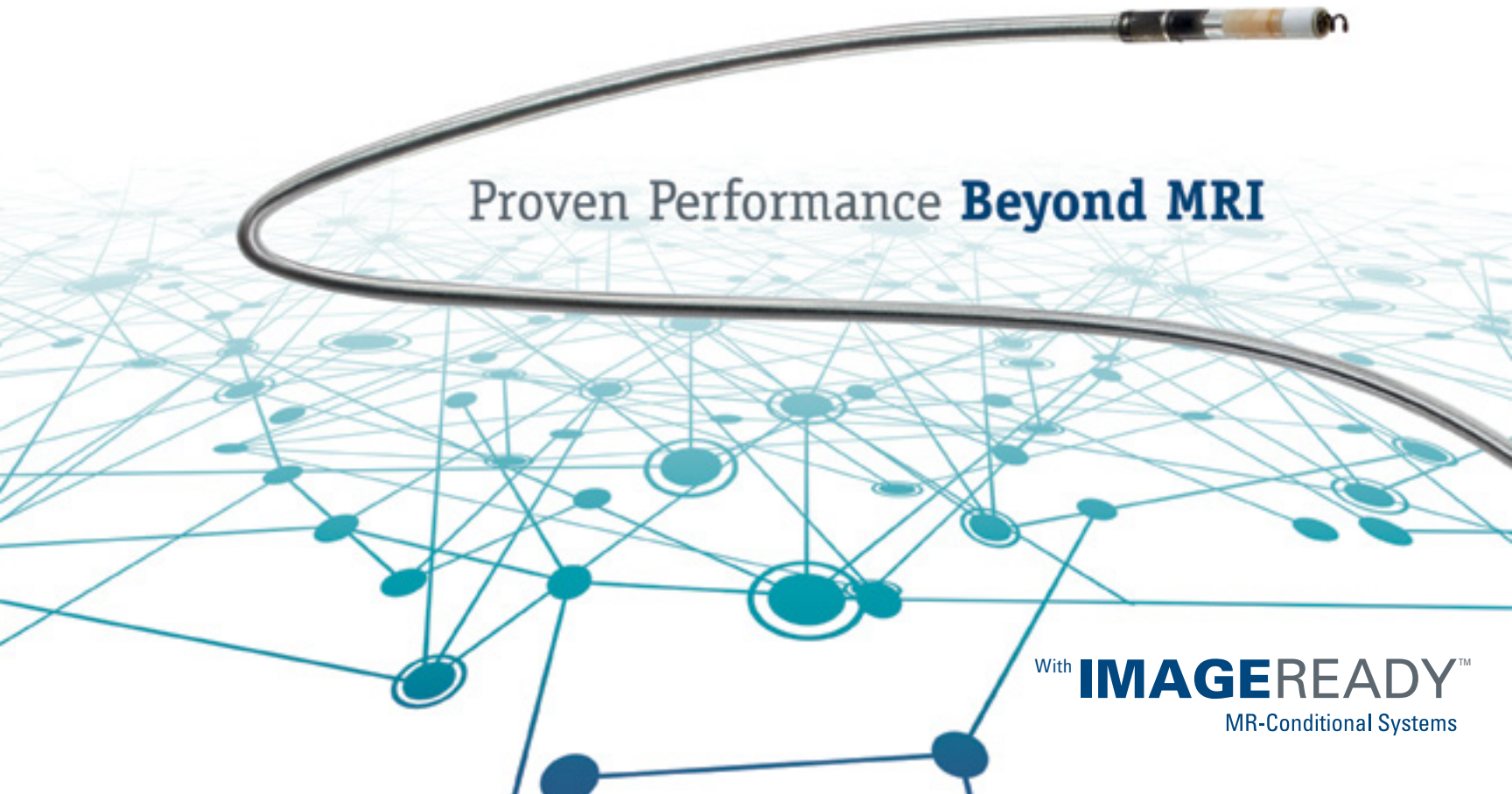
Boston Scientific
Advancing science for life™

INGEVITY™ MRI
Pacing Lead



Proven Performance **Beyond MRI**

With IMAGEREADY™
MR-Conditional Systems

Industry-Tested

INGEVITY™ MRI Pacing Lead, the industry's leading-edge pacing technology,[1] is also the most extensively studied.[2]

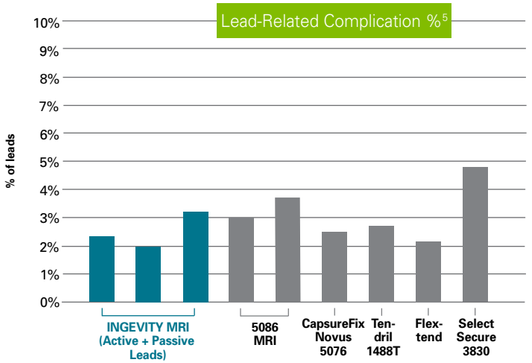
Safety, performance, and effectiveness of the INGEVITY MRI Pacing Lead are backed by the industry's largest pacing study

- Comprised of 2 studies, INGEVITY and SAMURAI, with over 150 sites worldwide[3]
- Over 2,300 implant procedures completed[3]

Stacks Up To the Competition[2]

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)[3]
- No adverse events when performing MRI and no change in electrical performance[3]
- In the SAMURAI trial, no MR-related complications were observed[4]



Data Source	INGEVITY + SAMURAI*	INGEVITY Trial	SAMURAI Trial	Advisa Trial*	REVO Trial*	5076 Trial	1488 T Trial	Flextend Trial	3830 Trial
Lead-Related Comp %	2.3%	2.0%	3.2%	3.0%	3.7%	2.4%	2.7%	2.1%	4.8%
Sample Size	2264	1599	665	526	928	238	220	140	353
Manufacturer	BSC	BSC	BSC	MDT	MDT	MDT	STJ	BSC	MDT
Data Type**	MC, P	MC, P	MC, P	MC, P	MC, P	MC, P	MC, P	MC, P	MC, P
Year	2015	2015	2015	2013	2011	2000	2001	2000	2005

* MRI Lead Studied, ** MC = Multi-center, P = Prospective

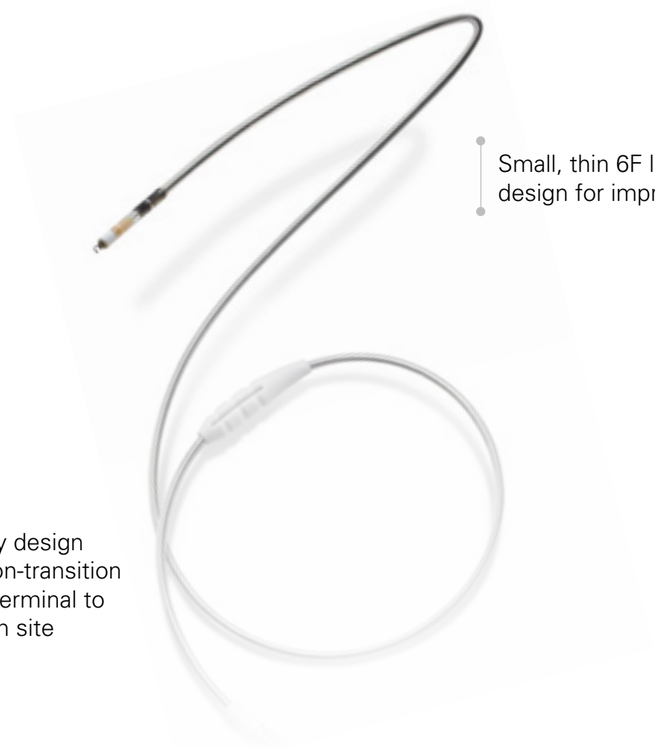
Peer-Approved

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[4,6]

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[4,6]
- **99.4%** of physicians surveyed agree or somewhat agree that INGEVITY MRI Pacing Lead was easy to pass through small vessels[4,6]
- **97.1%** of physicians surveyed rated radiopacity as met or exceeded expectations[4,6]



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

ImageReady™ MR-Conditional Pacing Systems

INGEVITY™ MRI leads are approved for use with the ACCOLADE MRI and ESSENTIO MRI pacemakers as an ImageReady MR-Conditional Pacing System[7]

- Safe and effective for full body scanning in 1.5T MRI environments when MRI Conditions of Use are met[7]
- First Level Controlled Operating Mode (SAR 4W/Kg) for all INGEVITY MRI lead models[7]
- 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

Assured Performance Beyond MRI

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[8]
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[9]

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

For more information, visit www.BostonScientific.com/imageready, or call 1.844.427.2674 (1.844.4BSC.MRI)

LATITUDE™ NXT Patient Management System from Boston Scientific CRM

Intended Use

The LATITUDE™ NXT Patient Management System is intended for use to remotely communicate with acompatible pulse generator from Boston Scientific CRM 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 NXT System. For contraindications for use 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 be delayed or not occur. The secondary notification feature does not eliminate or reduce the need to check the website. Implanted device data and alerts are typically available for review on the LATITUDE NXT website within 15 minutes of a successful interrogation. However, data uploads may take significantly longer (up to 14 days). If the Communicator is unable to interrogate the implanted device or if the Communicator is unable to contact the LATITUDE NXT server to upload data, up to two weeks may elapse before the LATITUDE NXT server detects these conditions and informs the clinic user that monitoring is not occurring. If both of these conditions occur at the same time, this notification could take up to 28 days. Implanted device data and alert notification may be delayed or not occur at all under various conditions, which include but are not limited to the following: System limitations; the Communicator is unplugged; the Communicator is not able to connect to the LATITUDE NXT server through the configured phone system; the implanted device and the Communicator cannot establish and complete a telemetry session; the Communicator is damaged or malfunctions; the patient is not compliant with prescribed use or is not using the LATITUDE NXT System as described in the patient manual; if subscribed to the LATITUDE Cellular Data Plan, missing two or more payments discontinues the subscription; the clinic user can identify any patients that are not being monitored as described above by using the Not Monitored filter on the View Patient List.

Adverse Effects: None known.

System Limitations

The LATITUDE NXT System does not provide continuous real-time monitoring. As a remote monitoring system, the LATITUDE NXT System provides periodic patient monitoring based on clinician configured settings. There are many internal and external factors that can hinder, delay, or prevent acquisition and delivery of implanted device, sensor, and patient information as intended by the clinician. These factors include: implanted device clock; patient environment; cellular data service; telephone system; communicator memory capacity; clinic environment; schedule/configuration changes; or data processing.

Refer to the product labeling for specific instructions for use. Rx only.
(Rev. C)

Pacing Leads 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 physician's manual(s) for specific indications, contraindications, warning/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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Medical Professionals:
1.800.CARDIAC (227.3422)
Patients and Families:
1.866.484.3268

CRM-328908-AA APR2016

Sources

1. Patent publication number-US20100331936 A1, BSC internal documents ;ELN 2837210, ELN 6283393, ELN 2837210 and ELN 6283393.
2. St. Jude Medical 1488 Tendril Users Manual, Medtronic Capture Fix Novus 5076 Technical Manual, Medtronic Select Secure 3830 Technical Manual, Guidant-Flextend Clinical Report, Medtronic Advisa MRI Trial Report-HRS 2013; 10:685-691, Medtronic MRI SureScan Pacing System Clinical Study Report.
3. INGEVITY Clinical Report: 12 month follow-up, 2015-01. SAMURAI + 1 month follow-up - 2015-02.
4. SAMURAI Clinical Report: MRI visit + 1 month follow-up, 2015-02.
5. St. Jude Medical 1488 Tendril User's Manual, Medtronic Capture Fix Novus 5076 Technical Manual, Medtronic Select Secure 3830 Technical Manual, Guidant-Flextend Clinical Report , Medtronic Advisa MRI Trial Report-HRS 2013; 10:685-691, Medtronic MRI Sure Scan Pacing System Clinical Study Report.
6. INGEVITY Clinical Report: 12 month follow-up, 2015-01.
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.
8. Not available with ESSENTIO MRI Pacemaker models.
9. PULSAR MAX Blended Sensor Clinical Trial Results: Chronotropic competence is defined by the Model of the Cardiac Chronotropic Response to Exercise, Wilkoff B, Corey J, Blackburn G. A mathematical model of the cardiac chronotropic response to exercise. Journal of Electrophysiology 1989;3:176-180.