Boston Scientific
Advancing science for life™

# INGEVITY™ MRI Pacing Lead

## Active Fixation Models: 7740, 7741 and 7742
## 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 the only pacing lead designed to be delivered through a 6F introducer and is specifically designed with four layers of insulation between conductors.

### Lead Specifications and Reimbursement Information

| Product | INGEVITY MRI Pacing Lead Active | Passive Straight | Passive J |
|---|---|---|---|
| **Model/Length** | 7740 / 45 cm<br>7741 / 52 cm<br>7742 / 59 cm | 7731 / 52 cm<br>7732 / 59 cm | 7735 / 45 cm<br>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** | ImageReady™ MR-Conditional Pacing System when used with ACCOLADE™ MRI[1]<br>- No MR exclusion zone, no height restriction<br>- Full body scan 1.5T (SAR 4W/Kg)<br>- Active and passive fixation leads | | |
| **Introducer without guide wire** | 6F (2.0 mm) | | |
| **Introducer with guide wire** | 9F (3.0 mm) | | |
| **Fixation** | Extendable/retractable helix | Tined | Tined |
| **Expected number of rotations to fully extend/ retract the helix[2]** | 7 turns with straight stylet<br>8 turns with J stylet | - | - |
| **Recommended maximum number of turns to extend / retract the helix[2]** | 30 | - | - |
| **Nominal fixation helix penetration depth** | 1.8 mm | - | - |

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## Lead Specifications and Reimbursement Information *(continued)*

| Product | Active | INGEVITY MRI Pacing Lead Passive Straight | Passive J |
|---|---|---|---|
| **Nominal Electrode:** | | | |
| Fixation helix surface area | 4.5 $mm^2$ | - | - |
| Tip surface area | - | 5 $mm^2$ | 5 $mm^2$ |
| Distance between electrodes | 10.7 mm | | |
| Anode electrode | 20 $mm^2$ | | |
| **Nominal Diameter:** | | | |
| Insertion | 2.0 mm (6 F) | | |
| Anode electrode | 2.0 mm | | |
| Lead body | 1.9 mm | | |
| Fixation helix | 1.2 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™ | | |
| **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-code** | 1898 | | |

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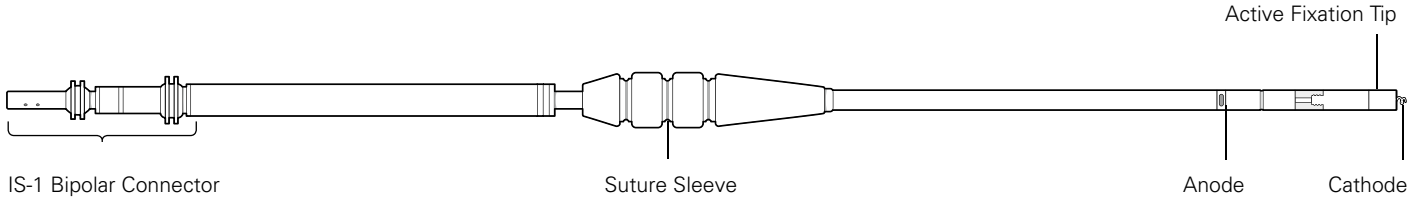
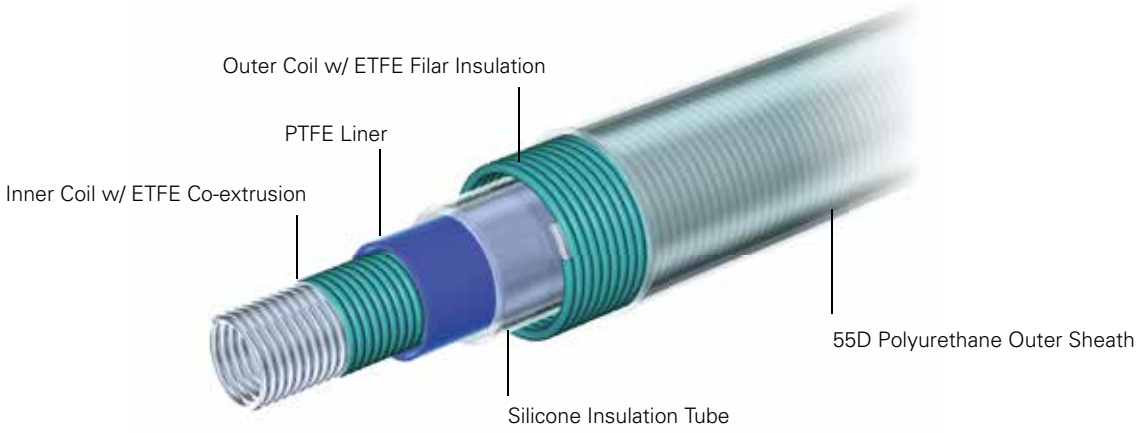
## Features

**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 review the warranty card included with the product labeling.

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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.

## 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.

Fully Retracted

Fully Extended

**Pacing Systems from Boston Scientific: INGEVITY™ MRI Extendable/Retractable Fixation and Tined Fixation**

**INDICATIONS:** INGEVITY™ MRI Leads are intended for chronic pacing and sensing in the right atrium (only preformed atrial J with the Tined Fixation) and/or right ventricle (only straight with the tined fixation) when used with a compatible pulse generator.

**CONTRAINDICATIONS:** Use of these leads are contraindicated in: patients with a hypersensitivity to a nominal single dose dexamethasone acetate: 0.61 mg for Tined Fixation, 0.91 mg for Extendable Retractable Fixation; and patients with mechanical tricuspid heart valves.

**WARNINGS:** Refer to the product labeling before implanting the lead 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 Extendable/Retractable Fixation: The safety and efficacy of the tip electrode placement in the right ventricle above midseptum has not been clinically established.

**PRECAUTIONS:** Refer to the implant product labeling for cautions specific to clinical considerations, sterilization and storage, handling, implantation, hospital and medical environments, and follow up testing of the lead. Failure to observe these cautions could result in incorrect lead implantation, lead damage/dislodgment, or harm to the patient. Prior to implantation of this lead, confirm lead/pulse generator compatibility. Lead fracture, dislodgment, abrasion, or an incomplete connection can cause a periodic or continual loss of pacing or sensing or both. Defibrillation equipment should be kept nearby during the implant procedure. Optimum threshold performance might not be achieved if the lead is chronically repositioned because the steroid can be depleted.

For Extendable/Retractable Fixation: Avoid creating sharp bends while extending or retracting the helix. Sharp bends can increase the risk of breaking the conductor coil or fixation mechanism during helix extension or retraction. Do not rotate the terminal pin clockwise or counterclockwise more than the recommended maximum number of turns indicated in the specifications. Continuing to rotate the terminal pin once the helix is fully extended or retracted (as indicated by fluoroscopy) can damage the lead, cause a conductor coil break during fixation, cause lead dislodgment, tissue trauma, and/or cause acute pacing threshold to rise.

**POTENTIAL ADVERSE EVENTS**: Potential adverse events include, but are not limited to the following: allergic/physical/physiologic reaction, death, erosion/migration, fibrillation or other arrhythmias, lead or accessory breakage (fracture/insulation/lead tip), hematoma/seroma, inappropriate or inability to provide therapy (pacing/sensing), infection, procedure-related, and component failure. In rare cases severe complications or device failures can occur.

For a list of potential adverse events associated with MRI scanning, refer to the MRI Technical Guide.

*Refer to the product labeling for specific indications, contraindications, warnings/precautions and adverse events. Rx only. (Rev. A)*

**Pacing Systems from Boston Scientific -**

**ACCOLADE™, ACCOLADE™ MRI, PROPONENT™, PROPONENT™ MRI, ESSENTIO™, ESSENTIO™ MRI, ALTRUA™ 2, FORMIO™, FORMIO™ MRI, VITALIO™, VITALIO™ MRI, INGENIO™, INGENIO™ MRI, ADVANTIO™**

**INDICATIONS AND USAGE**

Boston Scientific pacemakers are indicated for treatment of the following conditions:

- Symptomatic paroxysmal or permanent second- or third-degree AV block
- Symptomatic bilateral bundle branch block
- Symptomatic paroxysmal or transient sinus node dysfunction with or without associated AV conduction disorders (i.e., sinus bradycardia, sinus arrest, sinoatrial [SA] block)
- Bradycardia-tachycardia syndrome, to prevent symptomatic bradycardia or some forms of symptomatic tachyarrhythmias
- Neurovascular (vaso-vagal) syndromes or hypersensitive carotid sinus syndromes

Adaptive-rate pacing is indicated for patients exhibiting chronotropic incompetence and who may benefit from increased pacing rates concurrent with increases in minute ventilation and/or level of physical activity.

Dual-chamber and atrial tracking modes are also indicated for patients who may benefit from maintenance of AV synchrony.

Dual chamber modes are specifically indicated for treatment of the following:

- Conduction disorders that require restoration of AV synchrony, including varying degrees of AV block
- VVI intolerance (i.e., pacemaker syndrome) in the presence of persistent sinus rhythm
- Low cardiac output or congestive heart failure secondary to bradycardia

**CONTRAINDICATIONS**

These Boston Scientific pacemakers are contraindicated in patients who have a separate implanted cardioverter defibrillator (ICD) with transvenous leads.

Use of certain pacing modes and/or features available in these Boston Scientific pacemakers is contraindicated for the following patients under the circumstances listed:

- Unipolar pacing or use of the MV Sensor with a Subcutaneous Implantable Cardioverter Defibrillator (S-ICD) because it may cause inappropriate therapy or inhibition of appropriate S-ICD therapy.
- Minute Ventilation in patients with both unipolar atrial and ventricular leads
- Single-chamber atrial pacing in patients with impaired AV nodal conduction
- Atrial tracking modes for patients with chronic refractory atrial tachyarrhythmias (atrial fibrillation or flutter), which might trigger ventricular pacing
- Dual-chamber and single-chamber atrial pacing in patients with chronic refractory atrial tachyarrhythmias
- Asynchronous pacing in the presence (or likelihood) of competition between paced and intrinsic rhythms

**WARNINGS**

**General**

Read the manual thoroughly before implantation to avoid damage to the pulse generator and/or lead. Such damage can result in patient injury or death. For single patient use only. Do not reuse, reprocess, or resterilize. Always have external defibrillation equipment available during implant and electrophysiologic testing. Using multiple pulse generators could cause pulse generator interaction, resulting in patient injury or a lack of therapy delivery. In response to applicable nonrecoverable or repeat fault conditions, the pulse generator will switch irreversibly to Safety Core operation. Do not kink, twist, or braid the lead with other leads. Do not use atrial tracking modes in patients with chronic refractory atrial tachyarrhythmias. Lead Safety Switch should be programmed Off for patients with an ICD. Unipolar pacing due to Lead Safety Switch is contraindicated for patients with an ICD. Unipolar pacing due to RAAT is contraindicated and should be programmed off for patients with an ICD. If programmed to a fixed atrial Sensitivity value of 0.15 mV, or a fixed sensitivity value of 2.0 mV or less in a unipolar lead configuration in any chamber, the pulse generator may be more susceptible to electromagnetic interference. Advise patients to seek medical guidance before entering environments that could adversely affect the operation of the active implantable medical device. Unless all of the MRI Conditions of Use are met, MRI scanning of the patient does not meet MR Conditional requirements for the implanted system, and significant harm to or death of the patient and/or damage to the implanted system may result. Do not subject a patient with an implanted pulse generator and/or lead to diathermy.

**PRECAUTIONS**

For specific information on precautions, refer to the following sections of the product labeling: clinical considerations; sterilization and storage; implantation; device programming; environmental and medical therapy hazards; hospital and medical environments; home and occupational environments; follow-up testing; explant and disposal; supplemental precautionary information. Advise patients to avoid sources of EMI. The pulse generator may inhibit pacing due to oversensing, or may switch to asynchronous pacing at the programmed pacing rate or at the magnet rate in the presence of EMI. These pulse generators are compatible for use with a Subcutaneous Implantable Cardioverter Defibrillator (S-ICD) when implanted with bipolar leads and programmed to a bipolar pacing configuration.

**POTENTIAL ADVERSE EVENTS**

Potential adverse events include, but are not limited to, the following: allergic/physical/physiologic reaction, death, erosion/migration, fibrillation or other arrhythmias, lead or accessory breakage (fracture/insulation/lead tip), hematoma/seroma, inappropriate or inability to provide therapy (pacing/sensing), infection, procedure related, and component failure. Patients may develop psychological intolerance to a pulse generator system and may experience fear of shocking, fear of device failure, or imagined shocking. In rare cases severe complications or device failures can occur.

For a list of potential adverse events associated with MRI scanning, refer to the MRI Technical Guide.

*Refer to the product labeling for specific indications, contraindications, warnings/precautions and adverse events.*

*Rx only. (Rev. A)*

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*Patients and Families:*
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1. Please refer to the MRI Technical Guide: ImageReady™ MR Conditional Pacing System as the system is designated as MR Conditional in accordance with specific conditions.
2. 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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