patient's clinical needs and primary indications

Remote Follow Up

Remote Monitoring	This device is designed to be LATITUDE™ NXT enabled; LATITUDE NXT availability varies by region
Thresholds	Automatic storage of last successful daily PaceSafe threshold test for all active chambers
Wireless	Remote follow-up for all devices (MICS)
Patient Triggered Monitor (PTM)	Triggers the storage of two minutes onset and one minute post – EGMs, intervals, and annotated marker data during a symptomatic episode by placing a magnet over the device

Safety Functions*

Safety Core	Is intended to provide life-sustaining therapy if certain non-recoverable or repeat fault conditions occur. Safety Core operates independently and acts as a backup to these components
Electrocautery Protection Mode	Provides asynchronous pacing at the programmed outputs and LRL when commanded by the programmer

*The Safety Functions do not have programmable parameters.

* CE Mark pending, not available for sale in the EEA.

1. Chronotropic competence is defined by the Model of the Cardiac Chronotropic Response to Exercise. Wilkoff B, Corey J, Blackburn G. A mathematical model of the cardiac chronotropic response to exercise. Journal of Electrophysiology. 1989;3:176–180. Refer to the Physician's System Guide for more information on adaptive-rate therapy. Additional clinical performance was assessed using INSIGNIA™ Ultra clinical data with the AutoLifestyle™ feature programmed On. Boston Scientific. Data on file. ALTRUA™ Pacemaker System Guide. 2008;1:20–25.monthly Full Interrogations (scheduled remote follow ups, and quarterly patient-interrogations).

CRM-251101-AA JUL2014 Printed in the Netherlands by Gosling.

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www.bostonscientific-international.com
www.bostonscientific.com/warranty

poz.1
poz.3

INGEVITY™+ Pacing Lead

Active Fixation Models: 7840, 7841, 7842

The INGEVITY+ pacing leads are 6F (2.0 mm) steroid-eluting, endocardial pace/sense leads designed for permanent implantation for either atrial or ventricular applications.

INGEVITY+ is built on the proven INGEVITY platform, with nearly 700,000 INGEVITY leads sold worldwide with a 99.2% reliability at 7 years.[1]

INGEVITY+ is specifically designed with three layers of insulation between conductors and a polyurethane lead body. The tri-filar inner coil design provides consistent, low, and repeatable turn counts when extending and retracting the helix[2].

These leads utilize an IS-1 bipolar connector. The tip features a flexible neck design and incorporates an IROX™ (iridium oxide) coating on the tip electrode.

Lead Specifications and Reimbursement Information

Product	INGEVITY+ Pacing Lead
Model/Length	7840 / 45 cm 7841 / 52 cm 7842 / 59 cm
Type	Bipolar Atrial / Ventricular Straight
Connector	IS-1 BI
Compatibility	Pulse generators with an IS-1 port, which accepts an IS-1 terminal
MRI Conditions of Use*	ImageReady™ MR-Conditional System when used with an MR-Conditional pulse generator - Full body scan 1.5T and 3T
Introducer without guide wire	6F (2.0 mm)
Introducer with guide wire	9F (3.0 mm)
Fixation	Extendable/retractable helix
Expected number of rotations to fully extend/retract the helix**	6 ± 2 turns with straight stylet 7 ± 3 turns with J stylet
Recommended maximum number of turns to extend / retract the helix**	30
Nominal fixation helix penetration depth	1.8 mm

[1]Q3 2019 Boston Scientific Corporation Product Performance Report
[2]Internal data on file
* Refer to the MRI Technical Guide for a complete list of cardiology and radiology conditions of use.
**Use fluoroscopy markers for verification of full extension/ retraction of the helix. The number of turns to extend or retract the helix may vary based on patient anatomy and implant conditions.

INGEVITY™+ Pacing Lead

Active Fixation Models: 7840, 7841, 7842

Lead Specifications and Reimbursement Information *(continued)*

Product	INGEVITY+ Pacing Lead
Nominal Electrode:	
Fixation helix surface area	4.5 mm^2
Distance between electrodes	10.7 mm
Anode electrode surface area	20 mm^2
Nominal Diameter:	
Insertion	2.0 mm (6 F)
Anode electrode	2.0 mm
Lead body	1.9 mm
Fixation helix	1.2mm
Material:	
External insulation	Polyurethane (55 D)
Internal insulation	Silicone rubber
Terminal ring contact	316 L stainless steel
IS-1 terminal pin contact	316L stainless steel
Tip electrode	IROX™ (iridium oxide) coated Pt-Ir
Anode electrode	IROX (iridium oxide) coated Pt-Ir
Conductor Type	Tri-filar inner coil of MP35N™ and single-filar outer coil of MP35N with a silver core.[1]
Steroid	0.91 mg dexamethasone acetate
Radiopaque Markers	Pt-Ir
Suture Sleeve	Radiopaque white silicone rubber
C-code	1898

[1]MP35N is a trademark of SPS Technologies, Inc.

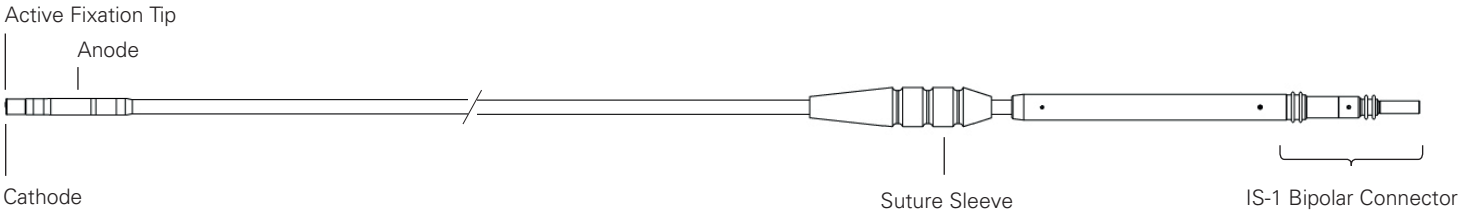
INGEVITY™+ Pacing Lead

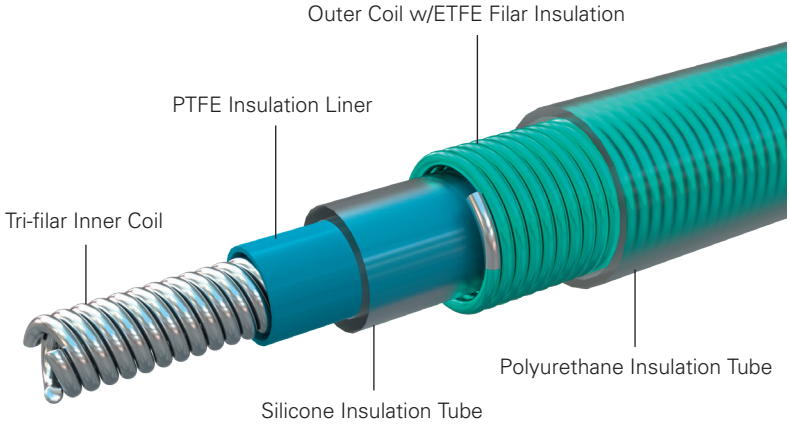
Active Fixation Models: 7840, 7841, 7842

Features

Lifetime Warranty: The INGEVITY+ pacing lead family is backed with a lifetime warranty.*

Lead Body Design: The isodiametric lead body consists of a coaxial design that includes a tri-filar inner coil and a single-filar outer coil. Both the inner and outer coils are designed for MR Conditional use in the MRI environment and provide robust flexural fatigue performance. In addition, the tri-filar inner coil provides consistent helix deployment performance. The conductors are separated by both a silicone rubber and Polytetrafluoroethylene (PTFE) lining. The outer coil is covered in Ethylene tetrafluoroethylene (ETFE) for extra insulation protection. The entire lead body is encompassed in a polyurethane outer insulation.





IROX™-coated Electrodes: The electrodes are coated with IROX to increase the microscopic surface area.

Steroid-eluting: Upon exposure to body fluids, the steroid elutes from the lead to help reduce tissue inflammation response at the distal electrode. The steroid suppresses the inflammatory response believed to cause threshold rises typically associated with implanted pacing electrodes.

Radiopaque Suture Sleeve: The radiopaque suture sleeve is visible under fluoroscopy and is used to secure, immobilize, and protect the lead at the venous entry site after lead placement. The window feature is designed to aid compression of the sleeve onto the lead during suturing.

*Limited lifetime warranty. For a full and complete description of the INGEVITY™+ warranty, please review the warranty card included with the product labeling.

INGEVITY™+ Pacing Lead

Active Fixation Models: 7840, 7841, 7842

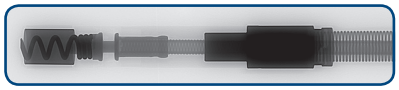
Active Fixation Features

Extendable / Retractable Fixation: The extendable/retractable helix design anchors the distal tip electrode to the endocardial surface without support of trabecular structures, offering various lead placement possibilities for the tip electrode in the right atrium and/or right ventricle. The helix serves as the cathode for endocardial pacing and sensing. The lead is designed with a tri-filar inner coil for consistent and repeatable turn counts when extending and retracting the helix. The helix is extended and retracted using the fixation tool.

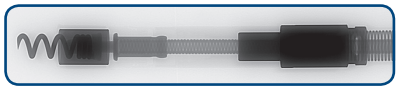
Mapping: The lead helix is electrically conductive to allow mapping (measuring pacing and sensing thresholds) of potential electrode positions without extending the helix into the tissue. Mapping prior to lead fixation is recommended as it can reduce the potential need for multiple lead positionings.

Fluoroscopic Markers: radiopaque markers near the distal tip can be seen under fluoroscopy. These markers show when the helix is fully retracted or fully extended.

Fully Retracted



Fully Extended



Packaged Accessories

- Vein Pick
- Fixation Tool
- Stylet Guide
- Stylets:

	Pre-loaded	Packaged
7840	45cm soft, long tapered	45cm soft, long tapered 45cm extra soft, tapered 45cm soft, atrial J 45cm soft, wide atrial J
7841	52cm soft, long tapered	52cm soft, long tapered 52cm extra soft, tapered 52cm soft, atrial J 52cm soft, wide atrial J
7842	59cm soft, long tapered	59cm soft, long tapered 59cm extra soft, tapered

INGEVITY™ + and INGEVITY™ MRI Extendable/Retractable Fixation and Tined Fixation Pacing Leads

INDICATIONS

This Boston Scientific lead is indicated for use as follows:

- intended for chronic pacing and sensing in the right atrium and/or right ventricle when used with a compatible pulse generator (INGEVITY+ and INGEVITY MRI extendable/retractable fixation)
- intended for chronic pacing and sensing in the right atrium (Preformed Atrial J) or right ventricle (Straight) when used with a compatible pulse generator (INGEVITY MRI tined fixation)

CONTRAINDICATIONS

Use of these leads are contraindicated for the following patients:

- Patients with a hypersensitivity to a nominal single dose of 0.91mg dexamethasone acetate (for INGEVITY+ and INGEVITY MRI extendable retractable fixation)
- Patients with a hypersensitivity to a nominal single dose of 0.61mg dexamethasone (for INGEVITY MRI tined fixation)
- Patients with mechanical tricuspid heart valves.

WARNINGS

Read the manual thoroughly before implantation to avoid damage to the pulse generator and/or lead. For single patient use only. Do not reuse, reprocess, or resterilize. Always have external defibrillation equipment available during implant and electrophysiologic testing. Ensure that an external defibrillator and medical personnel skilled in CPR are present during post-implant device testing should the patient require external rescue. Lead fracture, dislodgment, abrasion, or an incomplete connection can cause a periodic or continual loss of pacing or sensing or both. Although pliable, the lead is not designed to tolerate excessive flexing, bending, or tension. Do not kink, twist, or braid the lead with other leads. Implant of the system cannot be performed in an MRI site Zone III (and higher). Take care to obtain appropriate electrode position. Failure to do so may result in suboptimal lead measurements. Unless all of the MRI Conditions of Use (as described in the MRI Technical Guide) are met, MRI scanning of the patient does not meet MR Conditional requirements of the implanted system. Refer to the MRI Technical Guide for potential adverse events applicable when Conditions of Use are met or not met, as well as a complete list of MRI-related Warnings and Precautions. Do not subject a patient with an implanted pulse generator and/or lead to diathermy.
For INGEVITY+ and INGEVITY MRI extendable/retractable fixation: The safety and efficacy of the tip electrode placement in the right ventricle above midseptum has not been clinically established.

PRECAUTIONS

For specific information on precautions, refer to the following sections of the product labeling: clinical considerations, sterilization and storage, handling, implantation, hospital and medical environments, and follow-up testing.

POTENTIAL ADVERSE EVENTS

Based on the literature and on pulse generator and/or lead implant experience, the following alphabetical list includes the possible adverse events associated with implantation of products described in this literature: Air embolism; Allergic reaction; Arterial damage with subsequent stenosis; Bleeding; Bradycardia; Breakage/failure of the implant instruments; Cardiac perforation; Cardiac tamponade; Chronic nerve damage; Component failure; Conductor coil fracture; Death; Electrolyte imbalance/dehydration; Elevated thresholds; Erosion; Excessive fibrotic tissue growth; Extracardiac stimulation (muscle/nerve stimulation); Fluid accumulation; Foreign body rejection phenomena; Formation of hematomas or seromas; Heart block; Hemorrhage; Hemothorax; Inability to pace; Inappropriate therapy (e.g., shocks and antitachycardia pacing [ATP] where applicable, pacing); Incisional pain; Incomplete lead connection with pulse generator; Infection including endocarditis; Lead dislodgment; Lead fracture; Lead insulation breakage or abrasion; Lead tip deformation and/or breakage; Malignancy or skin burn due to fluoroscopic radiation; Myocardial trauma (e.g., tissue damage, valve damage); Myopotential sensing; Oversensing/undersensing; Pericardial rub, effusion; Pneumothorax; Pulse generator and/or lead migration; Syncope; Tachyarrhythmias, which include acceleration of arrhythmias and early, recurrent atrial fibrillation; Thrombosis/thromboemboli; Valve damage; Vasovagal response; Venous occlusion; Venous trauma (e.g., perforation, dissection, erosion).

For a list of potential adverse events associated with MRI scanning, refer to the ImageReady™ MR Conditional Pacing System or Defibrillation System MRI Technical Guide.
92436283 (Rev B)

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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Marlborough, MA 01752-1234
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Medical Professionals:
1.800.CARDIAC (227.3422)
Patients and Families:
1.866.484.3268

CRM-699008-AA

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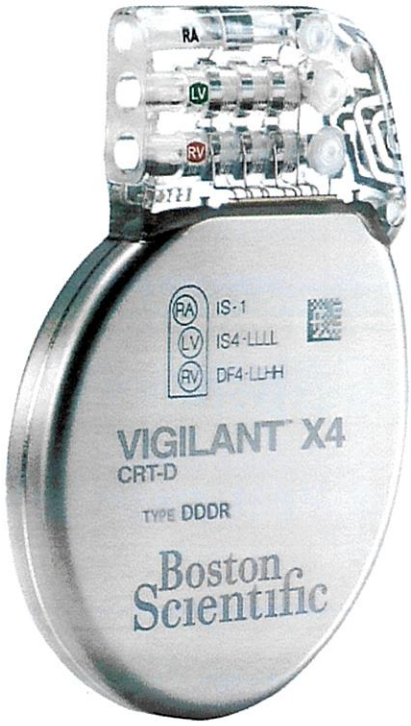
VIGILANT™ X4 CRT-D and VIGILANT™ CRT-D

Cardiac Resynchronization Therapy Defibrillator



SmartCRT™ is Boston Scientific's approach to personalise CRT therapy by providing physicians with smart solutions to optimise where, when, and how to pace. HeartLogic™, the first and only heart failure diagnostic validated to have high sensitivity, the ability to provide weeks of advanced notice and low alert burden for detecting early signs of worsening heart failure.* EnduraLife™ Battery Technology provides more power to use more of the device, featuring up to 13.3

safely undergo Full Body MRI scans up to 1.5T and 3T.***

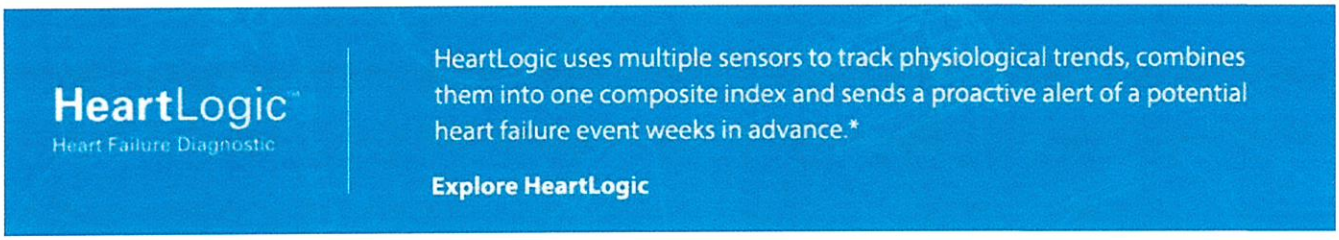
Explore

Product Details | Mechanical Specifications | Additional Longevity Information

Product Details

VIGILANT™ X4 CRT-D and VIGILANT™ CRT-D

Models G224 and G247



EnduraLife™ Battery Technology

ImageReady™ MR-Conditional Systems

HeartLogic™ Heart Failure Diagnostic

- VIGILANT X4 CRT-D offers SmartCRT™ technology, enabling physicians to offer a personalised care approach to all patients, including a wide range of options of where, when and how to pace
- EnduraLife™ battery technology can offer up to 14.7 years battery life[1] and 13.3 years with MultiSite Pacing switched on[1].
- The X4 CRT-D and ACUITY™ X4 lead portfolio features electrodes on a 3D spiral designed to allow pacing from a basal location without sacrificing fixation or thresholds; 17 pacing vector options to manage around PNS and high thresholds; and multiple lead shapes with a 2.6F (0.86mm) tapered lead tip to improve predictability of accessing target vessels.
- MultiSite Pacing allows 216 vector combinations to easily tailor device therapy, supported by automatic recommendations with the click of a button, for vectors and offsets in < 5 seconds.
- This small (32.5 cm^3) and thin (9.9 mm) high-energy device is designed to enhance patient comfort.[2]
- The PaceSafe™ RV, RA, and LV auto threshold feature is designed to maintain adequate output safety margins.
- Heart Failure Sensor Suite with a set of tools such as: Sleep Incline, LATITUDE™ NXT Remote Patient Management with weight scale and blood pressure sensors and Respiratory Rate Trend, to provide an advanced solution for patient comorbidities and HF monitoring.
- ImageReady™ MR-Conditional systems allow patients to receive full body MR-Conditional scans at 1.5T or 3T without exclusion zone, scan duration, or patient height restrictions**
- AcuShock™ Technology including Onset/Stability™, RhythmID™, Dynamic Noise Algorithm (DNA) for sensing, Automatic Gain Control (AGC) with programmable sensing floor, Narrow Band Pass Filter
- EasyView™ header and color coded lead ports designed to make the implant experience more efficient.
- SafetyCore™ technology is intended to provide lifesaving shock therapy and basic pacing functionality in the event of an unrecoverable fault.

Model	Type	Size (cm) (W x H x D)	Mass (g)	Volume (cc)	Connector Type (RA RV LV)	MR Conditional
G247	X4 CRT-D	5.37 x 8.18 x 0.99	73.8	32.5	RA:IS-1;RV:DF4;LV:IS4	Yes
G224	CRT-D	5.37 x 8.18 x 0.99	73.6	32.5	RA:IS-1;RV:DF4;LV:IS-1	Yes

Pulse Generator Longevity (All Models[a,b,c,d,e,f])

EnduraLife™ Battery Technology provides clinically-proven, industry-leading projected longevity.*** The following tables represent sample pulse generator life expectancy estimation (implant to explant) with EnduraLife™ battery as provided in product labeling. For specific programmable parameter ranges, refer to product labeling at **www.bostonscientific-elabeling.com** >, or contact Boston Scientific technical services or your local representative.

MultiSite Pacing Off

Projected longevity	Ventricular Chambers	RA/RV	LV	LVb[e]	500Ω with Latitude™[c]	700Ω with Latitude™[c]	700Ω no Latitude™, MV/RS, or HFSS[d]
Typical programmed setting	BiV	2.5 V	3.0 V	Off	9.7	10.5	11.3
Maximum labelled longevity	LV-Only	2.0 V / Off	2.0 V	Off	12.9	13.2	14.7

MultiSite Pacing On

Projected longevity	Ventricular Chambers	RA/RV	LV	LVb[e]	500Ω with Latitude™[c]	700Ω with Latitude™[c]	700Ω no Latitude™, MV/RS, or HFSS[d]
Typical programmed setting	BiV MSP	2.5 V	3.0 V	3.0 V	8.2	9.1	9.7
Maximum labelled longevity	LV-Only MSP	2.0 V / Off	2.0 V	2.0 V	11.5	12.1	13.3

Additional Longevity Information

- Warranty information available at **www.bostonscientific.com/warranty**.
- Devices use Li/MnO2 chemistry.
- The Usable Battery Capacity is 1.9 Amp-hours (typical implant to battery capacity depleted).
- Shelf life is 2 years (before use by date).

Boston Scientific
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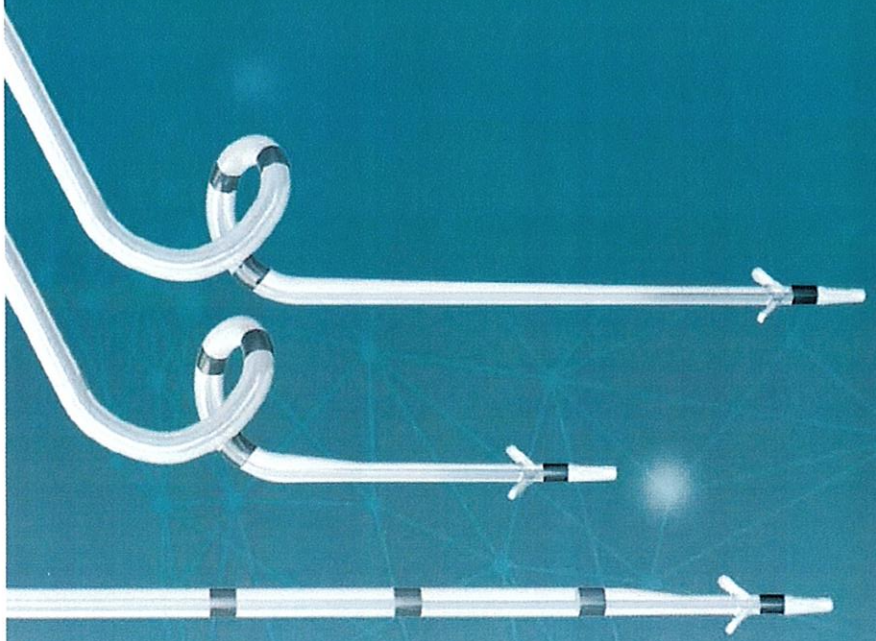
ACUITY™ X4
Quadripolar LV Leads

New Solutions.
Meaningful Outcomes.



The first and only LV leads uniquely designed to promote non-apical pacing options, helping physicians to pace from an optimal site for improved CRT response.

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The X4 CRT System

Designed to Help Optimize CRT-response

With multiple tip shapes and unique electrode configurations, ACUITY™ X4 leads are specifically designed to help you get to the optimal pacing site.

Therapy-based Vector Selection

LV Vector Guide™ helps you choose the most therapeutic vector for pacing based on RV/LV Delay.

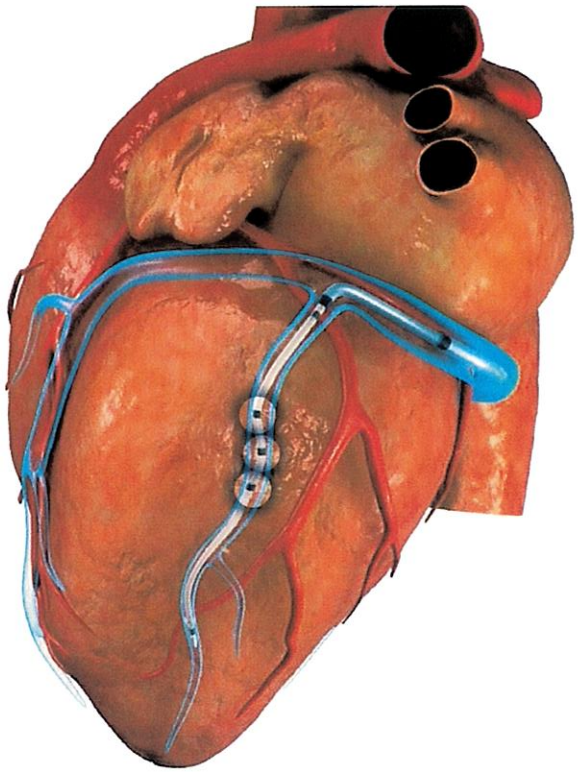
Clinically Meaningful Difference in Longevity

The X4 CRT-D is powered by ENDURALIFE™ Battery Technology, which continues to outlast the competition.[1-4]

Discover more about ACUITY X4 leads.

BostonScientific.com/ACUITYX4

ACUITY™ X4
Quadripolar LV Leads



Designed to place more electrodes in mid or basal location of the left ventricle, the ACUITY X4 Spiral leads press the **proximal electrodes** against the vessel wall.

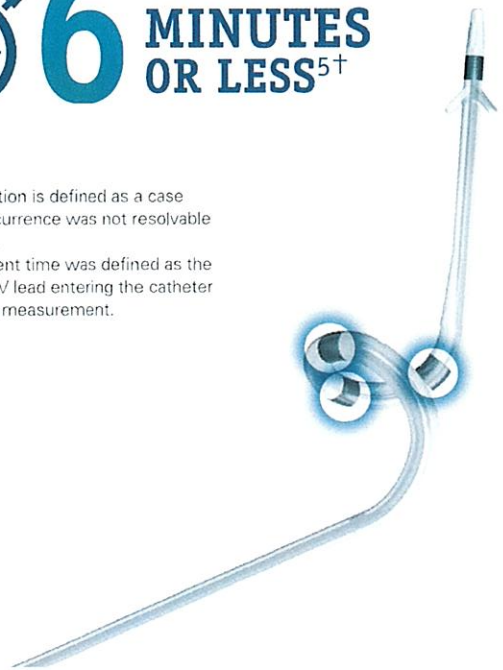
Improving Delivery & Optimizing Pacing Performance

IN THE NAVIGATE X4 STUDY:

- Dual fixation mechanisms on ACUITY X4 Spiral models led to stability rates of 99.1%[5]
- Leads experienced a 99.6% phrenic nerve stimulation complication-free rate[5*]

HALF OF ACUITY X4 SPIRAL LEADS WERE PLACED IN **6 MINUTES OR LESS**[5†]

*A PNS complication is defined as a case when a PNS occurrence was not resolvable without surgery.
† LV lead placement time was defined as the time from the LV lead entering the catheter to the first PSA measurement.



Redefining Quadripolar Pacing to Improve CRT Response

IN THE NAVIGATE X4 STUDY:

ACUITY X4 SPIRAL LEADS WERE PROGRAMMED WITH A **PROXIMAL ELECTRODE AS THE PACING CATHODE**

77.3%[5]

Clinically Meaningful Patient Outcomes

IN THE NAVIGATE X4 STUDY:

Shorter implant time for ACUITY X4 Spiral leads[5] could mean reduced fluoroscopy time

ACUITY™ X4 LEADS **REQUIRED ZERO REOPERATIONS** DUE TO PACING CAPTURE OR THRESHOLDS[5]

Discover more about ACUITY X4 leads.
BostonScientific.com/ACUITYX4

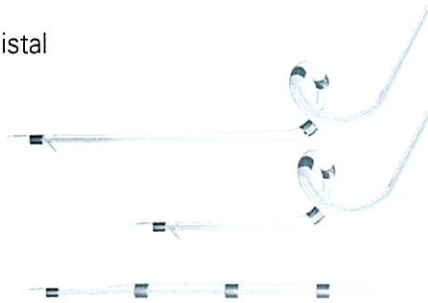
poz.3

ACUITY™ X4

Quadripolar LV Leads

Models (Straight) 4671, 4672 (Spiral S) 4674, 4675 (Spiral L) 4677, 4678

Improving Delivery and Optimizing Pacing Performance



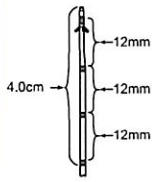
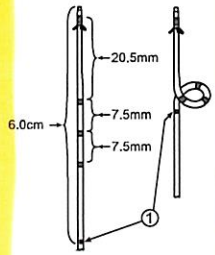
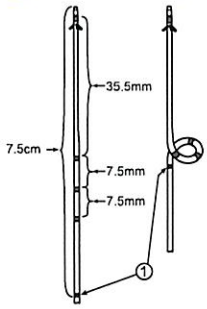
- Industry's smallest diameter,[1,2,3] atraumatic tip (2.6F) with small diameter silicone distal sections on all lead models designed to track into tortuous vasculature
- Three tip configuration designs are intended to provide choices for a variety of patient anatomies
- Inner catheter deliverable to provide additional options for lead placement
- Dual Fixation: silicone rubber tines and a distal, 3D shape on spiral models designed to provide an additional or alternative passive fixation option
- Electrodes on the 3D spiral help overcome challenges in mid-base (proximal) ventricular regions:
  - The 3D shape presses electrodes against vessel walls, thereby improving the threshold performance of proximal electrodes[4]
  - Electrodes oriented around the circumference of the spiral increase the chances that at least one of three electrodes will be adjacent to the myocardium in any coronary vasculature location

Redefining Quadripolar Pacing to Improve CRT Response

- Only Boston Scientific offers quadripolar technology with multiple electrode configuration options to allow the lead to be fixated distally and tailor the electrode placement to the patient anatomy, which may promote basal or mid-ventricular pacing
- An industry-leading 17 pacing vectors are available when used with a Boston Scientific X4 CRT-D or X4 CRT-P
  - Using LV VectorGuide™ will streamline testing and help you quickly determine the optimal pacing configuration for each X4 CRT-D patient.

Reimbursement Information C-Code: C-1900

Product Specifications

Length/Model	86cm - 4671 95cm - 4672	86cm - 4674 95cm - 4675	86cm - 4677 95cm - 4678
Electrode Spacing		 1 – Radiopaque Marker	 1 – Radiopaque Marker
Fixation Method	Tines	- Tines - 3D Spiral	- Tines - 3D Spiral

ACUITY™ X4

Quadripolar LV Leads

Models (Straight) 4671, 4672 (Spiral S) 4674, 4675 (Spiral L) 4677, 4678

Product Specifications *(continued)*

Compatibility	IS4-LLLL
Delivery Method	Over the wire
Recommended Guide Catheter Size	0.081 in (2.06 mm) minimum inner diameter
Diameter	
Proximal Body	5.2F (1.7mm)
Distal Body	3.9F (1.3mm)
Distal Tip	2.6F (0.9mm)
Insulation Material	
External Insulation	Polyurethane and silicone
Internal Insulation	Polyurethane, silicone, ETFE
Conductor Material	
Coil (pin to distal electrode)	Low titanium MP35N
Cable (rings to proximal electrodes)	Low titanium MP35N with tantalum core
Electrodes	
Material	IROX coated platinum iridium
Tip Electrode Surface Area	4.1mm²
Proximal Electrode Surface Area	8.3mm²
Steroid	Dexamethasone acetate
Suture Sleeve	Radiopaque white silicone, three grooves
Accessories included	Vein pick, ACUITY X4 Flushing Tool/Wire Guide, ACUITY X4 Connector Tool

Accessories

ACUITY X4 Connector Tool (Model 4625)

The Connector Tool can be attached to a lead with or without a guidewire inserted and performs the following functions when attached to the lead:

- Protects the lead terminal during the implant procedure when determining lead electrical performance
- Provides a safe and secure connection between PSA patient cables and the lead terminal

ACUITY X4 Flushing Tool/Wire Guide (Model 4604)

The flushing tool/wire guide performs the following functions when attached to the lead:

- Provides compatibility with luer lock and luer slip tip syringes for flushing the lead
- Provides a wire guide to ease insertion of a guide wire

1 ACUITY™ X4 Physician's Lead Manual: 359160-002 EN US 2015-07
2 ATTAIN™ PERFORMA™ 4298 Technical Manual: M948374A001. ATTAIN™ PERFORMA™ STRAIGHT 4398 Technical Manual: M948374A001. ATTAIN™ PERFORMA™ S 4598 Technical Manual: M950705A001.
3 Quartet™ Users Manual 100042495
4 Clinical Summary: 358487-022 EN US 2016-01.

ACUITY X4 Brief Summary

Indications This Boston Scientific lead is indicated for use as follows: Intended for chronic, left-ventricular pacing and sensing via the coronary venous system when used in conjunction with a compatible pulse generator. The Boston Scientific ACUITY X4 lead is a steroid eluting (dexamethasone acetate) IS4 quadripolar lead.

Contraindications Use of this Boston Scientific lead is contraindicated for the following patients: Patients with a hypersensitivity to a maximum single dose of 0.54 mg dexamethasone acetate.

Warnings Read the manual thoroughly before implantation to avoid damage to the pulse generator and/or lead. Such damage can result in patient injury or death. For single patient use only. Do not reuse, reprocess, or resterilize. Always have external defibrillation equipment available during implant and electrophysiologic testing. Ensure that an external defibrillator and medical personnel skilled in CPR are present during post-implant device testing should the patient require external rescue. When using a right ventricular (RV) pace/sense lead in conjunction with this left coronary venous pace/sense lead, it is recommended that a polyurethane- insulated lead be used. Lead fracture, dislodgment, abrasion, or an incomplete connection can cause a periodic or continual loss of pacing or sensing or both. Although pliable, the lead is not designed to tolerate excessive flexing, bending or tension. Do not kink, twist, or braid the lead with other leads as doing so could cause lead insulation abrasion damage or conductor damage. Use caution handling the lead terminal when the Connector tool is not present on the lead. Do not directly contact the lead terminal with any surgical instruments or electrical connections such as PSA (alligator) clips, ECG connections, forceps, hemostats and clamps. Do not contact any other portion of the lead terminal, other than the terminal pin, even when the lead cap is in place. When implanting a system which uses both a DF4-LLHH/LLHO2 and IS4-LLLL3 lead, ensure that the leads are inserted and secured in the appropriate ports. Only use the Connector Tool for electrical connections to pacing system analyzers or similar monitors. Take care to obtain appropriate electrode position. Do not expose a patient to MRI scanning. Do not subject a patient with an implanted pulse generator and/or lead to diathermy since diathermy may cause fibrillation, burning of the myocardium, and irreversible damage to the pulse generator because of induced currents.

Precautions Refer to the lead product labeling for cautions specific to clinical considerations, sterilization and storage, handling, implanting hospital and medical environments, and testing the lead. Failure to observe these cautions could result in incorrect lead implantation, lead damage and/or harm to the patient.

Potential Adverse Events Potential adverse events include, but are not limited to the following: allergic/physical/physiologic reaction, death, erosion/migration, fibrillation or other arrhythmias, lead or accessory breakage (fracture/insulation /lead tip) hematoma/seroma, inappropriate or inability to provide therapy (pacing/sensing), infection, procedure-related, and component failure. In rare cases severe complications or device failures can occur.

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

Boston Scientific
Advancing science for life™

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Medical Professionals:
1.800.CARDIAC (227.3422)
Patients and Families:
1.866.484.3268

CRM-348801-AB FEB2016

Reliance™ 4-Front

Implantable Defibrillation Lead

Reliance 4-Front silicone leads

RELIANCE 4-FRONT leads are 7.3F (2,4 mm), steroid-eluting, endocardial cardioversion/defibrillation and pace/sense leads. 4-FRONT is built on the reliable RELIANCE™ platform and has a smart size reduction while maintaining insulation thickness.

Key Resources

Physician Technical Manual ›

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- Submit Your Questions
- Learn on EDUCARE

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Product Specifications | Features | Key Benefits

Product Specifications

Lead Specifications

RELIANCE 4-Front™, Single-coil

RELIANCE 4-Front™, Dual-coil

Need Help? Contact Us

connector and incorporate the IROX™ (iridium oxide) coating. The silicone lead body has a fabricious coating and the electrode coils are backfilled with silicone.

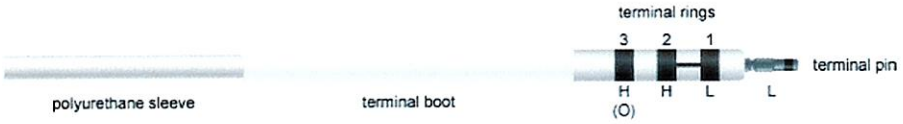
Product	Dual-coil Active	Single-coil Active	Dual-coil Passive	Single-coil Passive
Model/Length	0675 59 cm 0676 64 cm	0672 59cm 0673 64cm	0665 59 cm 0636 64 cm	0662 59 cm 0663 64 cm
Terminal Configuration[1]	DF4-LLHH	DF4-LLHO[2]	DF4-LLHH	DF4-LLHO
PG Compatibility	RELIANCE 4-FRONT leads with the DF4-LLHH / LLHO label are equivalent and are compatible with a device containing either a GDT-LLHH or DF4-LLHH port			
Lead Introducer without Guide Wire	8F[4] (2.6 mm)	8F[4] (2.6 mm)	8F[4] (2.6 mm)	8F[4] (2.6 mm)
Lead Introducer with Guide Wire	10.5F (3.5 mm)	10.5F (3.5 mm)	10.5F (3.5 mm)	10.5F (3.5 mm)
Isodiametric Lead Body Diameter	7.3F (2.4 mm)	7.3F (2.4 mm)	7.3F (2.4 mm)	7.3F (2.4 mm)
Rotations Expected to Extend/Retract Helix[3]	11	11	n/a	n/a
Tip/Helix Electrode Surface Area (mm^2)	5.7	5.7	3.5	3.5
Proximal Coil Active Electrode Surface Area (mm^2)	660	n/A	660	n/a
Distal Coil Active Electrode Surface Area ($mm^{2)}$)	450	450	450	450
Tip to Proximal Coil Electrode Length (mm)	180	n/a	180	n/a
Tip to Distal Coil Electrode Length (mm)	12	12	12	12
Lead Body Insulation Material	layer of silicone, layer of polyurethane (for the first ~ 12 cm) and then the silicone trilumen			
Terminal Pin Material	MP35N nickel-cobalt alloy			
Pace/Sense Conductor Material	low titanium, MP35N nickel-cobalt alloy, PTFE sleeve			
Conductive Ring Material	MP35N nickel-cobalt alloy			
Shocking Conductor Material	1X19 Low titanium MP35N nickel-cobalt alloy, silver-core, drawn filled tube, ETFE coated			
Tip Electrode Material	IROX coated platinum / iridium			
Coil Electrode Covering Material	Silicone			
Shock Coil Material	Platinum clad tantalum clad titanium			
Steroid Material	Approximately 0.96 mg dexamethasone acetate nominally			

Features

Lifetime Warranty: The RELIANCE 4-FRONT defibrillation lead family is backed with a lifetime warranty[5].

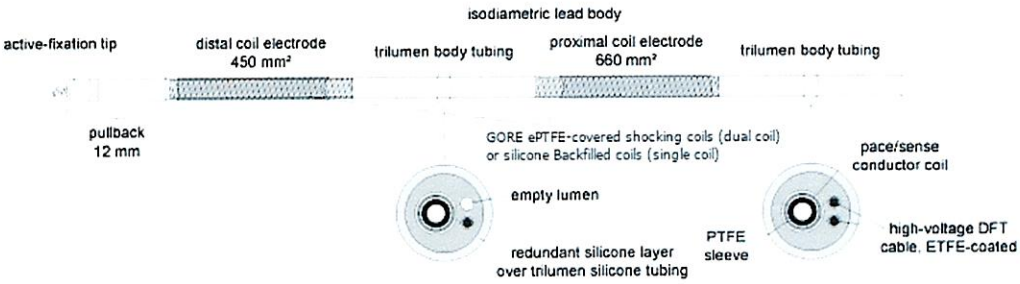
Terminal configuration: The RELIANCE 4-FRONT lead is DF4-LLHH for dual-coil leads and DF4-LLHO for single-coil leads, this suffix provides functional identifications of conductors:

L = Low Voltage



Rings 1 and 2 are electrically connected within the terminal for integrated bipolar pacing / sensing. Cable conductors

are utilized for both shock coils. Ring 2 is connected to the distal shock coil and ring 3 connects to the proximal coil.



Isodiametric lead body:

The isodiametric lead body contains one conductor for pacing / sensing. For defibrillation, the lead has two conductors in dual coil models and one for the single coil models leaving one lumen empty in single coil models. The conductors are insulated in separate lumens within the silicone rubber lead body. A second layer of silicone covers the lead body, providing additional insulation and a uniform body diameter. RELIANCE 4-FRONT has a 7.3F (2.4 mm) lead body which fits through an 8F (2.6 mm) non-hemostatic introducer when not retaining a guide wire.

Insulation:

Silicone construction: Silicone has been used in Boston Scientific leads for nearly 4 decades.

Polyurethane sleeve: The first 12 cm of the lead distal to the terminal boot incorporates a polyurethane sleeve underneath the outer silicone rubber insulation for enhanced abrasion resistance within the pocket.

Lubricious coating: The RELIANCE 4-FRONT lead family utilizes a proprietary coating that makes the silicone lead surface more lubricious. This reduces both the static and dynamic coefficients of friction, making the lead surface feel and handle like polyurethane while providing the time-tested reliability of silicone.

Silicone backfilled coil: is defined as a process where the coils are coated with silicone, cured for a short period of time and the silicone is wiped off from the topsurface of the filars, leaving silicone between the filars to mitigate tissue ingrowth

IROX coating: RELIANCE 4-FRONT features an IROX coated pace/sense cathode electrode, which may improve pacing performance. Lower and more predictable pacing thresholds may increase the longevity of the pulse generator.

Steroid distal tip: The tip electrode contains a nominal dose of steroid that elutes upon exposure to body fluids. The steroid suppresses the inflammatory response believed to cause threshold rises typically associated with implanted pacing electrodes. Lower thresholds are desirable because they can increase pacing safety margins and reduce pacing energy requirements, potentially increasing pulse generator longevity.

Pullback: Pullback is the distance the defibrillation electrode is removed from the lead tip, a critical factor in helping to direct energy deep into the ventricular apex. Standard for multiple generations of Boston Scientific defibrillation leads, the 12 mm RELIANCE 4-FRONT pullback design is important for low defibrillation thresholds, while optimizing sensing characteristics.

Radiopaque suture sleeve: The radiopaque suture sleeve is visible under fluoroscopy and is used to secure and protect the lead at the venous entry site after lead placement. The window feature is designed to aid compression of the sleeve onto the lead during suturing.

Passive-Fixation Features

Incorporates a flexible neck region and IROX coating for improved pacing performance.

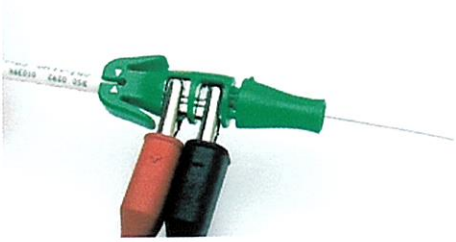
Active-Fixation Features

Terminal pin-driven extendable/retractable fixation helix: Rotating the knob of the EZ-4 Connector tool rotates the terminal pin which extends / retracts the helix. The IROX coated platinum-iridium helix anchors the pacing electrode to the endocardial surface without support of trabecular structures, offering various lead placement possibilities for the tip electrode in the right ventricle.

Fluoroscopic markers: The RELIANCE 4-FRONT active fixation model incorporates a radiographic marker system to enable clear visualization of the helix position under fluoroscopy.

Mapping: The RELIANCE 4-FRONT tip and helix design allows mapping even with the helix fully retracted. Helix is flush to prevent snagging while enabling mapping.

EZ-4 ™ Connector Tool



When connected to the lead, the EZ-4 Connector Tool performs the following functions:

1. Protects the lead terminal during the implant procedure.

2. Provides a safe and secure connection between the pacing system analyzer (PSA) patient cables and

the lead terminal.

3. Guides the stylet into the lead through the stylet funnel.

4. For leads with an extendable / retractable helix, rotates the terminal pin clockwise or counterclockwise to extend or retract the helix.

The EZ-4 Connector Tool is intended to be left on the lead for the duration of the implant, until the lead terminal is inserted into the header.

Key Benefits

RELIANCE 4-FRONT is the latest in ICD lead technology, built on the proven RELIANCE platform to provide:

- The most reliable lead on the market[6]
- A modest size reduction
- An improved implant experience
- Enhanced extraction capability

ACUITY™ Pro

Designed for Consistent Cannulation

- Supportive mid-shaft section for increased pushability and enhanced torque transmission.
- Multiple outer catheter shapes that support the Cross, Torque, Back, and Forth cannulation technique.

Options to Reach the Target Vessel

- Soft distal segments designed to enhance tracking into branch veins.
- Eight outer guide catheter options designed to accommodate various patient anatomy.
- Two inner guide catheter options aid in branch vessel sub-selection for direct delivery.

Simplified Implant Experience

- Use of the dilator can eliminate the need for an introducer to access the anatomy.
- Integrated cuttable hub eliminates the need to break the hub prior to catheter removal.
- Direct luer syringe compatibility enables selective venography for visualization of distal branches.
- Inner catheter delivery available with ACUITY Spiral and ACUITY X4 LV leads.

ACUITY Pro Catheter Models

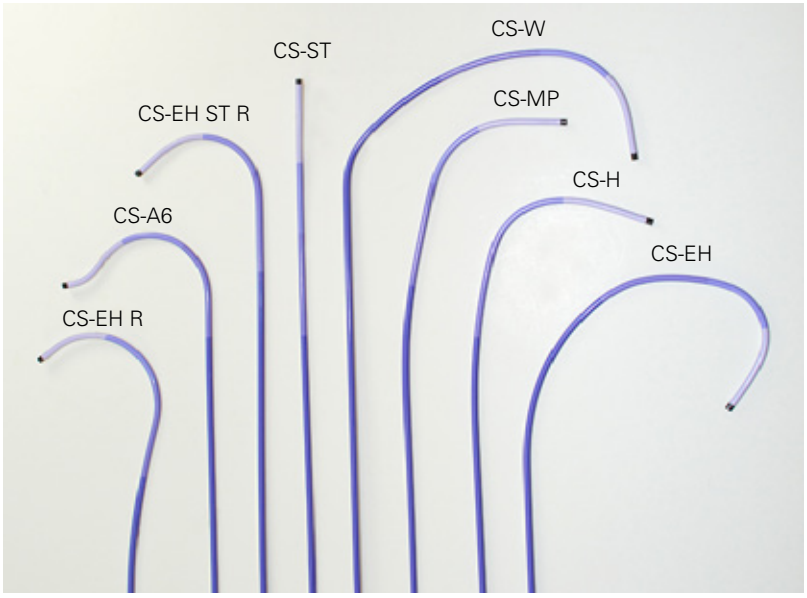
Catheter	Working Length	Total Length	Shape	Abbreviation	Model #
Outer	45 cm	50 cm	Extended Hook	CS-EH	8105
			Straight Right	CS-EH ST R	8107
			Right	CS-EH R	819
			Wide	CS-W	8111
			Multipurpose	CS-MP	8113
			Coronary Sinus Hook	CS-H	8115
			Amplatz	CS-A6	8117
			Straight	CS-ST	8119
	54 cm	59 cm	Extended Hook (CS-EH)	CS-EH	8104
			Straight Right	CS-EH ST R	8106
			Right	CS-EH R	8108
			Wide	CS-W	8110
			Multipurpose	CS-MP	8112
			Coronary Sinus Hook	CS-H	8114
			Amplatz	CS-A6	8116
			Straight	CS-ST	8118
Inner	60 cm	65 cm	90 degree	CS-IC-90	8101
			130 degree	CS-IC-130	8103
	69 cm	74 cm	90 degree	CS-IC-90	8100
			130 degree	CS-IC-130	8102

ACUITY™ Pro

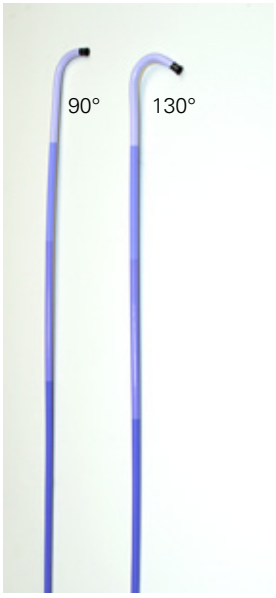
ACUITY Pro Nominal Specifications		
	Inner Diameter	**Outer Diameter**
Outer Catheter	0.102″ • 7.8 F • 2.60 mm	0.120″ • 9.2 F • 3.07 mm
Inner Catheter	0.082″ • 6.3 F • 2.10 mm	0.097″ • 7.4 F • 2.47 mm

Inner Catheter Lead Delivery		
Lead Length	**ACUITY Pro Catheter Length**	**Max lead length beyond catheter tip**
86 cm	60 cm	13 cm
86 cm	69 cm	4 cm
95 cm	60 cm	22 cm
95 cm	69 cm	13 cm

Outer Catheter Shapes



Inner Catheter Shapes



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ACUITY® Pro

9F Guide Catheter

for use with
ACUITY® Pro Lead Delivery System

TABLE OF CONTENTS

℞ ONLY

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

WARNING

Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found, call your Boston Scientific representative.

For single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

DEVICE DESCRIPTION

Contents

One (1) 9F ACUITY Pro guide catheter, one (1) ACUITY™ Universal Cutter, one (1) guidewire introducer, one (1) torque device, two (2) trans valve introducer (TVI) tools, and one (1) dilator.

User Information

Intended users of the ACUITY Pro guide catheter are those physicians trained in the implantation of cardiac resynchronization therapy (CRT) devices for the treatment of heart failure.

There are no additional training requirements for the intended users of the ACUITY Pro guide catheter to ensure safe and effective use.

The 9F ACUITY Pro guide catheter is designed for venous use to provide a pathway through which contrast or devices, including Boston Scientific or Guidant left ventricular pacing leads, can be introduced into the coronary venous system. It is designed to provide access to the coronary venous system, and may be used in conjunction with smaller, appropriately sized catheters in a telescoping manner to improve the access and delivery capabilities of the system. The catheter is designed with a flexible distal segment and soft tip to atraumatically enter the main coronary sinus (CS) and branch veins.

The 9F ACUITY Pro guide catheter includes a hub with an integrated hemostasis valve and luer lock flush port (Figure 1.0). The user cuts the hub and valve with the ACUITY Universal Cutter.

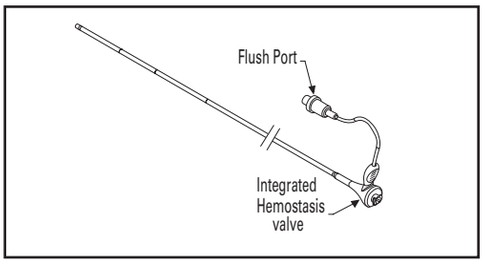

Figure 1.0 – Image of flush port and integrated valve

The transvalve introducer (TVI) (Figure 2.0) is a tool to aid insertion of devices through the guide catheter hub hemostasis valve.

The guidewire introducer (Figure 3.0) is a guidewire insertion tool with a plastic hub tapering down to the inside of a longer stainless steel tube.

The torque device (Figure 4.0) employs a plastic body and cap to tighten a metal collet onto a guidewire.

The dilator (Figure 5.0) is a tool that allows access into the venous vasculature without the use of a hemostatic introducer.

The ACUITY Universal Cutter (Figure 6.0) is a tool used to cut-away guide catheters following implantation of left ventricle (LV) leads in the coronary venous vasculature.

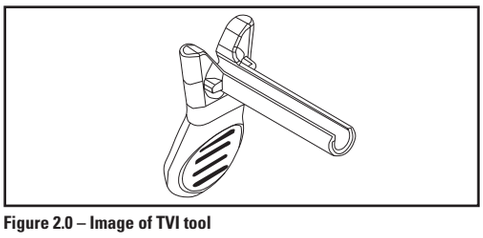

Figure 2.0 – Image of TVI tool

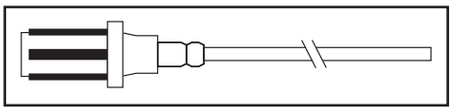

Figure 3.0 – Image of guidwire introducer

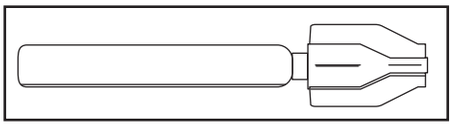

Figure 4.0 – Image of torque device

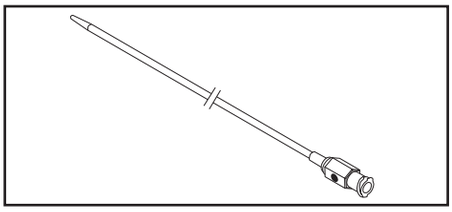

Figure 5.0 – Image of dilator

INTENDED USE / INDICATIONS FOR USE

The ACUITY Pro Lead Delivery System is intended to access the coronary venous system, and may be used alone (9F) or in dual-catheter delivery (7F with 9F). The catheter serves as a conduit for the delivery of contrast medium and devices, including implantable coronary venous leads, introduced into the coronary venous system.

The TVI tool is recommended for use during insertion of devices through the hemostasis valve of guide catheter hub.

The guidewire introducer is recommended for use during vascular procedures to assist with the introduction of the guidewire into the left ventricular lead delivery system.

The torque device is recommended for use during vascular procedures in conjunction with interventional and/or diagnostic devices (including left ventricular lead delivery systems) to facilitate steering of the guidewire within the vascular anatomy.

The dilator is recommended to provide support for venous access, while inserted into a 9F outer catheter, with or without the use of a hemostatic introducer.

The ACUITY Universal Cutter is intended to facilitate Boston Scientific or Guidant guide catheter removal after the Boston Scientific or Guidant coronary venous lead is positioned.

CONTRAINDICATIONS

None known.

WARNINGS

- Do not alter any of the system devices, except as described in this document.
- The user should not place side holes in the shaft of the guide catheter. Puncturing the shaft of the guide catheter with hospital instruments may lead to thrombogenesis or failure of shaft integrity.
- When this guide catheter is in the body, it should be manipulated while under high-quality fluoroscopic observations.
- When this guide catheter is in the body, care should be taken to prevent air embolism by maintaining a closed hemostasis valve or plugging the lumen.
- Do not apply excessive torque, tension or force when manipulating the guide catheter or advancing devices through the catheter as damage/injury could result.

- Severe reactions may occur in response to contrast agents in some patients who either had unknown contrast allergies or who were not adequately premedicated.

PRECAUTIONS

- It is recommended that the guide catheter be advanced using a guidewire technique.
- The dilator is designed for venous access. It is not recommended for CS cannulation.
- It is recommended that a finishing wire be used for removal of guide catheter from lead.
- Guide catheters should be used only by physicians thoroughly trained in their intended use.
- Prior to the procedure, all equipment to be used for the procedure should be carefully examined to verify proper function and integrity.
- Remove the guide catheter carefully from the tray to reduce the possibility of damage.
- It is recommended to secure the outer guide catheter when removing the inner guide catheter if no hemostatic introducer was used for venous access.

ADVERSE EVENTS

Vessel trauma may result from the improper use of this device. Follow the enclosed directions carefully.

Other potential adverse reactions that may result from the improper use of this device include, but are not limited to:

- air embolism
- hematoma at the puncture site
- hemorrhage
- infection
- vascular thrombosis
- vessel dissection
- vessel perforation
- vessel spasm

HOW SUPPLIED

This product is non-pyrogenic.

Do not use if package is opened or damaged.

Do not use if labeling is incomplete or illegible.

Use the device prior to the "Use By" date noted on the product label.

Handling and Storage

Store in a cool, dry, dark place.

PREPARATION FOR USE

Dilator (if used)

1. Remove from package.
2. Attach a syringe filled with sterile heparinized normal saline to hub and flush until fluid exits distal tip of dilator.

Guide Catheter

1. Carefully remove components from the sterile packaging and place on sterile flat surface.
   Set accessories off to the side for later use.
2. Attach a syringe filled with sterile heparinized normal saline to the side flush port and flush until fluid exits tip of guide catheter.
3. Attach a syringe filled with sterile heparinized normal saline to the luer connector port and flush until fluid exits tip of guide catheter.

DIRECTIONS FOR USE

The following information includes, but is not limited to, methods for using the lead delivery system.

Dilator (if used)

1. Insert dilator into flushed 9F guide catheter and insert over 0.035 inch guidewire to access venous vasculature.
2. Remove dilator and continue advancing the 9F guide catheter into right atrium to access CS ostium.

Guidewire Introducer

1. Insert the guidewire introducer, shaft end first, into the proximal opening of the hub.
2. Carefully insert the distal tip of the guidewire through the guidewire introducer and into the guide catheter.
3. After the guidewire has been positioned at the desired location, the guidewire introducer should be removed.

Torque Device

1. Loosen the cap of the torque device.
2. Insert the proximal end of the guidewire into the funnel-shaped hole on the distal end of the torque device cap. Once positioned at the desired location, tighten the cap to secure the torque device to the guidewire.
3. Rotate and advance the torque device to steer the guidewire to the desired position.
4. To move the torque device to a new position, loosen the cap, slide the device along the guidewire to the desired position, and tighten the cap.
5. Remove torque device prior to loading additional devices over the guidewire.

Guide Catheter (with dilator)

1. Insert the 9F ACUITY® Pro guide catheter into an introducer sheath or directly into the venous vasculature.
2. Remove dilator from 9F guide catheter.
3. Advance the guide catheter into the CS. Obtain a stable position with the guide catheter. If a contrast injection is desired, attach a contrast filled syringe to the flush port or luer connector on hub.
4. Insert the TVI tool to open the hemostasis valve. Insert the desired device(s) into the guide catheter through the hub of the catheter. Remove the TVI tool once the device has passed through the hub.
5. Once a satisfactory lead position has been achieved, prepare the guide catheter for removal.
6. If a finishing wire is utilized, first remove guidewire or stylet and then insert finishing wire prior to removing the guide catheter.
7. It is recommended to pull back the guide catheter from sub-selected branch vein into CS while maintaining stable position of the lead.
8. Cut guide catheter per ACUITY™ Universal Cutter directions for use below.

Guide Catheter (without dilator)

1. Insert the guide catheter into an introducer sheath.
2. Advance the guide catheter into the CS. Obtain a stable position with the guide catheter. If a contrast injection is desired, attach a contrast filled syringe to the flush port or luer connector on hub.
3. Insert the TVI tool to open the hemostasis valve. Insert the desired device(s) into the guide catheter through the hub of the catheter. Remove the TVI tool once the device has passed through the hub.
4. Once a satisfactory lead position has been achieved, prepare the guide catheter for removal.
5. If a finishing wire is utilized, first remove guidewire or stylet and then insert finishing wire prior to removing the guide catheter.
6. It is recommended to pull back the guide catheter from sub-selected branch vein into CS while maintaining stable position of the lead.
7. Cut guide catheter per ACUITY Universal Cutter directions for use below.

ACUITY Universal Cutter

1. Attach the cutter to the proximal lead body by snapping it into the distal lead management groove. Attach the lead to the proximal lead management hook of the cutter by rolling the lead into the hook. (See Figure 6.0 for cutter attachment)

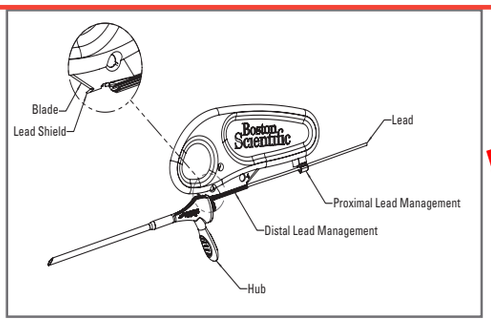

Figure 6.0 – Image of cutter engagement

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2. Hold the cutter securely with one hand while resting that hand on a stable surface. Grasp the thumb tab portion of the guide catheter hub with the other hand.
3. Pull the guide catheter back to the cutter and engage the tip of the lead shield into the proximal end of the catheter hub.
4. Pull the hub and guide catheter across the cutter blade and away from the lead until the guide catheter is completely cut.
5. Once the lead is visualized and the guide catheter has been completely removed, set the guide catheter aside.
6. While maintaining a secure hold on the lead distal to the cutter, carefully remove the cutter from the lead.
7. While observing under fluoroscopy, carefully remove the finishing wire or guidewire, verifying final lead position. If removing a 7F guide catheter first, do not remove the finishing wire until all guide catheters have been removed.
8. If removing a 7F guide catheter first, ensure that the 9F guide catheter is secured prior to removing the 7F guide catheter.

WARRANTY

Boston Scientific Corporation (BSC) warrants that reasonable care has been used in the design and manufacture of this instrument. **This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose.** Handling, storage, cleaning and sterilization of this instrument as well as other factors relating to the patient, diagnosis, treatment, surgical procedures and other matters beyond BSC's control directly affect the instrument and the results obtained from its use. BSC's obligation under this warranty is limited to the repair or replacement of this instrument and BSC shall not be liable for any incidental or consequential loss, damage or expense directly or indirectly arising from the use of this instrument. BSC neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this instrument. **BSC assumes no liability with respect to instruments reused, reprocessed or resterilized and makes no warranties, express or implied, including but not limited to merchantability or fitness for a particular purpose, with respect to such instruments.**

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EMBLEM™ MRI S-ICD SYSTEM

Subcutaneous Implantable Defibrillator

System Specifications

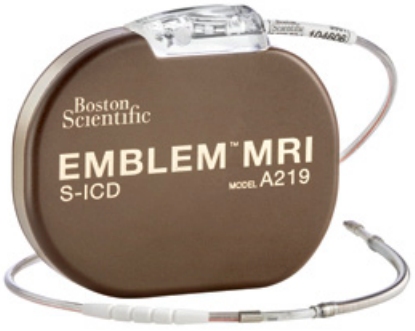
The EMBLEM MRI S-ICD is the second device in the EMBLEM S-ICD family and builds on previous size, longevity and remote patient management enhancements. Like transvenous ICDs, the EMBLEM MRI S-ICD System utilizes a pulse generator capable of delivering life-saving therapy. Unlike traditional ICDs, the 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, 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	80 J biphasic (only programmable during manual shock and induction test: 10 J - 80 J, steps of 5 J)
Shocks per episode	Maximum of 5 shocks

Diagnostic Tools

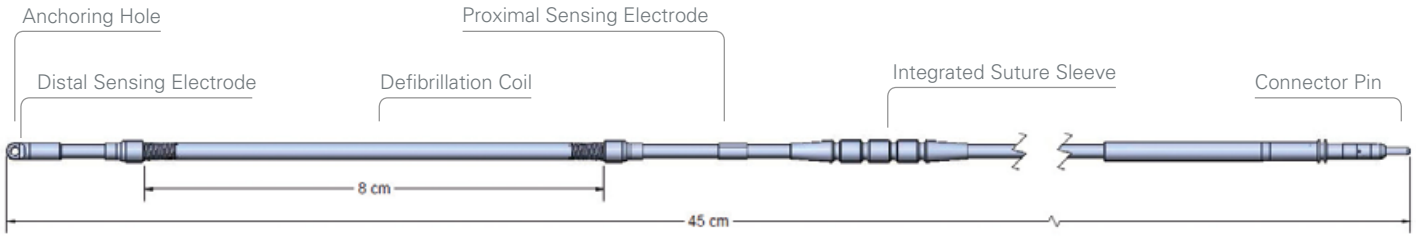
NEW AF Monitor	Information Provided: • Number of days with measured AF in the last 90 days • Estimate of measured AF in the last 90 days (%) Performance: Sensitivity >= 87 % Positive Predictive Value >=90 %
Episode storage	S-ECG storage for over 40 arrhythmic events (treated & untreated)
Other data	Electrode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

* 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	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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