INGEVITY™ MRI
Pacing Lead

Proven Performance Beyond MRI

With IMAGE READY™
MR-Conditional Systems


**Stacks Up To The Competition**

**INGEVITY™ MRI Pacing Lead**, the industry’s leading-edge pacing technology, is also the most extensively studied.

Safety, performance, and effectiveness of the INGEVITY MRI Pacing Lead are backed by the industry’s largest pacing study:

- Comprised of 2 studies, INGEVITY and SAMURAI, with over 150 sites worldwide
- Over 2,300 implant procedures completed

In the industry’s largest clinical studies for pacing leads, INGEVITY™ demonstrated:

- Very low rates of complications at 2.1%
- A dislodgment complication rate of 1.2% (26/2264)
- No adverse events when performing MRI and no change in electrical performance
- In the SAMURAI trial, no MR-related complications were observed

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**Table: Lead-Related Complication %**

<table>
<thead>
<tr>
<th>Study</th>
<th>Sample Size</th>
<th>Manufacturer</th>
<th>Data Type</th>
<th>Year</th>
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</thead>
<tbody>
<tr>
<td>INGEVITY MRI (Active + Passive Leads)</td>
<td>2264</td>
<td>BSC</td>
<td>MC, P</td>
<td>2015</td>
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<tr>
<td>MRI CapsureFix</td>
<td>1599</td>
<td>BSC</td>
<td>MC, P</td>
<td>2015</td>
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<td>Novus</td>
<td>526</td>
<td>MDT</td>
<td>MC, P</td>
<td>2015</td>
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<td>INGEVITY + SAMURAI*</td>
<td>928</td>
<td>MDT</td>
<td>MC, P</td>
<td>2015</td>
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<tr>
<td>Advisa Trial*</td>
<td>238</td>
<td>STJ</td>
<td>MC, P</td>
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<td>SAMURAI Trial</td>
<td>220</td>
<td>BSC</td>
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<td>REVO Trial*</td>
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<td>MDT</td>
<td>MC, P</td>
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<td>5076 Trial</td>
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<td>Flextend Trial</td>
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<td>Ten-dril</td>
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<td>BSC</td>
<td>MC, P</td>
<td>2000</td>
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</tbody>
</table>

* MRI Lead Studied, ** MC = Multi-center, P = Prospective
99.3% of physicians surveyed were satisfied with overall handling performance of INGEVITY MRI Pacing Lead. Thoughtfully engineered to ease delivery and improve maneuverability during implant.

In the studies:

- 99.7% of physicians surveyed rated handling and maneuverability as met or exceeded their expectations.
- 99.4% of physicians surveyed agree or somewhat agree that INGEVITY MRI Pacing Lead was easy to pass through small vessels.
- 97.1% of physicians surveyed rated radiopacity as met or exceeded expectations.

Small, thin 6F lead body design for improved handling.

Isodiametric lead body design provides a smooth, non-transition body feel from tip to terminal to ease access to fixation site.

Discover more INGEVITY™ benefits at www.BostonScientific.com/INGEVITY
LATITUDE™ NXT Patient Management System from
Boston Scientific

The LATITUDE™ NXT Patient Management System is intended for use to remotely communicate with an implanted patient device and transfer data to a central database. The LATITUDE NXT System provides patient data that can be used as part of the clinical evaluation of the patient.

Contraindications

The LATITUDE NXT Patient Management System is contraindicated for use with any implanted device other than a compatible Boston Scientific implanted device. Not all Boston Scientific implanted devices are compatible with the LATITUDE System. For contraindications related to the implanted device, refer to the System Guide for the Boston Scientific implanted device being interrogated.

Precautions

Alerts may appear on the LATITUDE NXT website on a daily basis. Primary notification of alert conditions is through the View Patient List page on the LATITUDE NXT website. The clinician needs to log onto the LATITUDE NXT website in order to receive alerts. Although secondary notification through email and SMS text messages is available, these reminders are dependent on external systems and may not be reliable. The clinician shall verify alert conditions directly through the LATITUDE System prior to taking any medical action. For more information on the ImageReady MR-Conditional Pacing Systems, visit www.BostonScientific.com/imageready, or call 1.844.4BSC.MRI (1.844.427.2674).

Assured Performance Beyond MRI

• Safe and effective for full body scanning in 1.5T and 3T MRI environments when MRI Conditions of Use are met1

• First Level Controlled Operating Mode (SAR 4W/Kg) for all INGEVITY MRI lead models2

• Broad portfolio with 7 active and passive fixation MRI pacing lead models approved in combination with SR, DR, and EL ACCOLADE MRI and ESSENTIO MRI pacemaker models3

• Assured Performance beyond MRI - INGEVITY MRI leads are approved for use with the ACCOLADE MRI and ESSENTIO MRI pacemakers as an ImageReady MRI-Conditional Pacing System4

• Respiration-Based Pacing System - Only Boston Scientific offers respiration-based pacing therapy to help fully restore Chronotropic Competence5

• ImageReady MR-Conditional Pacing Systems offer:
  - Automated Daily Monitoring
  - LATITUDE™ NXT Patient Management System allows for earlier intervention and improved patient outcomes
  - Post-Operative System Test (POST) - Eases patient discharge with an automatic system evaluation that improves workflow after implant
  - Actionable Data - Provides a comprehensive view of your patients’ AT/AF and HF status so that you can intervene earlier and more efficiently monitor their disease progression*
  - Respiration-Based Pacing System - Only Boston Scientific offers respiration-based pacing therapy to help fully restore Chronotropic Competence5

INGEVITY MRI leads are approved for use with the ACCOLADE MRI and ESSENTIO MRI pacemakers as an ImageReady MR-Conditional Pacing System7

(Rev. C)
**Pacing Leads from Boston Scientific – INGEVITY™ MRI**

**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 these leads are contraindicated in patients with a hypersensitivity to a nominal single dose desacetasyl acetic acid. 0.01 mg for Tied Fixation, 0.05 mg for Extendable Retractable Fixation, and patients with mechanical tricuspid heart valves.

**WARNINGS:**

Refer to the product labeling before implanting this lead to avoid damage to the pulse generator and/or lead. For single patient use only. Do not reuse, resorb, or resterilize. Always have external defibrillatory equipment available during implant and electrophysiological testing. Ensure that an external defibrillator and medical personnel skilled in CPR are present during post-implant device testing should the patient require external rescus. Lead fracture, dislodgment, abrasion, or an incomplete connection can cause a periodic or continual loss of pacing or sensing or both. Although4 the lead is not designed to tolerate excessive flexing, bending, or tension. Do not kink, twist, or braided this lead with other leads. Implant of the system cannot be performed in an MRI suite Zone 3 (i.e., high field). Take care to obtain appropriate MRI equipment. Failure to do so may result in lead movement, dislodgment, or loss of 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 MRI-related Warnings and Precautions.

**CONTRAINDICATIONS:**

Patients with 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 conditions:

- **During an MRI procedure:**
  - Pacing
  - Defibrillation
  - Dual-chamber and single-chamber atrial pacing in patients with chronic refractory atrial tachyarrhythmias
  - Anti-shock pacing in the presence (or likelihood) of competition between pacable and intrinsic rhythms.

**PRECAUTIONS:**

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 product labeling for cautions specific to the clinical considerations, sterilization and handling, implantation and post-operative care, 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. Defibrillatory equipment should be kept nearby during the implant procedure. Optimal threshold performance might not be achieved if the lead is chronically repositioned because the atrial record is not stable.

**For Extendable Retractable Fixation:**

Avoid coating sharp bands while extending or retracting the helix. Sharp bands 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 tangle, tissue trauma, and/or cause acute pacing threshold to rise.

**POTENTIAL ADVERSE EVENTS:**

Pace out events include, but are not limited to the following allergic/physical/physiologic reaction, death, erosion/insersion, fixation, 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 for specific indications, contraindications, warnings/procedures and adverse events.

Re: only (Rx: A)

### Sources

1. Patent publication number-US20100331936 A1, BSC internal documents; ELN 2837210, ELN 6283393, ELN 2672102 and ELN 6283393.
4. SAMURAI Clinical Report: MRI visit + 1 month follow-up, 2015-02.
6. INEVIY Clinical report: MRI Technical Guide: ImageReady™ MRI-Conditional Pacing System as the system is designated as MR-conditional in accordance with specific conditions.
7. N/A with respect to ESSENTIAL MRI Parameter Manual.

### Pacing Systems - ACCOLADE™MRI, ESSENTIAL™MRI, VITALITY™MRI, INGEVITY™MRI, ADVANTIO™MRI

**INDICATIONS**

Boston Scientific pacemakers are indicated for the following conditions:

- Symptomatic paroxysmal or permanent second- or third-degree AV block
- Symptomatic bilateral bundle branch block
- Symptomatic paroxysmal or transient sino nodal dysfunction
- AV conduction disorders including second- or third-degree AV block, sick sinus syndrome, atrial fibrillation, atrial flutter, and atrioventricular (AV) block associated with AV conduction disorders
- Certain forms of symptomatic tachycardias
- Neurovascular (vaso-vagal) syndromes or hypotensive/syncope disorders
- Adverse arrhythmias in patients who may benefit from observation or treatment.

**CONTRAINDICATIONS**

These Boston Scientific pacemakers are contraindicated for the following conditions:

- Permanent AV block (second- or third-degree) requiring a separate pacemaker
- Permanent atrial fibrillation (i.e., pacemaker syndrome) in the presence of persistent sinus rhythm
- Low cardiac output or congestive heart failure secondary to cardiac ischemia.

**PRECAUTIONS:**

For use in conjunction with a compatible defibrillator. The following precautions should be observed in the presence of an ICD: Do not allow the patient to enter an MRI suite. MRI scanning of the patient does not meet MR Conditional requirements of the implanted system. Refer to the MRI Technical Guide for potential MRI-related Warnings and Precautions.