

INGEVITY™ MRI PACING LEAD

ImageReady™ MR Conditional Pacing System

Passive Fixation Features

Tip electrode: Serves as the cathode for intracardiac right atrial and/or right ventricular pacing/sensing, using a platinum-iridium design that increases the effective active area for sensing and increases chronic lead tip stability while maintaining a small surface area for pacing. The high impedance performance and low pacing thresholds may combine to increase the pacing longevity of the pulse generator.

Tined: Silicone rubber tines located proximal to the distal pacing electrode provide fixation in the atrial appendage (preformed atrial J) or in the apex of the right ventricle (straight).

Fluoroscopic visibility: The platinum-iridium electrode design increases the visibility of the passive lead tip under fluoroscopy.

Preformed Atrial J-shaped fixation: The distal portion of the preformed atrial J lead is anchored in position by removing the stylet and allowing the distal tip to assume a J shape that lodges in the atrial appendage.

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 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.



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INGEVITY™ MRI, active fixation, Models 7740, 7741, 7742 INGEVITY™ MRI, passive fixation, Models 7731, 7732, 7735, 7736

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

Boston Scientific INGEVITY™ MRI leads provide improved maneuverability and tip control allowing for precise fixation for maximum stability after implant. The only MR-Conditional brady lead specifically designed for better overall performance.

INGEVITY™ - Designed from the ground up for the MR environment.

LEAD SPECIFICATIONS

Product	INGEVITY™ MRI Active	INGEVITY™ MRI Passive	INGEVITY™ MRI Passive
Model/Length	7740 / 45 cm 7741 / 52 cm 7742 / 59 cm	7731 / 52 cm 7732 / 59 cm	7735 / 45 cm 7736 / 52 cm
Type	Bipolar Atrial / Ventricular Straight	Bipolar Ventricular Straight	Bipolar Atrial Pre-formed J
Connector	IS-1 BI		
Compatibility	Pulse generators with an IS-1 port, which accepts an IS-1 terminal		
MRI Conditions of Use	Patient is implanted with the ImageReady™ MR Conditional Pacing System ^a Full body scan at 3T or 1.5T (SAR 4W/Kg) ^a		
Introducer without guide wire	6F (2.0mm)		
Introducer with guide wire	9F (3.0mm)		
Fixation	Extendable/retractable helix	Tined	Tined
Expected number of rotations to fully extend/retract the helix^b	7 turns with straight stylet 8 turns with J stylet	-	-
Recommended maximum number of turns to extend/retract the helix^b	30	-	-
Nominal fixation helix penetration depth	1.8mm	-	-
Tip to marker band distal edge	0.1 mm	-	-

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

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a) Please refer to the Pacing System MRI Technical Guide for other specified MRI conditions.

b) 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.

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Product	INGEVITY™ MRI Active	INGEVITY™ MRI Passive	INGEVITY™ MRI Passive
Nominal Electrode:			
Fixation helix surface area	4.5mm ²	-	-
Tip surface area	-	5 mm ²	5mm ²
Distance between electrodes	10.7 mm		
Anode electrode	20mm ²		
Nominal Diameter:			
Insertion	2.0mm (6F)		
Anode electrode	2.0 mm		
Lead body	1.9 mm		
Fixation helix	1.2mm	-	-
Material:			
External insulation	Polyurethane (55D)		
Internal insulation	Silicone rubber		
Terminal ring contact	316L 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	Single wound helical coils of MP35N™ ^c		
Steroid	0.91 mg dexamethasone acetate	0.61 mg dexamethasone acetate	0.61 mg dexamethasone acetate
Radiopaque markers	Pt-Ir		
Suture sleeve	Radiopaque white silicone rubber		

c) MP35N is a trademark of SPS Technologies, Inc.

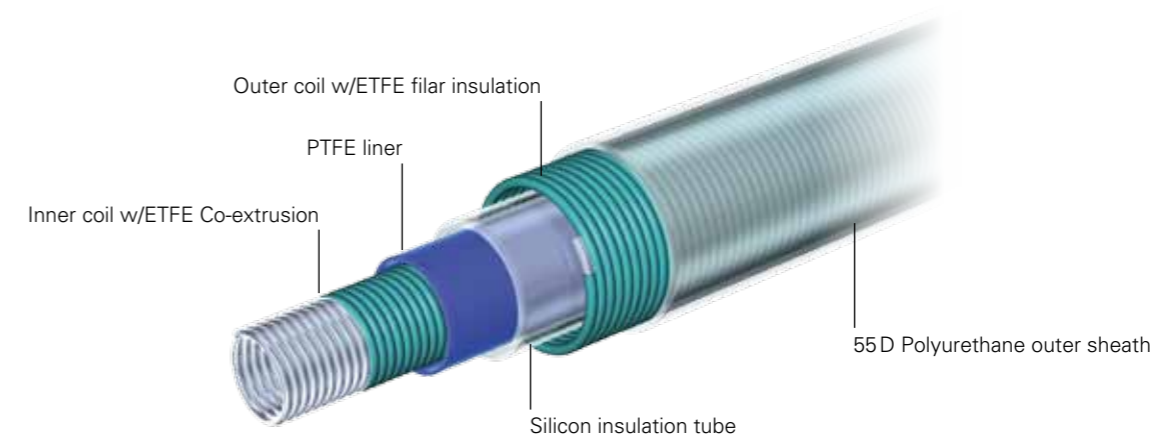
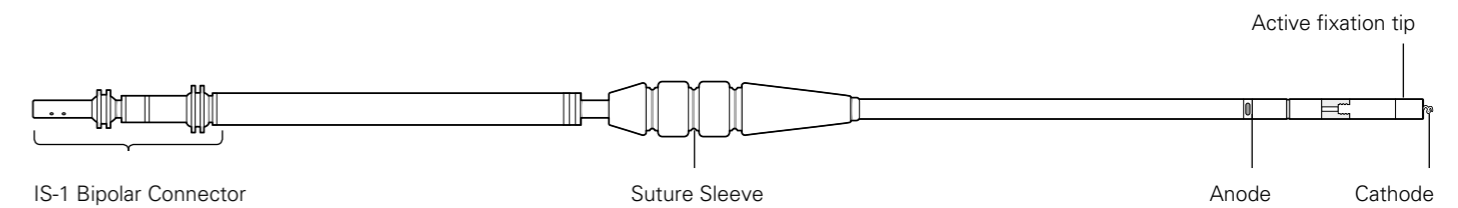
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Features

Lifetime Warranty: The INGEVITY™ MRI pacing lead family is backed with a lifetime warranty.¹

Lead Body Design: The isodiametric lead body consists of a coaxial design, that includes single-filar inner and outer coils, for improved flex fatigue with redundant insulation. The conductors are separated by both a silicone rubber and Polytetrafluoroethylene (PTFE) lining. Both the inner and outer coil are 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.

MRI Markers: INGEVITY™ MRI leads can be used as part of the ImageReady™ MR Conditional Pacing System when connected to Boston Scientific MR Conditional pulse generators. Two radiopaque platinum marker bands are visible in the terminal region (see x-ray image below). Two (2) radiopaque bands near the lead terminal region (see x-ray image below) are designed to aid in identification of this lead as MR Conditional when used as part of the ImageReady™ MR Conditional Pacing.



MRI Fluoroscopic Markers in lead terminal