INGEVITY™ MRI
Pacing Lead

Proven Performance Beyond MRI

With IMAGEREADY™
MR-Conditional Systems
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%[^3]
- A dislodgment complication rate of 1.2% (26/2264)^
- No adverse events when performing MRI and no change in electrical performance[^3]
- In the SAMURAI trial, no MR-related complications were observed[^4]

[^1]: MRI Lead Studied
[^2]: MC = Multi-center, P = Prospective

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### Lead-Related Complication %

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Data Source</th>
<th>Sample Size</th>
<th>Data Type</th>
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<tbody>
<tr>
<td>INGEVITY MRI (Active + Passive Leads)</td>
<td>Advisa Trial*</td>
<td>1488</td>
<td>MC, P</td>
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<td>MRI CapsureFix</td>
<td>INGEVITY + SAMURAI*</td>
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<td>5076</td>
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<td>5076</td>
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</tr>
</tbody>
</table>

* MRI Lead Studied, ** MC = Multi-center, P = Prospective
99.3% In the INGEVITY™ and SAMURAI studies combined, 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 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 Competence.

Assured Performance Beyond MRI

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

• Safe and effective for full body scanning in 1.5T MRI environments when MRI Conditions of Use are met.
• First Level Controlled Operating Mode (SAR 4W/Kg) for all INGEVITY MRI lead models.
• 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 models.

ImageReady MR-Conditional Pacing Systems offer:

Automatic 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 Competence.

* Data provided by the ACCOLADE System is intended to support screening and management of AFib but does not diagnose AF.

ImageReady™ MR-Conditional Pacing Systems

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For more information, visit www.BostonScientific.com/imageready, or call 1.844.427.2674 (1.844.4BSC.MRI).
Pacing Leads from Boston Scientific – INGEVITY™ MRI
Extensible/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 is contraindicated in patients with: a previous history to a minor single dose dopamine aspartate 0.14 mg for Tined Fixation; 0.51 mg for Extensible/Retractable Fixation; and patients with mechanical transvenous implant valves.

WARNINGS
Refer to the product labeling before implanting the lead to avoid damage to the pulse generator and/or lead. For single use only. Do not re-sterilize, reprocess, or resterilize. Always have external defibrillation equipment readily available. Any lead marked with the “Caution: Federal law restricts this device to sale by or on the order of a licensed practitioner” (as indicated by4 fluoroscopy) is contraindicated during fixation processes. Do not rotate the terminal fixation mechanism during helix extension or retraction. Do not rotate the terminal fixation mechanism if the lead is chronically repositioned because the steroid can be depleted.

loss of pacing or sensing or both. Defibrillation equipment should be kept nearby for immediate use. Lead fracture, dislodgment, abrasion, or an inappropriate connection can cause a cardiac rhythm disturbance or lead dislodgment.

Place the patient require a temporary external source. Lead fracture, dislodgment, abrasion, or an inappropriate connection can cause a cardiac rhythm disturbance, or prevent the lead from achieving its designated target function.

Do not rotate the terminal fixation mechanism if the lead is chronically repositioned because the steroid can be depleted.

Potential adverse events include, but are not limited to the following: allergy/physical/physiologic reaction, death, erosion/vasorum, fibrillation or other arrhythmias, lead or accessory breakage (fracture/insulation/connector), 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. The product labeling for specific indications, contraindications, warnings/precautions and adverse events.

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 re-sterilize, reprocess, or resterilize. Always have external defibrillation equipment readily available. Any lead marked with the “Caution: Federal law restricts this device to sale by or on the order of a licensed practitioner” (as indicated by4 fluoroscopy) is contraindicated during fixation processes. Do not rotate the terminal fixation mechanism if the lead is chronically repositioned because the steroid can be depleted.

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Pacemakers from Boston Scientific – ACCELLAD™, ACCELLAD™ MRI, PROPONENT™, PROPONENT™ MRI, ESSENTIO™, ESSENTIO™ MRI, ALTRUA™ 2, FORMIO™, FORMIO™ MRI, VITALIO™, VITALIO™ MRI, INGENIO™ MRI, ADVANTIO™

INDICATIONS AND USAGE
Boston pacemakers are indicated for treatment of the following conditions:• Symptomatic paroxysmal or permanent second- or third-degree AV block • Symptomatic bradycardia, bradycardia arrest, sinus arrest, sinus (SA) block• Bradycardia/tachycardia syndrome, to prevent symptomatic bradycardia or some forms of symptomatic tachycardhythmias. Neurovascular (vaso-vagal) syncope or hypersensitive carotid sinus syncope.

Adaptive-rate pacing is indicated for patients exhibiting chronic tachyarrhythmia 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 conditions:• Conduction disorders that require reprogramming of AV synchrony, including varying degrees of AV block • Intraventricular (i.e., pacemaker syndrome) in the presence of persistent sinus rhythm • Low cardiac output or congestive heart failure secondary to bradycardia

CONTRAINDICATIONS
These 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 MRI Sensor with a Subcutaneous Implantable Cardiodefrillator (S-ICD) when implanted with bipolar leads and programmed to a bipolar pacing configuration.

Patients and Families:
1.800.CARDIAC (227.3422)
Medical Professionals:
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www.bostonscientific.com
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Rhythm Management
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Sources
7. Please refer to the MRI Technical Guide: ImageReadyTM MR-Conditional Pacing System as the system is designated as MR-conditional in accordance with specific conditions.

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