INGEVITY™+ Pacing Lead

Active Fixation models: 7840, 7841, 7842
Passive Fixation models: 7831, 7832, 7835, 7836

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 including Left Bundle Branch Area pacing as an alternative to right ventricular pacing.

INGEVITY+ pacing leads are 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 the helix.[1] The stylet driven lead allows for continuous pacing and impedance monitoring during lead body rotations.

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.



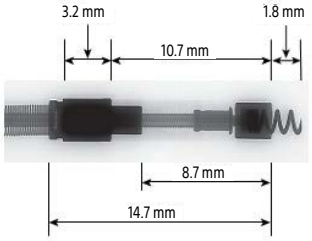
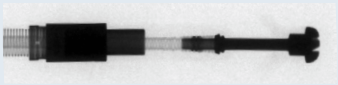
Lead specifications and reimbursement information

Product	Active Fixation Pacing Lead	Passive Fixation Pacing Lead
Model/Length	7840/45 cm straight 7841/52 cm straight 7842/59 cm straight	7831/52 cm straight 7832/59 cm straight 7835/45 cm J-shape 7836/52 cm J-shape
Type	Bipolar atrial/Ventricular straight and J-shape	
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	Tined
Expected number of rotations to fully extend/retract the helix†	6 ± 2 turns with straight stylet 7 ± 3 turns with J stylet	NA
Recommended maximum number of turns to extend/retract the helix†	30	NA
Nominal fixation helix penetration depth	1.8 mm	NA
Recommended maximum number of fixation/positioning attempts and lead body rotations in interventricular septum	60 total rotations in each direction (clockwise and counterclockwise) in a total of 3 fixation/positioning attempts as described below: • Maximum fixation/positioning attempts = 3 • Maximum clockwise lead body rotations per attempt = 20 • Maximum counterclockwise body rotations per attempt = 20	NA

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Lead specifications and reimbursement information *(continued)*

	Active Fixation Pacing Lead	Passive Fixation Pacing Lead
Nominal Electrode: Fixation helix surface area Distance between electrodes Anode electrode surface area Distal tip fluoroscopic view and distances	4.5 mm^2 10.7 mm 20 mm^2 	NA
Nominal Electrode: Tip surface area Distance between electrodes Anode electrode surface area Distal tip fluoroscopic view and distances	NA	5 mm^2 10.7 mm 20 mm^2 
Nominal Diameter: Insertion Anode electrode Lead body Fixation helix	2.0 mm (6 F) 2.0 mm 1.9 mm 1.2 mm	2.0 mm (6 F) 2.0 mm 1.9 mm NA
Material: External insulation Internal insulation Terminal ring contact IS-1 terminal pin contact Tip electrode Anode electrode	 Polyurethane (55 D) Silicone rubber 316 L stainless steel 316L stainless steel IROX™ (iridium oxide) coated Pt-Ir 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	0.61 mg dexamethasone acetate
Radiopaque Markers	Pt-Ir	
Suture Sleeve	Radiopaque white silicone rubber	
C-code	1898	

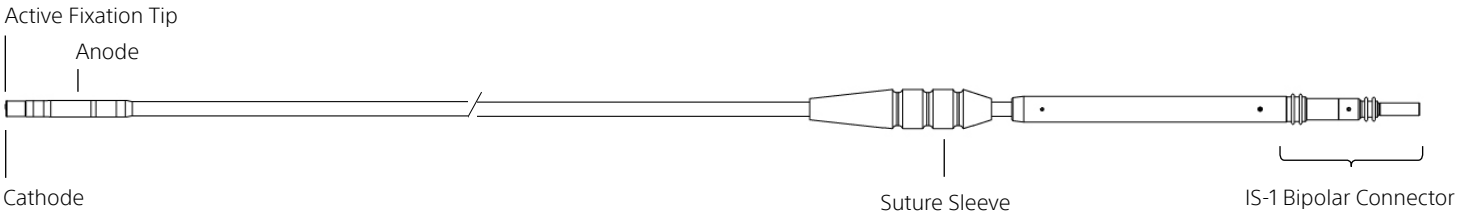
INGEVITY™+ Pacing Lead

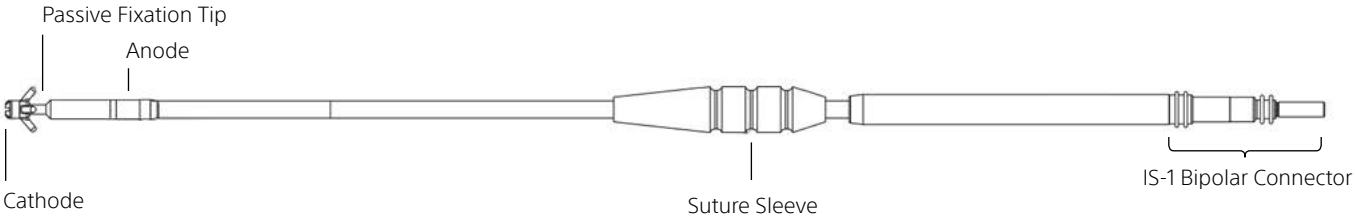
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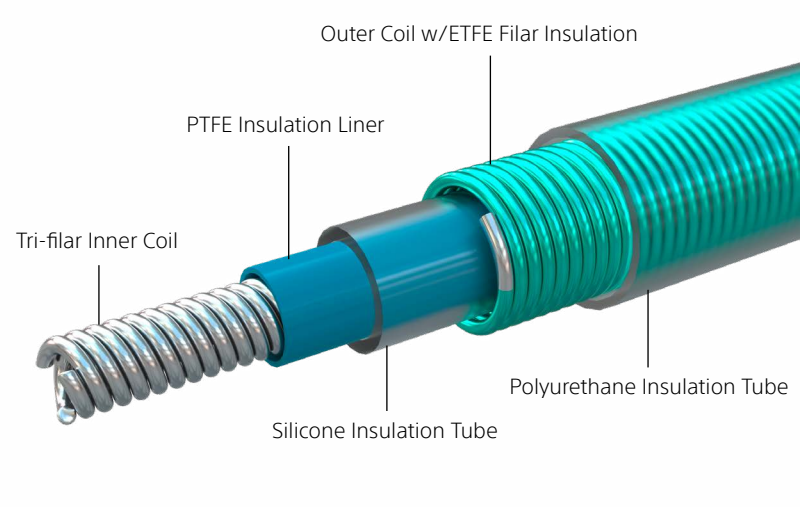
Features

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.

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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.

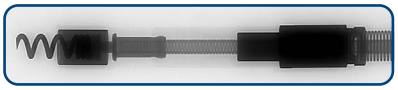
Mapping: The lead helix is electrically conductive to allow mapping (measuring pacing and sensing thresholds) of potential electrode positions without extending the helix into the tissue. Mapping prior to lead fixation is recommended as it can reduce the potential need for multiple lead positionings.

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	45 cm soft, long tapered	45 cm soft, long tapered, 45 cm extra soft, tapered 45 cm soft, atrial J, 45 cm soft, wide atrial J
7841	52 cm soft, long tapered	52 cm soft, long tapered, 52 cm extra soft, tapered 52 cm soft, atrial J, 52 cm soft, wide atrial J
7842	59 cm soft, long tapered	59 cm soft, long tapered, 59 cm extra soft, tapered
7831	52 cm soft, long tapered	52 cm soft, long tapered, 52 cm extra soft, tapered
7832	59 cm soft, long tapered	59 cm soft, long tapered, 59 cm extra soft, tapered
7835	None	45 cm soft, long tapered (2), 45 cm extra soft, tapered
7836	None	52 cm soft, long tapered (2), 52 cm extra soft, tapered

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Other separate accessories:

- Site Selective Pacing Catheters
- Helix Locking Tool

INGEVITY™+ Pace/Sense Lead
INGEVITY™+ Tined Fixation Pace/Sense Lead
INGEVITY™ MRI Tined Fixation Pace/Sense Lead
INGEVITY™ MRI Extendable/Retractable Fixation Pace/Sense Lead
Indications, Safety and Warnings

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www.bostonscientific.com

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

* 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.

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

** Only available with active fixation models.

1. Internal data on file.

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CRM-2625410-AA Rx Only