

IMAGEREADY™

MR-Conditional Systems

Cardiology/Radiology Checklists

Use the following checklists to ensure that patients who have a Boston Scientific pacing system labeled MR-conditional can receive an MR scan safely. Prior to the procedure, please see the full instructions (including warnings/precautions and potential adverse events) in the Boston Scientific ImageReady MR-Conditional Pacing System MRI Technical Guide, or www.BostonScientific.com/imageready or Boston Scientific MRI Hotline 1.844.4.BSC.MRI (1.844.427.2674).

Patient Name: _____ Date of Birth: _____
Pacemaker Model: _____ RV Lead Model: _____ Atrial Lead Model: _____

The following conditions must be met in order for a patient with a Boston Scientific ImageReady MR-Conditional Pacing System to undergo an MRI scan:

For Cardiologists ~ MRI Conditions for Use¹

- Patient is implanted with an ImageReady MR-Conditional Pacing System
- At least six weeks have elapsed since implantation and/or any lead revision or surgical modification of the MR-conditional pacing system
- Pulse-generator implant location restricted to left or right pectoral region
- No cardiac-related implanted devices, components, or accessories present (such as lead adapters or extenders) other than an ImageReady MR-Conditional Pacing System
- No abandoned leads or pulse generators
- No evidence of fractured lead or compromised pulse-generator-lead integrity (impedance out of normal range, or evidence or record of damage to generator seal plug or sealing rings)
- Pacing threshold $\leq 2.0V$ in pace-dependent patients
- Bipolar pacing operation or pacing Off
- Patient does not have elevated body temperature or compromised thermoregulation at time of scan
- Pulse generator in MRI Protection Mode during scan

For Radiologists ~ MRI Conditions for Use¹

- MRI magnet strength of 1.5T and 3T
 - Radio frequency (RF) field of approximately 64 MHz for 1.5T
 - Radio frequency (RF) field of approximately 128 MHz for 3T
 - Spatial gradient no greater than 50T/m (5,000 G/cm) over the pacing system
- Horizontal, H proton, closed bore scanners only
- Specific Absorption Rate (SAR) limits:
 - INGEVITY™ MRI Pacing Leads: SAR limits for Normal Operating Mode or for First Level Controlled Operating Mode must be observed for the entire active scan session as follows:
 - Whole body averaged, ≤ 4.0 W/Kg
 - Head, ≤ 3.2 W/Kg
- Gradient Field limits: Maximum specified gradient slew rate ≤ 200 T/m/s per axis
- No local transmit-only coils or local transmit/receive coils placed directly over the pacing system; the use of receive-only coils is not restricted
- Patient in supine or prone position only
- Patient must be monitored during the MRI scan by pulse oximetry and/or electrocardiography (ECG)

This form may contain patient confidential information. If you receive this form in error, please do not forward it and contact Boston Scientific Technical Services at (800) 227-3422.

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1. Please refer to the MRI Technical Guide: ImageReady™ MR - Pacing System as the system is designated as MR-conditional in accordance with specific conditions.

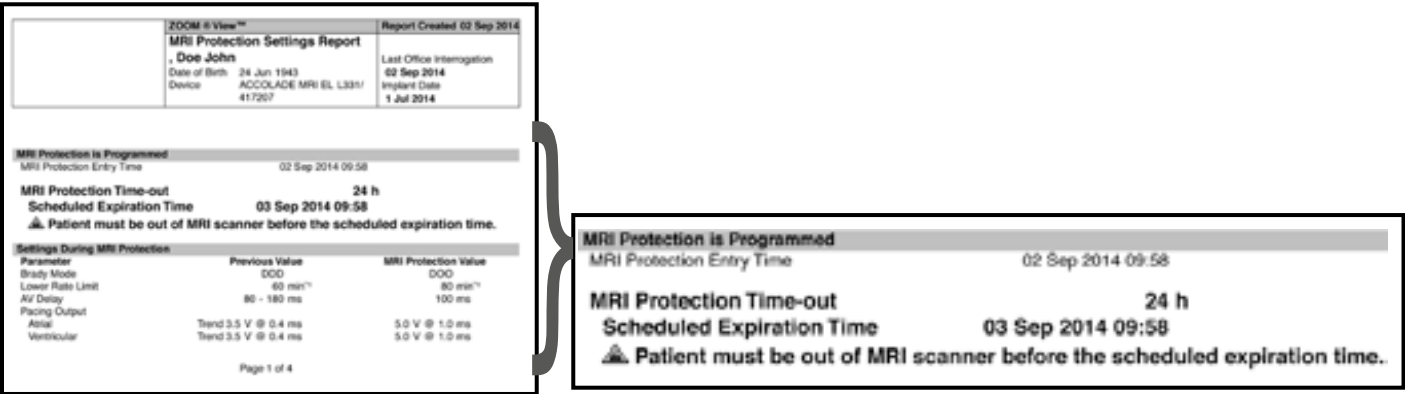
Cardiology/Radiology Checklists

A sample patient flow sequence for an ImageReady™ MR-Conditional Pacing System patient who needs an MRI scan is described below. For a more detailed description of the programming and scanning procedure, see the MRI Technical Guide for the ImageReady MR Conditional Pacing System, or visit www.BostonScientific.com/imageready.

Sample Patient Flow

1. MRI recommended to patient by specialist (for example, orthopedist or oncologist).
2. Patient or specialist or radiologist contacts the electrophysiologist/cardiologist who manages the patient’s MR Conditional Pacing System.
3. Electrophysiologist/cardiologist determines patient eligibility for scan per the Cardiology Conditions of Use stated in the MRI Technical Guide.
4. If physician determines patient is eligible, the programmer is used to put the pulse generator in MRI Protection Mode as close in time to the scan as reasonable. The MRI Protection Settings Report is printed (see Figure 1), placed in the patient’s file, and provided to the radiology personnel. The report documents MRI Mode settings and details. If the Time-out feature is used, the report includes the exact time and date when MRI Protection Mode will expire. Each lead implanted in the patient is identified, and this information is communicated to the HCPs involved in performing the MRI scan.
5. The radiologist confirms that Radiology Conditions of Use are met, described in the MRI Technical Guide. The radiologist checks the patient file and/or printed report. If the Time-out feature is used, the radiologist verifies that adequate time remains to complete the scan.
6. Patient undergoes scan according to protocol.
7. The pulse generator is returned to pre-MRI operation, either automatically if the Time-out parameter was set, or manually using the programmer. Follow-up testing of the pacing system may then be performed.

Figure 1:



Pacing Systems - ACCOLADE™/MRI, ESSENTIO™/MRI, VITALIO™/MRI, 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 this 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. For potential adverse events applicable when the Conditions of Use are met or not met, refer to the MRI Technical Guide. 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.

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

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)

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Rhythm Management

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