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

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 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

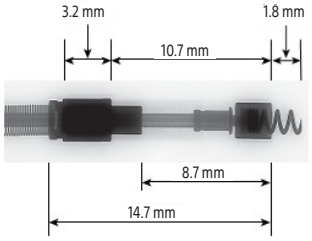
Product	INGEVITY+ Pacing Lead
Model / Length	7840 / 45 cm 7841 / 52 cm 7842 / 59 cm
Type	Bipolar Atrial / Ventricular Straight
Connector	IS-1 BI
Compatibility	Pulse generators with an IS-1 port, which accepts an IS-1 terminal
MRI Conditions of Use*	ImageReady™ MR-Conditional system when used with an 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
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

[1]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 Distance between electrodes Anode electrode surface area Distal tip fluoroscopic view and distances	 4.5 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 1.2mm
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
Radiopaque Markers	Pt-Ir
Suture Sleeve	Radiopaque white silicone rubber
C-code	1898

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

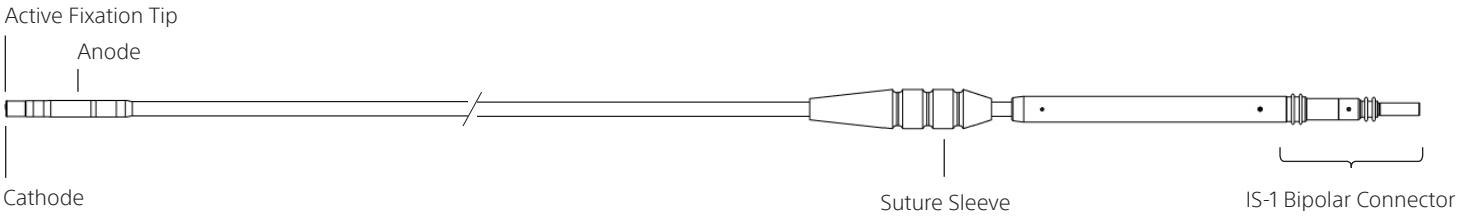
INGEVITY™+ Pacing Lead

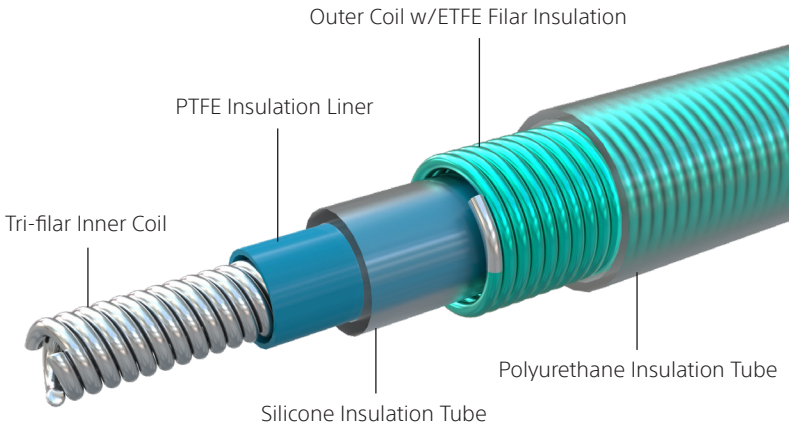
Active Fixation Models: 7840, 7841, 7842

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

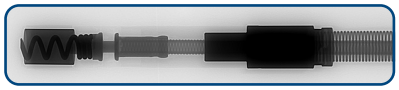
Active Fixation Features

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.

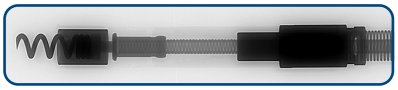
Mapping: The lead helix is electrically conductive to allow mapping (measuring pacing and sensing thresholds) of potential electrode positions without extending the helix into the tissue. Mapping prior to lead fixation is recommended as it can reduce the potential need for multiple lead positionings.

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	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

Other separate accessories:

- Site Selective Pacing Catheters
- Helix Locking Tool

INGEVITY™+ Pacing Lead

Active Fixation Models: 7840, 7841, 7842

INGEVITY™ + Pace/Sense Lead

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. In addition, pacing and sensing in the left bundle branch area is indicated with a single or dual chamber pacemaker as an alternative to the right ventricle.

CONTRAINDICATIONS

Use of this Boston Scientific lead is contraindicated for the following patients:

• Patients with a hypersensitivity to dexamethasone acetate
• Patients with mechanical tricuspid heart valves.

WARNINGS

General

• **Labeling knowledge**. Read this manual thoroughly before implantation to avoid damage to the pulse generator and/or lead. Such damage can result in patient injury or death.
• **Backup defibrillation protection.** Always have external defibrillation equipment available during implant and electrophysiologic testing. If not terminated in a timely fashion, an induced ventricular tachyarrhythmia can result in the patient's death.
• **Resuscitation availability**. 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.** Lead fracture, dislodgment, abrasion, or an incomplete connection can cause a periodic or continual loss of pacing or sensing or both.

Clinical Considerations

• **His Bundle Pacing.** These leads have not been evaluated for safety and performance in His bundle pacing; therefore, they are not intended for implantation in the His bundle. Evidence indicates that there is increased risk with His bundle pacing, compared to conventional pacing, including increased implantation procedure duration, elevated pacing threshold, increased occurrence of lead dislodgment and sensing issues, and more rapid battery depletion.[1]

[1] Zanon F, Ellenbogen KA, Dandamudi G, et al. Permanent His-bundle pacing: a systematic literature review and meta-analysis. Europace. 2018;20(11):1819-1826.

Handling

• **Excessive flexing.** Although pliable, the lead is not designed to tolerate excessive flexing, bending, or tension. This could cause structural weakness, conductor discontinuity, and/or lead dislodgment.
• **Do not kink leads.** Do not kink, twist, or braid the lead with other leads as doing so could cause lead insulation abrasion damage or conductor damage.

Implanted Related

• **Do not implant in MRI site Zone III.** Implant of the system cannot be performed in an MRI site Zone III (and higher) as defined by the American College of Radiology2. Some of the accessories packaged with pulse generators and leads, including the torque wrench and stylet wires, are not MR Conditional and should not be brought into the MRI scanner room, the control room, or the MRI site Zone III or IV areas.

2 ACR Manual on MR Safety, version 1.0, 2020.

• **Ensure position on interventricular septum.** Prior to fixation when implanting in the left bundle branch area, ensure the lead is positioned on the interventricular septum, not on the ventricular free wall. If the lead is not positioned on the interventricular septum, rotating the lead body could result in perforation and/or effusion.
• **Lead body rotation mechanism.** The lead body rotation mechanism is only used for placement of the lead within the interventricular septum, not to anchor the distal tip of the lead to the endocardial surface of the right atrium or right ventricle.
• **Avoid perforation of interventricular septum when rotating lead body.** To avoid perforation of the septum, monitor the location of the lead tip in the interventricular septum when rotating the lead body.
• **Helix entanglement.** Acute lead repositioning in and/or removal from the interventricular septum may cause the helix to become entangled and may result in lead component separation or deformation, and/or damage to the endocardium, valve, or vein. To reduce this risk, re-orient the catheter to the position used for the original implant prior to repositioning the lead. Consider lead abandonment as an alternative.
• **Avoid excessive force.** Avoid excessive forward force and/or torque on the lead and/ or catheter since these can damage the lead and/or cause tissue damage, such as cardiac perforation. Monitor electrical performance since abnormal values can indicate damage and/or tissue trauma.

Post-Implant

• **Magnetic Resonance Imaging (MRI) exposure.** 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, and significant harm to or death of the patient and/or damage to the implanted system may result. 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.
• **Diathermy.** 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.
• **Chronic removal of lead.** In a chronic situation, exercise caution if a lead must be removed from the interventricular septum since the helix may become deformed and/or entangled which could result in lead component separation and/or damage to the endocardium, valve, or vein. Monitor the condition of the helix and lead during an attempt to remove the lead. Consider lead abandonment as an alternative.

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.

Handling

• **Do not immerse in fluid.** Do not wipe or immerse the tip electrode in fluid. Such treatment will reduce the amount of steroid available when the lead is implanted. • **Chronic repositioning.** Optimum threshold performance might not be achieved if the lead is chronically repositioned because the steroid can be depleted. • **Protect from surface contamination.** The lead uses silicone rubber which can attract particulate matter, and therefore, must always be protected from surface contamination. • **No mineral oil on lead tip**. Mineral oil should never come in contact with the helix. Mineral oil on the helix may inhibit tissue ingrowth and conduction.

Implantation

• **Do not over extend or over-retract the helix**. Do not overextend or over-retract the helix. Exceeding the recommended maximum number of turns indicated in the specifications (Table 7 Specifications on page 36) may damage the conductor coil or fixation mechanism. • **Terminal pin maximum number of turns.** Do not rotate the terminal pin clockwise or counterclockwise more than the recommended maximum number of turns indicated in the specifications (Table 7 Specifications on page 36). Continuing to rotate the terminal pin can damage the lead, cause a conductor coil break during fixation, cause lead dislodgment, tissue trauma, and/or cause acute pacing threshold to rise. • **Maximum lead body rotations.** Do not exceed the recommended maximum number of fixation/positioning attempts and lead body rotations indicated in the specifications (Table 7 Specifications on page 36) during fixation/positioning attempts in the interventricular septum. Exceeding the recommended maximum number may damage the lead body and/or helix. It is recommended to replace the lead after 3 fixation/positioning attempts. • **Helix pre-extension.** If the helix is pre-extended prior to insertion into a lead delivery catheter, carefully insert the lead into the catheter to avoid damage to the helix.
• **Ensure a pre-extended helix remains within catheter.** Whether the helix is preextended prior to or after insertion into the catheter, ensure the helix does not extend beyond the end of the catheter until the fixation step to prevent damage to the tissue and/or lead. • **Prevent dislodgment.** To prevent dislodgment, avoid rotating the terminal pin counterclockwise after fixating the lead.

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: Acute or chronic septal perforation; Air embolism; Allergic reaction; Arterial damage with subsequent stenosis; Arteriovenous (AV) fistula; Bleeding; Bradycardia; Breakage/failure of the implant instruments; Cardiac perforation; Cardiac tamponade; Chronic nerve damage; Component failure; Conductor coil fracture; Coronary artery injury/acute coronary syndrome/myocardial infarction; 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; Prolonged exposure to fluoroscopic radiation; Prolonged procedure time; Pulse generator and/or lead migration; Renal failure from contrast media used during lead placement; Syncope; Tachyarrhythmias, which include acceleration of arrhythmias and early, recurrent atrial fibrillation; Thrombosis/thromboemboli; Trapped/damaged lead fixation helix (including unretrieved device fragment);Valve damage; Vasovagal response; Venous occlusion; Venous trauma (e.g., perforation,dissection, erosion).

Transient procedural adverse events are expected in some patients. These include, but are not limited to, discomfort, pain, and other systemic symptoms that might be related to medications or other interventions performed during implant.

If adverse events occur, invasive corrective action and/or modification or removal of the pulse generator and/or lead may be needed.

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. 97288068 (Rev A.1)

Any serious incident that occurs in relation to this device should be reported to Boston Scientific using the information on the back cover and to the relevant local regulatory authority.

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician trained or experienced in device implant and follow-up procedures.

Prior to use, please refer to all applicable "Instructions for Use" for more information on Intended Use/Indications for Use, Contraindications, Warnings, Precautions, Potential Adverse Events, and Operator's Instructions.

Boston Scientific
Advancing science for life™

Cardiology
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-AB