Boston Scientific
Advancing science for life™

INGEVITY™ MRI Pacing Lead

Passive Fixation Models: 7731, 7732, 7735 and 7736

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

INGEVITY MRI is specifically designed with four layers of insulation between conductors-and a polyurethane lead body.

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 MRI Pacing Lead Passive Straight	Passive J
Model/Length	7731 / 52 cm 7732 / 59 cm	7735 / 45 cm 7736 / 52 cm
Type	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*	ImageReady™ MR-Conditional Pacing 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	Tined	Tined

* Refer to the MRI Technical Guide for a complete list of cardiology and radiology conditions of use.

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Lead Specifications and Reimbursement Information *(continued)*

Product	INGEVITY MRI Pacing Lead Passive Straight	Passive J
Nominal Electrode:		
Tip surface area	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	
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	Single wound helical coils of MP35N DFT LT™[1]	
Steroid	0.61 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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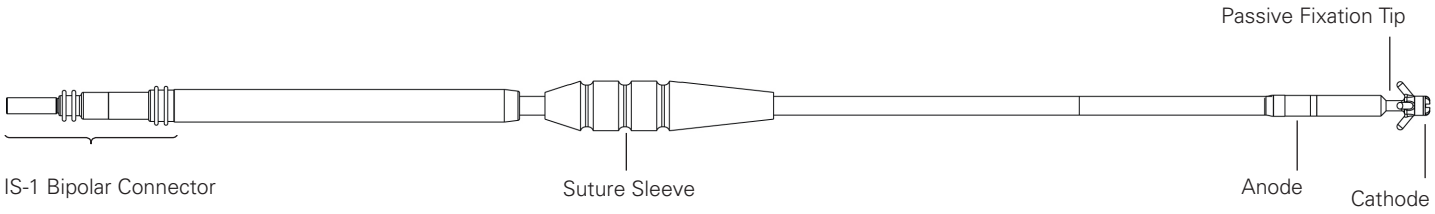
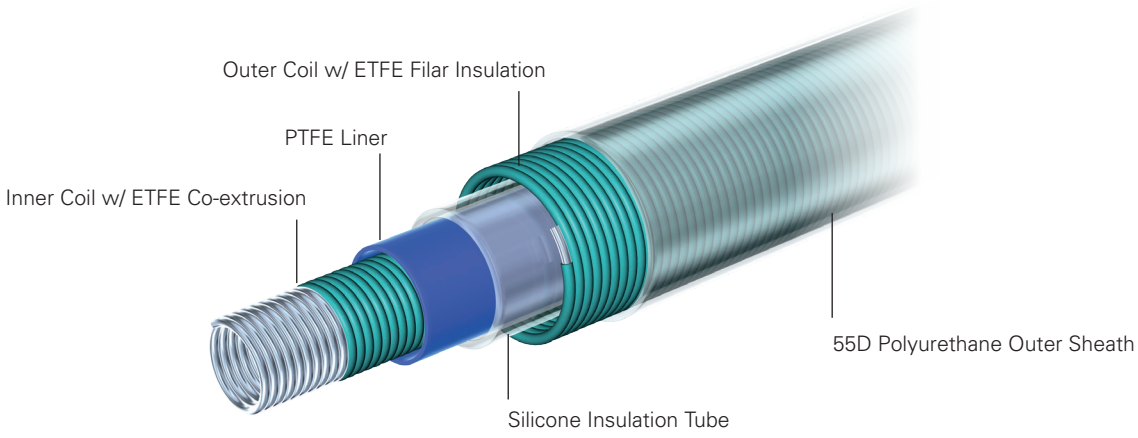
Features

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

Lead Body Design: The isodiametric lead body consists of a coaxial design, that includes single-filar inner and outer coils, to maximize fatigue life. 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.

*Limited lifetime warranty. For a full and complete description of the INGEVITY™ MRI family warranty - Please visit www.bostonscientific.com/warranty

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Passive Fixation Features

Tip Electrode: Serves as the cathode for intracardiac right atrial and/or right ventricular pacing/sensing, using a platinum-iridium design. 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 coated 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.

Packaged Accessories

- Vein Pick
- Stylet Guide
- Stylets:

	Pre-loaded	Packaged
7731 52 cm, straight	52 cm soft, long tapered	52 cm extra soft, tapered 52 cm soft, long tapered
7732 59 cm, straight	59 cm soft, long tapered	59 cm extra soft, tapered 59 cm soft, long tapered
7735 45 cm, atrial-J	None	45 cm extra soft, tapered 45 cm soft, long tapered (2)
7736 52 cm, atrial-J	None	52 cm extra soft, tapered 52 cm soft, long tapered (2)

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 MRIrelated 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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