Magnetic Resonance Imaging (MRI) and Implanted Medical Device Systems

Magnetic Resonance Imaging (MRI) uses powerful magnetic waves to produce images of the soft tissue on the interior of the human body. Many patients with implanted heart devices are not eligible to have an MRI scan because their pacing systems are not approved for use during an MRI scan or near MRI scanners. However, patients implanted with a Boston Scientific’s ImageReady™ MR-Conditional System may be eligible to undergo a full-body MRI scan. To download or view a copy of the MRI Technical Guide that defines MR-Conditional Pacing Systems, or to determine if a system is MR-Conditional, please visit the website below and refer to the appropriate geography:

www.bostonscientific.com/imageready

This article discusses MRI considerations for all Boston Scientific pacing and defibrillation systems (MR-Conditional or non-MR-Conditional), and the ZOOM LATITUDE Programmer/Recorder/Monitor (PRM).

Definition of “System”

An implanted system consists of the pulse generator, lead(s), and a port plug (where applicable). Only patients implanted with a complete system designed, optimized, and tested for the ability to function correctly under specified conditions during an MRI scan are eligible to be scanned. Furthermore, by complying with the MRI Conditions of Use found in the appropriate MRI Technical Guide, patient risks (Table 1) can be significantly mitigated during MRI scans as compared to comparable, non-MR-Conditional, pulse generators and leads.1

MR-Conditional Systems

Boston Scientific’s ImageReady MR-Conditional Pacing System consists of specific combinations of pulse generator and lead components. Note that system approval is geography-specific. To determine if the system under consideration is approved as MR-Conditional, please refer to the MRI Technical Guide for the specific geography of interest. Guides can be downloaded from www.bostonscientific.com/imageready.

MR-Unsafe Systems

Conditions for Use must be met for a patient to undergo a MRI scan. Use of any other components or combination of components not detailed in the MRI Technical Guide has not been approved as MR-Conditional. If the system in its entirety is not listed in the appropriate MRI Technical Guide, it has not been approved as MR-Conditional.

For patients with MRI Unsafe systems is contraindicated by MRI manufacturers and warned against by medical device manufacturers. If MRI scanning is being considered, a careful and complete risk-benefit analysis should be completed. If MRI cannot be avoided, patients must be closely monitored and appropriate device function should be verified upon cessation of MRI.2

After confirming via the MRI Technical Guide (available at bostonscientific.com/imageready) that the system is MR-Conditional, it is recommended that both the attending cardiologist and radiologist review a copy of the guide in its entirety prior to performing an MRI scan.

1The American Society for Testing and Materials (ASTM) defines MR-Conditional in F2503:2008a: “An item with demonstrated safety in the MR environment within defined conditions. At a minimum, address the conditions of the static magnetic field, the switch gradient magnet field and the radiofrequency fields. Additional conditions, including specific configuration to the item, may be required.”

2Many device diagnostics are performed automatically once per hour, therefore, device evaluation should not be concluded until device diagnostics have been updated and reviewed at least one hour after MRI.
Among other information, the guide contains:

- Conditions for Scanning/Use (Cardiology and Radiology)
- Potential adverse events
- Valid combinations of pulse generators and leads by scanner strength
- MRI scan procedure protocol, including details regarding programming the device into MRI Protection Mode.

Additionally, a ZOOM™ LATITUDE™ PRM must be available throughout the MRI procedure and must remain outside MRI Zones III and IV. The PRM is used to program the device into MRI Protection Mode (only available for MR-Conditional devices). If the MRI Protection Time-out value of Off is selected, the PRM will also be necessary following the procedure to program MRI Protection Mode Off. Please note, the MRI Protection Checklist, which will appear on the PRM, summarizes the conditions that must be met at the time of scanning in order for a patient to be eligible for an MR-Conditional Scan.

**What is MRI Protection Mode?**

In preparation for an MRI scan, the pulse generator in an MR-Conditional system is programmed to MRI Protection Mode using the PRM. Please refer to the MRI Technical Guide for a complete description of MRI Protection Mode. MRI Protection Mode modifies the behavior of the device and has been designed to accommodate the electromagnetic environment of the scanner. Additionally, a time-out feature may be programmed to cancel MRI Protection mode after a specified number of hours. Features disabled or changed when MRI-Protection mode is entered include (where applicable):

- Tachy Therapy
- Brady Therapy (Mode and Output may be programmable)
- Magnet Operation
- MV Sensor (includes Rate Response Pacing, Respiratory Rate Trend, and AP Scan)
- Accelerometer (Rate Responsive Pacing and Activity Level Trend)
- Daily Diagnostics disabled (Pace Impedance, Intrinsic Amplitude and Pace Threshold tests)
- RF Communications
- Beeper Function (not applicable to brady devices)

**WARNING:** The beeper may be rendered inaudible due to an MRI scan. Coming in contact with the strong magnetic field of an MRI scanner causes permanent loss of the beeper volume. This cannot be recovered, even after leaving the MR scan environment and exiting MRI Protection Mode. Before an MRI procedure is performed, a physician and patient should weigh the benefit of the MR procedure against the risk of losing beeper volume. It is strongly recommended that patients are followed on LATITUDE NXT after an MRI scan if they are not already. Otherwise, an in-clinic follow-up schedule of every three months is strongly recommended to monitor device performance.

**During and After Scanning**

**During the Scan**

During MRI Protection Mode, the patient may not receive Bradycardia pacing (including backup pacing), depending on available device features and programming. Also, the patient will not receive Cardiac Resynchronization Therapy, or Tachycardia therapy (including ATP and defibrillation). Therefore, the patient needs to be continuously monitored for the entire time that the system is in-MRI Protection Mode, including during the scan. Continuous monitoring includes maintaining normal voice and visual contact, as well as monitoring pulse oximetry and ECG for the entire duration that the pulse generator is in MRI Protection Mode. Ensure that an external defibrillator and medical personnel skilled in cardiopulmonary resuscitation (CPR) are present as long as the pulse generator is in MRI Protection Mode, including during the scan, should the patient require external rescue.

After the Scan

Continue patient monitoring until the pulse generator is returned to pre-MRI operation.

Do not leave the pulse generator in MRI Protection Mode any longer than necessary following the scan. Upon exiting MRI-Protection Mode (either timer-initiated or manually exited) all parameters are immediately restored to pre-MRI Protection Mode values with three exceptions:

- Tachy devices: the beeper remains turned off.
- AUTOCATH™ and Boston Scientific pacers: If Minute Ventilation (MV) was programmed to ON or Passive at the time of entry into MRI Protection Mode, an automatic six-hour calibration of the sensor begins upon exit from the mode. MV-driven rate response is not available during this calibration.
- Pacers: If PaceSafe RV Automatic Capture was programmed to ON the device will remain in suspension until the next scheduled 21 hour ambulatory automatic threshold test.

Changing the beeper setting to ON will remove the MRI warning message and the beeper parameters will be re-set to pre-MRI Mode values and become programmable again. To test if the beeper is audible:

1. Program the beeper On
2. Place a magnet over the device and listen for beeps
3) If beeper is audible, leave the beeper On. If not audible, program the beeper Off.

Following user-initiated cancellation of MRI Protection Mode, the PRM will automatically navigate to the Lead Tests screen and prompt the user to perform the following lead tests:

- Lead impedance
- Pacing threshold
- Intrinsic amplitude

These tests may be performed subsequent to automatic (Time-out) exit from MRI Protection Mode as well.

**Post-Therapy Pulse Generator Follow-Up**

Following any surgery or medical procedure with the potential to affect pulse generator function, you should perform a thorough follow-up, which may include the following:

- Interrogating the pulse generator with a programmer
- Reviewing clinical events and fault codes
- Reviewing the Arrhythmia Logbook, including stored electrograms (EGMs)
- Reviewing real-time EGMs
- Testing the leads (threshold, amplitude, and impedance) – see above
- Performing a manual capacitor re-formation
- Reviewing MV sensor-based diagnostics, MV sensor performance, and performing a manual MV sensor calibration if desired
- Verifying battery status
- Programming any permanent brady parameter to a new value and then reprogramming it back to the desired value
- Saving all patient data
- Verifying the appropriate final programming prior to allowing the patient to leave the clinic

**Potential Interactions between MRI Scanners and implanted medical device systems**

**MR-Conditional System**

Boston Scientific MR-Conditional pulse generators and leads, when used together under the Conditions of Use outlined in the MRI Technical Guide, were designed to significantly reduce the device interactions traditionally associated with MRI scans (Table 1). However, both radiologist and cardiologist should be familiar with the potential interactions listed in Table 1, since it is possible that interactions may not be fully mitigated when an MR-Conditional system is exposed to atypical conditions.

**MR-Unsafe Systems**

Unless a patient’s implanted Boston Scientific system is approved as MR-Conditional and all of the MRI Conditions of Use detailed in the appropriate MRI Technical Guide are met, MRI scanning of the patient is not recommended. Potential interactions are listed in Table 1.
Table 1. Potential interactions between MRI scanners and implanted medical device systems. Note that implantation of an MR-Conditional system and compliance with the MRI Conditions of Use found in the appropriate MRI Technical Guide, can successfully mitigate many of the potential interactions (listed in this Table) during MRI scans.

<table>
<thead>
<tr>
<th>Potential interaction(s)</th>
<th>ICDs &amp; CRT-Ds</th>
<th>S-ICD</th>
<th>Pacemakers &amp; CRT-Ps</th>
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</thead>
<tbody>
<tr>
<td>Loss of beeper function</td>
<td></td>
<td></td>
<td>No beeper</td>
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<tr>
<td>Side effects of MRI Protection Mode Pacing at elevated fixed rate and increased output including: reduced exercise capacity, acceleration of heart failure, arrhythmia induction</td>
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<tr>
<td>Induced arrhythmias</td>
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<td>Slight movement or heating of the device</td>
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<td>Side effects of pacing at a fixed high rate such as competition with intrinsic rhythms and arrhythmias. Competitive pacing may increase the rate of pacing-induced arrhythmia until the device is reprogrammed.</td>
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<tr>
<td>Physical movement of device and/or leads</td>
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<tr>
<td>Damage to pulse generator and/or leads</td>
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<tr>
<td>Lead heating, which may cause tissue damage and/or pacing threshold changes</td>
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<tr>
<td>Inhibition of pacing (pacing therapy not provided when needed, including post-shock therapy)</td>
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<tr>
<td>Asynchronous pacing (pacing therapy provided independent of intrinsic cardiac activity)</td>
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<tr>
<td>Inappropriate pacing</td>
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<tr>
<td>Increased rate of lead dislodgment prior to six weeks of implant</td>
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<tr>
<td>Inhibition of tachyarrhythmia therapy (ATP/shock therapy not provided when needed)</td>
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<tr>
<td>Inappropriate tachyarrhythmia therapy (ATP/shock therapy provided when not needed)</td>
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<tr>
<td>Sensing changes</td>
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<tr>
<td>Pacing threshold changes</td>
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<tr>
<td>Irregular or intermittent capture or pacing</td>
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<tr>
<td>Deactivation of tachyarrhythmia therapy*</td>
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<tr>
<td>Erratic device behavior</td>
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<tr>
<td>Triggered ventricular pacing up to the Maximum Tracking Rate (MTR)</td>
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<tr>
<td>Erroneous episodes stored in pulse generator EGM and counter memory</td>
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<tr>
<td>Apparent drop in battery voltage or appearance of replacement indicator†</td>
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<tr>
<td>Pulse generator pulling or twisting at implant site</td>
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<td>Pulse generator vibration</td>
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<tr>
<td>Unintended stimulation (gradient-field induced current incident on lead causing a short pulse)</td>
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</table>

*Requires reprogramming to restore.
†In most instances, the indicator can be reset/cleared in defibrillators with a manual capacitor reformation.

For additional information and considerations, please refer to the American Heart Association’s Scientific Statement on the safety of MRI in patients with cardiovascular devices.

Common identified medical risks associated with an MRI procedure for patients who do not have an implanted medical device also apply to MRI scans with a MR-Conditional Pacing System. Consult MRI scanner documentation for a complete list of risks associated with MRI scanning.

Pacing Systems from Boston Scientific – INGENIO™, ADVANTIO™, and VITALIO™

Indications

INGENIO™, ADVANTIO™, and VITALIO™ indications include: symptomatic paroxysmal or permanent second- or third-degree AV block; symptomatic atrial arrhythmias; complete atrioventricular block; symptomatic sinus node dysfunction with or without associated AV conduction disorders; bradycardia-tachycardia syndrome; to prevent symptomatic bradycardia or some forms of symptomatic tachyarrhythmias; neurometabolic (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. Pacemakers’ 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: conduction disorders that require restoration of AV synchrony, including varying degrees of AV block; VVI intolerance (eg, pacemaker syndrome) in the presence of persistent sinus rhythm or low cardiac output or congestive heart failure secondary to bradycardia.

Contraindications

Pacemakers are contraindicated for the following patients under the circumstances listed: patients who have a separate implanted cardioverter-defibrillator (ICD); use of 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 fibillation 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

Read the product labeling thoroughly before implanting the pulse generator to avoid damage to the system. For single use only. Do not re-use, re-process or re-sterilize. Always have external defibrillation protection available during implant and electrophysiologic testing. Do not use this pulse generator with another pulse generator. In response to applicable nonrecoverable or repeat fault conditions, the pulse generator may switch irreversible to Safety Core operation. Do not kink, twist, or braid leads. Do not use atrial tracking modes in patients with chronic refractory atrial tachyarrhythmias. In devices with the lead safety switch programmed to On, the lead polarity will switch to unipolar in the presence of a lead impedance of ≤ 500 or ≥ 2000 Ω. If programmed to a fixed atrial sensitivity value of 0.15 mV, 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. Do not expose a patient to MRI scanning. 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 electric or magnetic interference (EMI) because EMI may cause the pulse generator to deliver inappropriate therapy or inhibit appropriate therapy.

Potential Adverse Events

Potential adverse events include, but are not limited to, the following: allergic/physical/physiologic reaction, death, erosion/migration, lead or accessory breakage (fracture/insulation/lead tip), hematoma/seroma, inappropriately or inability to provide therapy (pacing/sensing), infection, related procedure, and component failure. 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 – ALTRUA™ and INGENIO™

Indications

Pacemaker indications include: symptomatic paroxysmal or permanent second- or third-degree AV block; symptomatic atrial arrhythmias; bradycardia-tachycardia syndrome; to prevent symptomatic bradycardia or some forms of symptomatic tachyarrhythmias; neurometabolic (vaso-vagal) syndromes or hypersensitive carotid sinus syndromes. Adaptive-rate pacing is indicated for patients who may benefit from increased pacing rates concurrent with increases in minute ventilation and/or level of physical activity. Pacemakers’ 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: conduction disorders that require restoration of AV synchrony, including varying degrees of AV block; VVI intolerance (eg, pacemaker syndrome) in the presence of persistent sinus rhythm.

Contraindications

Pacemakers are contraindicated for the following patients under the circumstances listed: patients with unipolar pacing leads or in MV mode with an implanted ICD because it may cause unwanted delivery or inhibition of ICD therapy; use of the MV sensor in patients with only unipolar leads, because a bipolar lead is required in either the atrium or the ventricle for AV measurement (INGENIO™ Ultra, ALTRUA™ 20/40); MV mode in patients with both unipolar atrial and ventricular leads (INGENIO™ Ultra, ALTRUA™ 60); single-chamber atrial pacing in patients with impaired AV nodal conduction; atrial tracking modes for patients with chronic refractory atrial tachyarrhythmias; asynchronous pacing in the presence (or likelihood) of competition between paced and intrinsic rhythms.

Warnings

Read the product labeling thoroughly before implanting the pulse generator to avoid damage to the system. For single use only do not re-use, re-process or re-sterilize. Always have external defibrillation protection available during implant and electrophysiologic testing. Do not use this pulse generator with another pulse generator. In response to applicable nonrecoverable or repeat fault conditions, the pulse generator may switch irreversible to Safety Core operation. Do not kink, twist, or braid leads. Do not use atrial tracking modes in patients with chronic refractory atrial tachyarrhythmias. Leads 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

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electromagnetic interference. Advise patients to seek medical guidance before entering environments that could adversely affect the operation of the active implantable medical device. Do not expose a patient to MRI scanning. Do not subject a patient with an active implantable medical device to diathermy. Do not use atrial leads for pacing beyond the indications validated in the clinical trials. These devices are contraindicated in patients who have a separate implanted cardioverter-defibrillator (ICD). Single-chamber atrial pacing is contraindicated in patients with impaired AV nodal conduction. Atrial tracking modes are contraindicated for patients with chronic refractory atrial tachyarrhythmias (atrial fibrillation or flutter), which might trigger ventricular pacing. Asynchronous pacing is contraindicated in the presence (or likelihood) of competition between paced and intrinsic rhythms.

Warnings
Read the product labeling thoroughly before implanting the pulse generator to avoid damage to the system. For single-chamber only. Do not reuse, reprocess, or resterilize. Always have external defibrillation protection available during implant and electrophysiologic testing. Do not use this pulse generator with another pulse generator. In response to applicable non-recoverable or repeat fault conditions, the pulse generator will switch irreversibly to Safety Core operation. Do not kink, twist, or braid leads. Do not use atrial tracking modes in patients with chronic refractory atrial tachyarrhythmias. Do not use atrial only modes in patients with heart failure. In devices with the lead safety switch programmed to On, the lead polarity will switch to unipolar in the presence of a lead impedance of 5 200 or ≥ 2000. If programmed to a fixed atrial sensitivity value of 0.15 mV, 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. Do not expose a patient to MRI scanning. Do not subject a patient with an implanted pulse generator and/or lead to diathermy. Left ventricular (LV) lead dislodgment to a position near the atria can result in atrial oversensing and LV pacing inhibition.

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 electromagnetic interference (EMI) because EMI may cause the pulse generator to deliver inappropriate therapy or inhibit appropriate therapy.

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 may occur.

Refer to the product labeling for specific indications, contraindications, warnings/precautions and adverse events.
ICD Systems from Boston Scientific – DYNAGEN™ EL ICD, DYNAGEN™ MINI ICD, INOGEN™ EL ICD, INOGEN™ MINI ICD, ORIGEN™ EL ICD, ORIGEN™ MINI ICD

Indications and Usage
Boston Scientific implantable cardioverter defibrillators (ICDs) are intended to provide ventricular antitachycardia pacing (ATP) and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias.

Contraindications
Use of these Boston Scientific pulse generators are contraindicated for the following: patients whose ventricular tachyarrhythmias may have reversible cause, such as: digitalis intoxication, electrolyte imbalance, hypoxia, sepsis; or patients whose ventricular tachyarrhythmias have a transient cause, such as: acute myocardial infarction (MI), electrocution, drowning; or patients who have a unipolar pacemaker.

Warnings
Read this manual thoroughly before implantation to avoid damage to the pulse generator and/or lead. For single patient use only. Do not reuse, reprocess, or resterilize. Program the pulse generator Tachy Mode(s) to Off during implant, explant, or postmortem procedures to avoid inadvertent high voltage shocks. 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. Patients should seek medical guidance before entering environments that could adversely affect the operation of the active implantable medical device, including areas protected by a warning notice that prevents entry by patients who have a pulse generator. Do not expose a patient to MRI scanning. Do not subject a patient with an implanted pulse generator and/or lead to diathermy. If desired, ensure that Patient Triggered Monitor is enabled prior to sending the patient home. Once the Patient Triggered Monitor feature has been triggered by the magnet and an EGM has been stored, or after 60 days have elapsed from the date that Store EGM was enabled, the patient should not apply the magnet. For leads that require the use of a Connector Tool, use caution handling the lead terminal when the Connector Tool is not present on the lead. Do not directly contact the lead terminal with any surgical instruments or electrical connections such as PSA (alligator) clips, ECG connections, forceps, hemostats, and clamps. Do not contact any other portion of the DF4-LLHH or DF4-LLLO lead terminal, other than the terminal pin, even when the lead cap is in place. Do not use this pulse generator with another pulse generator. This combination could cause pulse generator interaction, resulting in patient injury or a lack of therapy delivery. Do not kink, twist, or braid the lead with other leads as doing so could cause lead insulation abrasion damage or conductor damage. Do not use atrial tracking modes in patients with chronic refractory atrial tachyarrhythmias. Tracking of atrial arrhythmias could result in ventricular tachyarrhythmias.)

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 electromagnetic interference (EMI).

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 A)
**Warnings**

Read the product labeling thoroughly before implanting the pulse generator to avoid damage to the ICD system. For single patient use only. Do not reuse, reprocess, or resterilize. Program the pulse generator ventricular Tachy Mode to OFF during implant, explant or post-mortem procedures. Always have external defibrillator protection available during implant and electrophysiologic testing. Ensure that an external defibrillator and medical personnel skilled in cardiopulmonary resuscitation (CPR) are present during post-implant device testing. Patients should seek medical guidance before entering environments that could adversely affect the operation of the active implantable medical device, including areas protected by a warning notice that prevents entry by patients who have a pulse generator. Do not expose a patient to MRI scanning. Do not subject a patient with an implanted pulse generator to diathermy. Do not use atrial tracking modes (or an AVT device) in patients with chronic refractory atrial tachyarrhythmias. Do not use this pulse generator with another pulse generator. Do not kink, twist or braid lead with other leads. For Patient Triggered Monitor (PTM) feature, make sure the feature is enabled prior to sending the patient home with a magnet. Once the PTM feature has been triggered and the magnet response programming is set to inhibit therapy, the patient should not reapply the magnet.

**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; supplemental precautionary information. Advise patients to avoid sources of electromagnetic interference (EMI). Refer to the product labeling for specific indications, contraindications, warnings/potential adverse events and adverse effects. Rx only. (Rev. S)

**CRT-D Systems from Boston Scientific – PUNCTUA™, ENERGEN™, and INCEPTA™**

**Indications and Usage**

The PUNCTUA™, ENERGEN™, and INCEPTA™ Cardiac Resynchronization Therapy Defibrillators (CRT-Ds) are indicated for patients with heart failure who receive stable optimal pharmacologic therapy (OPT) for heart failure and who meet any one of the following classifications:

- Moderate to severe heart failure (NYHA Class III-IV) with EF ≤ 35% and QRS duration ≥ 120 ms
- Left bundle branch block (LBBB) with QRS ≥ 130 ms, EF ≤ 30%, and mild (NYHA Class II) ischemic or nonischemic heart failure or asymptomatic (NYHA Class I) ischemic heart failure

There are no contraindications for this device.

**Warnings**

Read the product labeling thoroughly before implanting the pulse generator to avoid damage to the system. For single patient use only. Do not reuse, reprocess, or resterilize. Program the pulse generator Tachy Mode to OFF during implant, explant or postmortem procedures. Always have external defibrillator protection available during implant and electrophysiologic testing. Ensure that an external defibrillator and medical personnel skilled in CPR are present during post-implant device testing. Advise patients to seek medical guidance before entering environments that could adversely affect the operation of the active implantable medical device, including areas protected by a warning notice that prevents entry by patients who have a pulse generator. Do not expose a patient to MRI scanning. Do not subject a patient with an implanted pulse generator to diathermy. Do not use atrial-tracking modes in patients with chronic refractory atrial tachyarrhythmias. Do not use atrial-only modes in patients with heart failure. LV lead dislodgment to a position near the atria can result in atrial oversensing and LV pacing inhibition. Physicians should use medical discretion when implanting this device in patients who present with slow VT. Do not kink, twist or braid the lead with other leads. Do not use defibrillation patch leads with the CRT-D system. Do not use this pulse generator with another pulse generator. For Patient Triggered Monitor (PTM) feature, make sure the feature is enabled prior to sending the patient home with a magnet. Once the PTM feature has been triggered and the magnet response programming is set to inhibit therapy, the patient should not reapply the magnet.

**Precautions**

For specific information on precautions, refer to the following sections of the product labeling: clinical considerations; sterilization and storage; implantation; device programming; follow-up testing; implant and disposal; environmental and medical therapy hazards; hospital and medical environments; home and occupational environments; and supplemental precautionary information. Advise patients to avoid sources of electromagnetic interference (EMI) because EMI may cause the pulse generator to deliver inappropriate therapy or inhibit appropriate therapy. Refer to the product labeling for specific indications, contraindications, warnings/potential adverse events and adverse effects. Rx only. (Rev. C)

**CRT-D System from Boston Scientific - COGNIS™**

**Indications and Usage**

These Boston Scientific Cardiac Resynchronization Therapy Defibrillators (CRT-Ds) are indicated for patients with heart failure who receive stable optimal pharmacologic therapy (OPT) for heart failure and who meet any one of the following classifications:

- Moderate to severe heart failure (NYHA Class III-IV) with EF ≤ 35% and QRS duration ≥ 120 ms
- Left bundle branch block (LBBB) with QRS ≥ 130 ms, EF ≤ 30%, and mild (NYHA Class II) ischemic or nonischemic heart failure or asymptomatic (NYHA Class I) ischemic heart failure

There are no contraindications for this device.

**Warnings**

Read the product labeling thoroughly before implanting the pulse generator to avoid damage to the system. For single patient use only. Do not reuse, reprocess, or resterilize. Program the pulse generator Tachy Mode to OFF during implant, explant or postmortem procedures. Always have sterile external and internal defibrillator protection available during implant and electrophysiologic testing. Ensure that an external defibrillator and medical personnel skilled in CPR are present during post-implant device testing. Advise patients to seek medical guidance before entering environments that could adversely affect the operation of the active implantable medical device, including areas protected by a warning notice that prevents entry by patients who have a pulse generator. Do not expose a patient to MRI scanning. Do not subject a patient with an implanted pulse generator to diathermy. Do not use atrial-tracking modes in patients with chronic refractory atrial tachyarrhythmias. Do not use atrial-only modes in patients with heart failure. LV lead dislodgment to a position near the atria can result in atrial oversensing and LV pacing inhibition. Physicians should use medical discretion when implanting this device in patients who present with slow VT. Do not kink, twist or braid the lead with other leads. Do not use defibrillation patch leads with the CRT-D system. Do not use this pulse generator with another pulse generator. For Patient Triggered Monitor (PTM) feature, make sure the feature is enabled prior to sending the patient home with a magnet. Once the PTM feature has been triggered and the magnet response programming is set to inhibit therapy, the patient should not reapply the magnet.

**Precautions**

For specific information on precautions, refer to the following sections of the product labeling: clinical considerations; sterilization and storage; implantation; device programming; follow-up testing; implant and disposal; environmental and medical therapy hazards; hospital and medical environments; home and occupational environments; and supplemental precautionary information. Advise patients to avoid sources of electromagnetic interference (EMI) because EMI may cause the pulse generator to deliver inappropriate therapy or inhibit appropriate therapy. Refer to the product labeling for specific indications, contraindications, warnings/potential adverse events and adverse effects. Rx only. (Rev. S)
S-ICD™ System from Boston Scientific CRM

Indications for Use
The S-ICD™ System is intended to provide defibrillation therapy for the treatment of life-threatening ventricular tachyarrhythmias in patients who do not have symptomatic bradycardia, incessant ventricular tachycardia, or spontaneous, frequently recurring ventricular tachycardia that is reliably terminated with anti-tachycardia pacing.

Contraindications
Unipolar pacemakers are contraindicated for use with the S-ICD System.

Warnings and Cautions
The S-ICD System contains sterile products for single use only. Do not reprocess. Handle the components of the SICD System with care at all times and maintain proper sterile technique. All implantable components are designed for use with the S-ICD System only. Connection of any S-ICD System component to any other ICD system will result in failure to deliver lifesaving defibrillation therapy.

General
• External defibrillation equipment should be available for immediate use during the implantation procedure and follow-up.

• Placing a magnet over the SQ-RX Pulse Generator suspends arrhythmia detection and therapy response. Removing the magnet resumes arrhythmia detection and therapy response.

• Battery depletion will eventually cause the SQ-RX Pulse Generator to stop functioning. Defibrillation and excessive numbers of charging cycles shorten the battery longevity.

• The S-ICD System has not been evaluated for pediatric use.

• The S-ICD System does not provide long-term bradycardia pacing, Cardiac Resynchronization Therapy (CRT) or Anti-Tachycardia Pacing (ATP).

Potential Adverse Events related to implantation of the S-ICD System may include, but are not limited to, the following:
- Acceleration/induction of atrial or ventricular arrhythmia
- Adverse reaction to induction testing
- Allergic/reaction to system or medication
- Bleeding
- Conductor fracture
- Cyst formation
- Death
- Electrode insulation failure
- Erosion/extrusion
- Failure to deliver therapy
- Fever
- Hematoma
- Hemorrhax
- Improper electrode connection to the device
- Inability to communicate with the device
- Inappropriate device response
- Inappropriate shock pacing
- Inappropriate shock delivery
- Infection
- Kidney function impairment
- Liver function damage
- Pneumothorax
- Post shock/pump disconnection
- Premature battery depletion
- Random component failures
- Stroke
- Subcutaneous emphysema
- Surgical revision or replacement of the system
- Syncope
- Tissue redness, irritation, numbness, or paresthesia

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

EMBLEM™Y-S’ICD System from Boston Scientific CRM

Indications for Use
The S-ICD System is intended to provide defibrillation therapy for the treatment of life-threatening ventricular tachyarrhythmias in patients who do not have symptomatic bradycardia, incessant ventricular tachycardia, or spontaneous, frequently recurring ventricular tachycardia that is reliably terminated with anti-tachycardia pacing.

Contraindications
Unipolar pacing and impedance-based features are contraindicated for use with the S-ICD System.

Warnings
Read the manual thoroughly before using the S-ICD System to avoid damage to the pulse generator and/or subcutaneous electrode. Such damage can result in patient injury or death. For single patient use only. Do not reuse, reprocess, or resterilize. All Boston Scientific S-ICD implantable components are designed for use with the Boston Scientific S-ICD System only. Connection of any S-ICD System components to a non-compatible component will result in failure to deliver lifesaving defibrillation therapy. Always use the internal defibrillation equipment and medical personnel skilled in CPR available during implant and follow-up testing. Using multiple pulse generators could cause pulse generator interaction, resulting in patient injury or a lack of therapy delivery. Test each system individually and in combination to help prevent undesired interactions. Concomitant use of the S-ICD System and implanted electromechanical devices (for example a ventricular assist device, VAD; or implantable insulin pump or drug pump) can result in interactions that could compromise the function of the S-ICD, the co-implanted device, or both. Electromagnetic (EM) or therapy delivery from the co-implanted devices can interfere with S-ICD sensing and/or rate assessment, resulting in inappropriate therapy or failure to deliver therapy when needed. In addition, a shock from the S-ICD pulse generator could damage the co-implanted device and compromise its functionality. To help prevent undesired interactions, test the S-ICD system when used in combination with the co-implanted device, and consider the potential effect of a shock on the co-implanted device. Handle the components of the SICD System with care at all times and maintain proper sterile technique. Do not modify, cut, kink, crush, stretch or otherwise damage any component of the S-ICD System. Use caution handling the subcutaneous electrode connector. Do not directly contact the connector with any surgical instruments such as forceps, hemostats, or clamps. Use appropriate anchoring techniques as described in the implant procedure to prevent S-ICD System dislodgement and/or migration. Use caution when placing a magnet over the S-ICD pulse generator to avoid the possibility of patient injury. In patients with a deep implant placement (greater distance between the magnet and the pulse generator) magnet application may fail to elicit the magnet response. Do not expose a patient with an implanted S-ICD System to diathermy. Do not expose a patient to MRI scanning. Advise patients to seek medical guidance before entering environments that could adversely affect the operation of the active implantable medical device, including areas protected by a warning notice that prevents entry by patients who have a pulse generator. The pulse generator may be more susceptible to low frequency electromagnetic interference at induced signals greater than 80 uV. The S-ICD System has not been evaluated for pediatric use.

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 considerations, sterilization and storage, implantation, device programming, environmental and medical therapy considerations, environmental and medical therapy hazards, follow-up testing, explant and disposal, supplemental precautionary information. Advise patients to avoid sources of EMI because EMI may cause the pulse generator to deliver inappropriate therapy or inhibit appropriate therapy.
Potential Adverse Events

Potential adverse events related to implantation of the S-ICD System may include, but are not limited to, the following: Acceleration/induction of atrial or ventricular arrhythmias, adverse reaction to induction testing, allergic/adaptive reaction to system or medication, bleeding, conductor fracture, cyst formation, defibrillation therapy delivery, discomfort or prolonged healing of incision, electrode deformation and/or breakage, electrode insulation failure, erosion/abrasion, failure to deliver therapy, fever, hematoma/seroma, hemoptysis, improper electrode connection to the device, inability to communicate with the device, inability to defibrillate or pace, inappropriate post shock pacing, inappropriate shock delivery, infection, kieloid formation, migration or dislodgement, muscle/nerve stimulation, nerve damage, pulmonary edema, post-shock/post-pulse discomfort, premature battery depletion, component failures, stroke, subcutaneous emphysema, surgical revision or replacement of the system, syncope, tissue redness, irritation, numbness or necrosis. Patients who receive an S-ICD System may develop psychological disorders that include, but are not limited to, the following: depression/anxiety, fear of device malfunction, fear of shocks, phantom shocks.

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

INGEVITY™ MRI Extensible/Retractable Fixation and Tined Fixed Leads

Indications

INGEVITY™ MRI Leads are intended for chronic pacing and sensing in the right atrium (only preformed atrial J with the Tined Fixed) 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 Fixed, 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 implantation 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 brad 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 may not be achieved if the lead is chronically repositioned because the steroid may be depleted.

For Extendable/Retractable Fixation: 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 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, fibration 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)

DEXTRUS™ Pacing Leads from Boston Scientific

Indications

The DEXTRUS™ transvenous, steroid-eluting, active fixation endocardial Leads are indicated for permanent pacing and sensing. Active fixation pacing leads with a bipolar (BP) IS-1 connector configuration are designed for use in conjunction with implantable pulse generators with IS-1 headers. The leads may be used with single or dual chamber pacing systems. The DEXTRUS Lead models are intended for placement in either the right atrium or right ventricle.

Contraindications

Transvenous endocardial pacing leads are contraindicated in the presence of severe tricuspid valvular disease and in patients with mechanical tricuspid heart valves. The DEXTRUS Lead is additionally contraindicated for patients who cannot tolerate a single systemic dose of up to 1.3 mg of dexamethasone acetate (DXA).

Warnings and Precautions

Potentially Harmful Therapeutic and Diagnostic Procedures As an implanted pacing lead is a direct, low resistance path to the myocardium for electrical current, the observance of high standards of electrical safety is required. Electrosurgical instruments, for example, could generate voltages of such amplitude that a direct coupling between the tip of the electrosurgery device and the implanted lead may result, possibly inducing myocardial lesions or serious cardiac arrhythmias (e.g., fibrillation). Some therapeutic and diagnostic procedures (e.g., diathermy, MRI, electrosurgery) may result in latent damage to the pacing system. This damage may not be detected when testing the pacemaker function immediately after the procedure, but may become evident at a later time, resulting in pacing system malfunction or failure. For single patient use only. Do not reuse, reprocess, or resterilize.

Prevention of Leakage Current Conduction

Pulse generators and testing equipment connected to the lead must be battery-powered. Proper grounding of line-powered devices in the vicinity of the patient is essential to prevent leakage currents arising from such devices to be conducted via the lead's terminal or any other non-insulated part.

Necessary Equipment for Implantation

During implantation the ECG should be recorded; a pacing system analyzer (PSA) and defibrillation equipment should always be readily available.

Handling the Lead

The lead should be handled very carefully at all times. Any severe application of force (bending, stretching, crimping, etc.) may permanently damage the lead. The metal portion of the lead connector should not be touched.

Lead/Pulse Generator Compatibility

Because of the numerous available 3.2 mm configurations, e.g., the IS-1 and VS-1 standards, lead/pulse generator compatibility should be confirmed with the pulse generator and/or lead manufacturer prior to the implantation of a pacing system.

Extending/Retracting the Fixation Helix

In the event of previous handling or repositioning of the lead, more than the minimum number of rotations may be required to minimize the risk of endothelial laceration. If it becomes necessary to abandon a lead, the connector pin should be capped to prevent the transmission of electrical signals to the heart.

Suture Sleeve

Always use a suture sleeve when implanting a lead. Use of the suture sleeve, which is provided with the lead, will lessen the possibility of lead dislodgment and protect the lead body from damage by a securing ligature.

Potential Adverse Events

Potential complications include, but are not limited to: thrombosis, embolism, body rejection phenomena, cardiac tamponade, pneumothorax, muscle/nerve stimulation, valve damage, fibillation, infection, skin erosion, ventricular ectopy and death. Lead perforation through the myocardium has been rarely observed. In rare cases, severe complications or device failures can occur.

Refer to the physician's manual(s) for specific indications, contraindications, warnings/precautions and adverse events. Rx only. (Rev. H)

ADDENDUM TO: 100000015633, Rev. A, US
Current Brief Summaries found at http://www.bostonscientific.com/
March 18, 2016
Indications

The ACUITY™ Spiral™ coronary venous, dexamethasone eluting, single electrode pace/sense leads are transvenous leads intended for chronic LV pacing and sensing via the coronary veins when used in conjunction with a compatible pulse generator.

Contraindications

Use of this lead is contraindicated in patients with a hypersensitivity to a nominal dose of 0.45 dexamethasone acetate drug.

Warnings

Read the product labeling thoroughly before implanting the lead to avoid damage to the system. For single patient use only. Do not re-use, reprocess, or re-sterilize. When using a right ventricular (RV) pace/sense lead in conjunction with an LV lead, it is recommended that a polyurethane-insulated RV lead be used. The use of battery-powered equipment is recommended during lead implantation and testing. Line-powered equipment used in the vicinity of the patient must be properly grounded. The lead connector must be insulated from any leakage currents that could arise from line-powered equipment. The lead is not designed to tolerate excessive flexing, bending, tension, or injection pressure. When using a finishing wire accessory kit, use the corresponding finishing wire model for the lead length. Do not expose a patient to the MRI environment. Patients with implanted leads should not receive diathermy treatment. Do not kink, twist, or brad the lead terminal with other leads. Lead fracture, dislodgment, abrasion, or incomplete connection can cause periodic or continual loss of pacing and/or sensing.

Precautions

Refer to the Sterilization and Handling and Lead Evaluation and Implant sections of the product labeling for precautions specific to handling, implanting, and testing the lead. Failure to observe these precautions could result in incorrect lead implantation, lead damage/dislodgment, or harm to the patient.

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.

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

Indications

ACUITY™ Steerable IS-1 and EASY TRAK™ 3 coronary venous, steroid-eluting, dual-electrode pace/sense Leads are transvenous leads intended for chronic LV pacing and sensing via the coronary veins when used in conjunction with a compatible pulse generator. Extended bipolar pacing and sensing is available using Acuity Steerable with an RV pace/sense/defibrillation lead or a bipolar RV pace/sense lead.

Contraindications

Use of the Acuity Steerable and Easy Trak Lead are contraindicated in patients with a hypersensitivity to a nominal dose of 1.0 mg (0.5 mg per electrode) of dexamethasone acetate drug. Some LV lead models are contraindicated in patients with mechanical tricuspid heart valves, or obstructed or inadequate vasculature for intravenous catheterization (Acuity Steerable).

Warnings

Read the product labeling thoroughly before implanting the lead to avoid damage to the system. For single patient use only. Do not re-use, reprocess, or re-sterilize. When using a right ventricular (RV) pace/sense lead in conjunction with an LV lead, it is recommended that a polyurethane-insulated RV lead be used. The use of battery-powered equipment is recommended during lead implantation and testing. Line-powered equipment used in the vicinity of the patient must be properly grounded. The lead connector must be insulated from any leakage currents that could arise from line-powered equipment. The lead is not designed to tolerate excessive flexing, bending, tension, or injection pressure. When using a finishing wire accessory kit, use the corresponding finishing wire model for the lead length. Do not expose a patient to the MRI environment. Patients with implanted leads should not receive diathermy treatment. When placing the lead with a stylet, use only a stylet designed for use with the ACUITY Steerable lead. Lead fracture, dislodgement, abrasion, or an incomplete connection can cause periodic or continual loss of pacing and/or sensing.

Precautions

Refer to the Sterilization and Handling and Lead Evaluation and Implant sections of the product labeling for precautions specific to handling, implanting, and testing the lead. Failure to observe these precautions could result in incorrect lead implantation, lead damage/dislodgment, or harm to the patient.

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.

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

Indications

The Boston Scientific EASYTRAK® 2+ IS-1 coronary venous, steroid-eluting, dual-electrode pace/sense leads, Models 4542/4543/4544, are transvenous leads intended for chronic, left-ventricular pacing and sensing via the coronary veins when used in conjunction with a compatible Boston Scientific cardiac resynchronization therapy (CRT) device that accepts the IS-1 connector.

Contraindications

Use of the EASYTRAK 2+ IS-1 lead is contraindicated in patients with a hypersensitivity to a nominal single dose of 0.7 mg of dexamethasone acetate drug.

Warnings

Instructions in the lead manual should be used in conjunction with other resource material including the applicable Boston Scientific CRT device physician’s manual and instructions for use on any implant accessories or tools. When using a right ventricular (RV) pace/sense lead in conjunction with the EASYTRAK 2+ IS-1 lead, it is recommended that a polyurethane insulated lead be used. Lead fracture, dislodgment, abrasion, or an incomplete connection can cause a periodic or continual loss of pacing or sensing or both. The use of battery-powered equipment is recommended during lead implantation and testing to protect against fibrillation that might be caused from line-powered equipment. The lead connector must be insulated from any leakage currents that could arise from line-powered equipment. The lead is not designed to tolerate excessive flexing, bending, tension, or injection pressure. When using a finishing wire accessory kit, use the corresponding finishing wire model for the lead length. Do not expose a patient to the MRI environment. Patients with implanted leads should not receive diathermy treatment. When placing the lead with a stylet, use only a stylet designed for use with the ACUITY Steerable lead. Line-powered equipment is recommended during lead implantation and testing. Line-powered equipment used in the vicinity of the patient must be properly grounded. The lead connector must be insulated from any leakage currents that could arise from line-powered equipment. The lead is not designed to tolerate excessive flexing, bending, tension, or injection pressure. When using a finishing wire accessory kit, use the corresponding finishing wire model for the lead length.

Precautions

Refer to the lead product labeling for precautions specific to handling, implanting and testing the lead. Failure to observe these precautions could result in incorrect lead implantation, lead damage and/or harm to the patient.

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.

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

Pacing Leads from Boston Scientific – FINELINE® II and FLEXEXTEND®

FINELINE® II and FLEXEXTEND® leads are intended for chronic pacing and sensing of the atrium and/or ventricle when used with a compatible pulse generator.

Contraindications

Use of these leads are contraindicated in: patients with a hypersensitivity to a single dose of approximately 1.0 mg of dexamethasone acetate, patients with tricuspid valvular disease, patients with mechanical tricuspid heart valves, and patients with an allergy to mannitol (FINELINE II).

Warnings

Refer to the product labeling before implanting the lead to avoid damage to the system. For single patient use only. Do not reuse, reprocess, or re-sterilize. The use of battery-powered equipment is recommended during lead implantation and testing. Line-powered equipment used in the vicinity of the patient must be properly grounded. Do not expose lead to MRI and diathermy exposure. The lead connector must be insulated from any leakage currents that could arise from line-powered equipment. The lead is not designed to tolerate excessive flexing, bending, or tension.

ADDENDUM TO: 100000015633, Rev. A, US

March 18, 2016

Current Brief Summaries found at http://www.bostonscientific.com/
Precautions
Refer to the implant product labeling for cautions specific to handling, implanting and testing the lead. Failure to observe these cautions could result in incorrect lead implantation, lead amace/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.

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, loss 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.

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

ENDOTAK RELIANCE™ G/SG Leads with DF4-LLHH and DF4-LLHO connectors from Boston Scientific

Indications
ENDOTAK RELIANCE™ G/SG Leads with Integrated Bipolar DF4-LLHH and DF4-LLHO connectors is intended for pacing, rate-sensing and delivery of cardioversion and defibrillation shocks when used with a compatible pulse generator.

Contraindications
Use of ICD leads are contraindicated in: patients who have a unipolar pacemaker, patients with a hypersensitivity to a maximum single dose of 1.3 mg dexamethasone acetate, and patients with mechanical tricuspid heart valves.

Warnings
Read this manual thoroughly before implantation 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 protection available during implant. Do not use any component of the lead system to assist in delivery of external-source rescue shocks. Ensure that an external defibrillator and medical personnel skilled in CPR are present during post-implant device testing. Lead fracture, dislodgment, abrasion, or an incomplete connection can cause a periodic or continual loss of pacing or sensing or both. The lead is not designed to tolerate excessive flexing, bending, or tension. Do not kink, twist, or braid the lead with other leads. The safety and efficacy of the tip electrode placement above midseptum has not been clinically established. In order to deliver defibrillation therapy, the single-coil models must be implanted with an additional defibrillation electrode. Use fluoroscopy to verify that the lead tip is directed toward the apex when the lead is implanted. Take care to obtain appropriate electrode position. When connecting the lead to the pulse generator, it is very important that proper connections are made. Do not expose a patient to MRI device scanning. Do not subject a patient with an implanted pulse generator and/or lead to diathermy.

For DF4-LLHH or DF4-LLHO leads, use caution handling the lead terminal when the Connector Tool is not present on the lead and do not directly contact the lead terminal with any surgical instruments or electrical connections such as PSA (alligator) clips, ECG connections, forceps, hemostats, and clamps. Do not contact any other portion of the DF4-LLHH or DF4-LLHO lead terminal, other than the terminal pin when the lead cap is in place. Only use the Connector Tool for electrical connections to pacing system analyzers or similar monitors. Do not attach alligator clips directly to the lead terminal or damage could occur.

Precautions
For specific information on precautions, refer to the following sections of the product labeling: clinical considerations; sterilization and storage; handling; implantation, hospital and medical environments, follow-up testing, explant and disposal

Potential Adverse Events
Potential adverse events from implantation of the ICD lead system 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 (shocks/pacing/sensing), infection, procedure related, and component failure. 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)

ICD Leads from Boston Scientific

Indications
ICD leads provide pacing and rate-sensing and deliver cardioversion and defibrillation shocks for ICD systems.

Contraindications
Use of ICD leads are contraindicated in: patients who have a unipolar pacemaker, patients with a hypersensitivity to a single dose of approximately 1.0 mg of dexamethasone sodium phosphate and/or 1.0 mg of dexamethasone acetate, patients with mechanical tricuspid heart valves.

ICD leads are not designed to tolerate excessive flexing, bending, or tension. Do not kink, twist, or braid the lead terminals as doing so could cause lead insulation abrasion damage.

Potential Adverse Events
Refer to the lead product labeling for cautions specific to handling, implanting and testing the lead. Failure to observe these cautions could result in incorrect lead implantation, lead damage, and/or harm to the patient. It has not been determined whether the warnings, precautions, or complications usually associated with injectable dexamethasone sodium phosphate/acetate apply to the use of the low concentration, highly localized, controlled-release device. For a listing of potentially adverse effects, refer to the Physician's Desk Reference. Tricuspid valvular disease may be exacerbated by the presence of a lead. Use medical judgment when deciding to place a lead in a patient with tricuspid valvular disease. The lead and its accessories one-time use. Do not reuse.

Potential Adverse Events
Potential adverse events from implantation of the ICD lead system 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 (shocks/pacing/sensing), infection, procedure related, and component failure. 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. M)

Left Ventricular Pace/Sense Leads from Boston Scientific – ACUITY X4™

Indications
This Boston Scientific lead is indicated for use as follows: Intended for chronic, left-ventricular pacing and sensing via the coronary venous system when used in conjunction with a compatible pulse generator. The Boston Scientific ACUITY X4 lead is a sterid-eluting (dexamethasone acetate) IS4 quadriplear lead.

Contraindications
This Boston Scientific lead is contraindicated for the following patients: Patients with a hypersensitivity to a maximum single dose of 0.54 mg dexamethasone acetate.

Warnings
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. Ensure that an external defibrillator and medical personnel skilled in CPR are present during post-implant device testing. 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.

ADDENDUM TO: 10000015633, Rev. A, US
Current Brief Summaries found at http://www.bostonscientific.com/
March 18, 2016

Precautions
Refer to the implant product labeling for cautions specific to handling, implanting and testing the lead. Failure to observe these cautions could result in incorrect lead implantation, lead amace/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.

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.

Refer to the physician’s manual(s) for specific indications, contraindications, warning/precautions and adverse events. Rx only. (Rev. B)
Precautions
Refer to the lead product labeling for cautions specific to clinical considerations, sterilization and storage, handling, implanting hospital and medical environments, and testing the lead. Failure to observe these cautions could result in incorrect lead implantation, lead damage and/or harm to the patient.

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

ZOOM™ LATITUDE™ Programming System from Boston Scientific

Intended Use
The Programmer/Recorder/Monitor (PRM) is intended to be used as part of the ZOOM™ LATITUDE™ Programming System to communicate with Boston Scientific implantable pulse generators. The software in use controls all communication functions for the pulse generator. For detailed software application instructions, refer to the associated product literature for the pulse generator being interrogated.

Contraindications
The PRM is contraindicated for use with any pulse generator other than a Boston Scientific pulse generator. For contraindications for use related to the pulse generator, refer to the associated product literature for the pulse generator being interrogated.

Warnings
The use of any cables or accessories with the PRM or Zoom Wireless Transmitter (ZWT) other than those specified by Boston Scientific in this manual may result in increased emissions or decreased immunity of the PRM or ZWT. Do not simultaneously touch the patient and any accessible connector contacts on the PRM (e.g., USB, parallel port, external VGA monitor, stimulation input, analog output, and expansion port). Other equipment may interfere with the PRM and ZWT, even if that equipment complies with the International Special Committee on Radio Interference (CISPR) emission requirements. To avoid the risk of electric shock, only connect the PRM to a grounded/earthed power source. Do not use the PRM or ZWT adjacent to or stacked with other equipment. PRM and ZWT must remain outside sterile field. Operation of the PRM with physiological signals that are lower than the minimum detectable amplitude may cause inaccurate results. Do not simultaneously touch the patient and the parts inside the printer door. The PRM and ZWT are MR Unsafe and must remain outside the MRI site Zone III (and higher) as defined by the American College of Radiology Guidance Document for Safe MR Practices.1 No modification of this equipment is allowed unless approved by Boston Scientific.

Precautions
For specific information on precautions, read the following sections of the product labeling: General, Preparations for Use, Maintenance and Handling.

Adverse Effects
None known. Refer to the product labeling for specific indications, contraindications, warnings/precautions and adverse effects. Rx only. (Rev. F)