

SUMMARY

This article provides tips for implanting Boston Scientific's INGEVITY™ MRI extendable/retractable fixation leads.

The information provided is not intended to supersede device-specific labeling. For complete implant instructions and potential risks, please refer to the applicable **Instructions For Use**.

Products Referenced

INGEVITY family of Pace/Sense Extendable/Retractable Fixation Leads

NOTE: A subset of INGEVITY leads are not designated as MR-Conditional (available in Canada only). However, these lead implant tips still apply.

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For comprehensive information on device operation, reference the full instructions for use or found at: www.bostonscientific-elabeling.com.

CAUTION: The law restricts this device to sale by or on the order of a physician.

Products referenced herein may not be approved in all geographies. Information is for the use in countries with applicable Health Authority product registrations.

All graphics produced by Boston Scientific Corporation, unless otherwise noted.

CRT-D: Cardiac Resynchronization Therapy Defibrillator

CRT-P: Cardiac Resynchronization Therapy Pacemaker

ICD: Implantable Cardioverter Defibrillator

S-ICD: Subcutaneous Implantable Defibrillator

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INGEVITY™ MRI Extendable/Retractable Fixation Lead Implant Tips

INGEVITY™ MRI extendable/retractable bipolar fixation, steroid-eluting, endocardial pace/sense leads are designed for permanent implantation in either atrial or ventricular applications. The lead body consists of a coaxial design that includes single-filar inner and outer coils for improved flex fatigue. There are four layers of protective insulation between conductors, which are designed for long-term reliability. See Figures 1 and 2.



Figure 1. Active Fixation Helix Mechanism

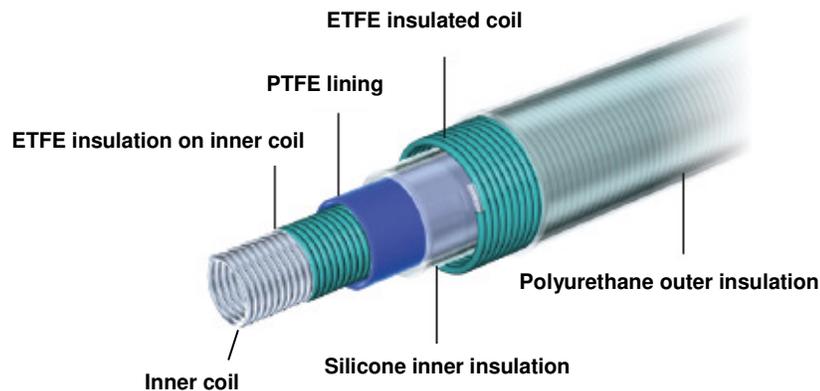


Figure 2. Lead Body Design

NOTE: Prior to lead implant please review product labeling (including the INGEVITY MRI *Physician's Lead Manual*) for full operating instructions.

Summary of Lead Implant Tips

The added layers of insulation and single-filar design may impact the rate at which torque is transferred from the terminal pin to the helix mechanism when extending or retracting the helix in tortuous anatomy. Please note that sharp bends in the lead terminal or lead body or excessive fixation tool rotation may result in binding of the helix, potentially followed by conductor coil breakage. The lead should not be used, and should be returned to Boston Scientific for analysis, if extension or retraction fails or if conductor coil breakage occurs.

The following tips will assist with a successful lead implant.

- Any curves introduced into the stylet could increase the number of turns needed to extend or retract the helix. The number of turns may vary based on patient anatomy and implant conditions.
- The recommended introducer size is 6F (9F when used with a guide wire).
- Avoid creating sharp bends in the lead terminal or lead body while extending or retracting the helix as this may contribute to an increase in the number of turns required to extend or retract the helix and increase the risk of breaking the conductor coil.

- Slowly rotate the fixation tool (approximately 1 rotation per second) to extend or retract the helix. Rotating too quickly may not allow the torque to transfer, resulting in binding and potential breakage of the conductor coil.
- The maximum number of rotations to extend or retract the helix is 30. Do not overextend or over-retract the helix. The lead conductor coil can be damaged or broken if terminal pin rotation continues once the helix is fully extended or retracted.
- Use fluoroscopy to confirm when the helix is fully extended or retracted.
- Verify electrical performance of the lead using a pacing system analyzer (PSA) before attaching the lead to the pulse generator. Verifying electrical performance will confirm lead integrity.
- Evaluate the lead signals using the pulse generator. A discontinuous signal may indicate a lead conductor break, fracture or an otherwise damaged lead, or an insulation break that would necessitate lead replacement.

Preparing to Implant

Verify helix extension/retraction prior to implantation. Before implanting the lead, verify the mechanical function of the lead. Attach the fixation tool (packaged with the lead) to the terminal pin. Rotate the terminal pin clockwise and counterclockwise to visually observe extension and retraction of the helix mechanism. After exercising the helix mechanism, remove the tool from the terminal pin, thereby releasing residual torque. Note that the amount of torque (number of turns) required to advance the helix to full extension will be different (likely greater) when the lead has been positioned in vivo.

CAUTIONS:

- Do not overextend or over-retract the helix. The lead conductor coil can be damaged or broken if terminal pin rotation continues once the helix is fully extended or retracted.
- If the helix cannot be extended or retracted, do not use the lead.
- To promote proper function, do not use a lead with a deformed helix or damaged helix fixation mechanism. To avoid electrode damage do not attempt to straighten or realign the helix.
- Avoid creating sharp bends in the lead terminal or lead body while extending or retracting the helix. Sharp bends can increase the risk of breaking the conductor coil during helix extension and retraction.

Prepare and insert the preferred stylet. If shaping the stylet is desired, remove the stylet from the lead and gently curve the stylet with any sterile, smooth-surfaced instrument. Avoid sharp bends, which will hinder lead positioning and helix extension or retraction and could increase risk of lead damage. Ensure the stylet is fully inserted before the lead is implanted.

NOTE: Any curves introduced into the stylet could increase the number of turns needed to extend or retract the helix. The number of turns may vary based on patient anatomy and implant conditions.

CAUTIONS:

- Do not use a sharp object to curve the distal end of a stylet. Do not curve a stylet while it is in the lead. If a curved stylet is preferred, gently curve a straight stylet before inserting it into the lead to avoid damage to the stylet and lead.
- Do not bend the lead with a stylet in place. Bending the lead could damage the conductor and insulation material.

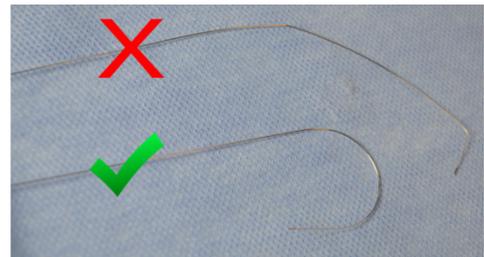


Figure 3. Bent stylet and gently curved stylet.

Select an appropriate lead introducer. Use the recommended introducer size, which is 6F with no guide wire and 9F when used with a guide wire.

NOTES:

- *The recommended size introducers are available from your local Boston Scientific representative or customer service.*
- *Undesirable kinking is more likely to occur when using an introducer that is larger than the recommended size.*

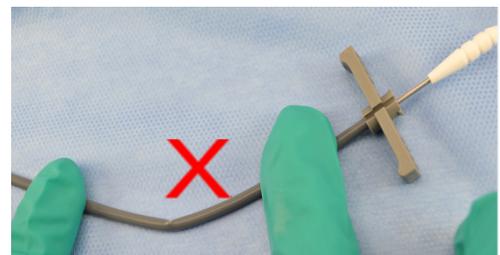


Figure 4. Bent/kinked introducer.

During Implant

Affix lead. When an acceptable position for the lead tip has been found (as indicated by impedance and pacing/sensing thresholds), the lead may be fixated to the heart wall.

- Attach the fixation tool to the terminal pin of the lead. Press the handles of the fixation tool together and place the lead's terminal pin in the preformed groove of the tool. Release the tension on the handles to secure the fixation tool on the terminal pin.
- Apply adequate pressure to the lead body to position the distal electrode against the desired fixation site.
- **Slowly** rotate the fixation tool clockwise (*approximately 1 rotation per second*) to extend the helix and affix it to the heart wall.

Stylet curvature, tortuous patient anatomy, blood or tissue in the helix mechanism, and lead repositioning can increase the number of turns required to fully extend or retract the helix. The number of turns to extend or retract the helix may vary based on patient anatomy and implant conditions. Maintain as straight a trajectory as possible coming out of the patient anatomy.

TIP! Physicians should consider carefully counting rotations. The expected number of turns to extend the helix is 7 with a straight stylet or 8 with a curved (J) stylet.

- View the radiopaque markers under fluoroscopy to determine if the helix is fully extended (Figure 5 and 6). If fluoroscopy reveals that the helix is not fully extended, continue to rotate the fixation tool while viewing under fluoroscopy until helix is fully extended. The fixation tool may be safely turned up to 30 times to extend the helix. Do not exceed the maximum number of 30 rotations.

TIP! Turn count or torque feedback will not verify fixation. Fluoroscopic viewing is needed to verify when full extension is achieved.

Gap closes and helix extends beyond the distal marker when helix is fully extended.



Figure 5. Fully Retracted Helix

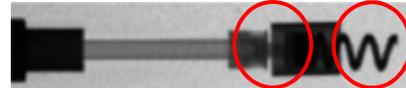


Figure 6. Fully Extended Helix

- Once the lead is affixed in the desired location, loosely hold the proximal end of the lead and remove the fixation tool from the terminal pin by pressing the handles together. When the fixation tool is released from the terminal pin, residual torque may cause minimal counter-rotation of the terminal pin.
- If retraction of the helix is required, remove the fixation tool to release torque built up from the previous extension attempt. Reattach the fixation tool to the terminal pin and slowly rotate the fixation tool counterclockwise (*approximately 1 rotation per second*) to retract the helix.

NOTE: If lead repositioning is necessary, the fixation tool should be removed each time the lead is repositioned and the helix is extended/retracted.

CAUTIONS:

- Avoid creating sharp bends in the lead terminal or lead body while extending or retracting the helix. Sharp bends can increase the risk of breaking the conductor coil during helix extension and retraction.
- Do not rotate the terminal pin clockwise or counterclockwise more than the recommended maximum (30 turns). Continuing to rotate the terminal pin once the helix is fully extended or retracted (as indicated by fluoroscopy) can damage the lead, cause lead dislodgement, tissue trauma, and/or cause acute pacing threshold rise.

Lead Performance Testing

- When the lead is placed in the desired location, partially withdraw the stylet so that the terminal pin is accessible.
- Verify electrical performance of the lead (pacing thresholds, intrinsic amplitudes, impedance) using a pacing system analyzer (PSA) before attaching the lead to the pulse generator. Verifying electrical performance will confirm lead integrity.
- Secure the lead.
- Verify the stylet and any terminal pin accessories are removed prior to connecting the lead to the pulse generator.
- Connect lead to pulse generator and perform electrical testing (pacing thresholds, intrinsic amplitudes, impedance, EGM continuity) with pulse generator.
- Unsatisfactory test measurements or a discontinuous electrogram signal may indicate a lead conductor coil break, fracture or an otherwise damaged lead, or an insulation break that would necessitate lead replacement.

For complete step by step lead implantation instructions, reference product labeling (including the INGEVITY MRI *Physician's Lead Manual*). For additional information, contact Boston Scientific Technical Services.

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 physician's manual(s) for specific indications, contraindications, warning/precautions and adverse events. Rx only. (Rev. A)
