Boston Scientific
Advancing science for life™

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.

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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.

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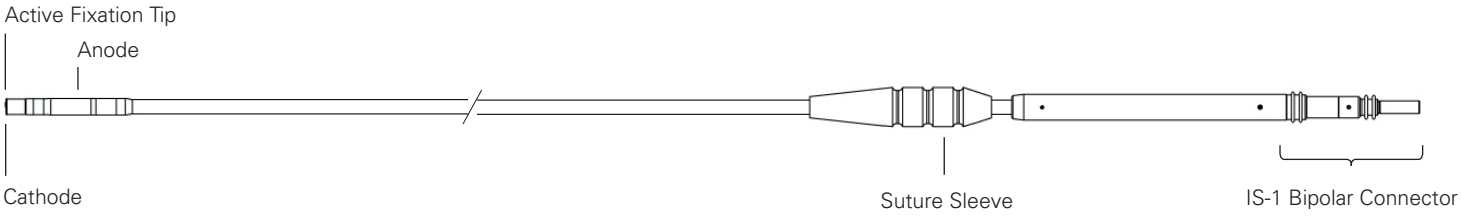
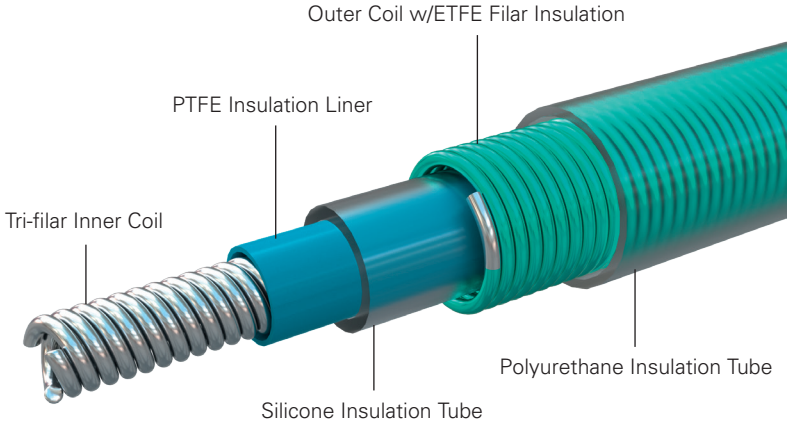
Features

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.

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

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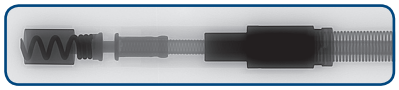
Active Fixation Features

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.

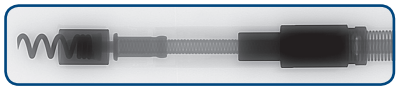
Mapping: The lead helix is electrically conductive to allow mapping (measuring pacing and sensing thresholds) of potential electrode positions without extending the helix into the tissue. Mapping prior to lead fixation is recommended as it can reduce the potential need for multiple lead positionings.

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	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.
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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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Rhythm Management
300 Boston Scientific Way
Marlborough, MA 01752-1234
www.bostonscientific.com

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

CRM-699008-AA