# ImageReady™ MR-Conditional Model List*

<table>
<thead>
<tr>
<th>Therapy</th>
<th>Device Name</th>
<th>Device Model Numbers</th>
<th>MRI System Configuration</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Pacemakers</strong></td>
<td><strong>ACCOLADE™ MRI</strong></td>
<td>L310, L311, L331</td>
<td>1.5T or 3T</td>
</tr>
<tr>
<td></td>
<td><strong>ESSENTIO™ MRI</strong></td>
<td>L110, L111, L131</td>
<td>1.5T</td>
</tr>
<tr>
<td></td>
<td><strong>VITALIO™ MRI</strong></td>
<td>K275, K277</td>
<td>1.5T</td>
</tr>
<tr>
<td></td>
<td><strong>S-ICD</strong></td>
<td><strong>EMBLEM™</strong></td>
<td>A209</td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>EMBLEM™ MRI</strong></td>
<td>A219</td>
</tr>
<tr>
<td><strong>CRT-P</strong></td>
<td><strong>VISIONIST™ X4</strong></td>
<td>U228</td>
<td>1.5T or 3T</td>
</tr>
<tr>
<td></td>
<td><strong>VALITUDE™ X4</strong></td>
<td>U128</td>
<td></td>
</tr>
<tr>
<td><strong>ICDs</strong></td>
<td><strong>RESONATE™</strong></td>
<td>D432, D433</td>
<td>1.5T or 3T</td>
</tr>
<tr>
<td></td>
<td><strong>VIGILANT™</strong></td>
<td>D232, D233</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>PERCIVA™ DF4</strong></td>
<td>D412, D413</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>PERCIVA™ DF1</strong></td>
<td>D400, D401</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>MOMENTUM™</strong></td>
<td>D120, D121</td>
<td>1.5T</td>
</tr>
<tr>
<td></td>
<td><strong>AUTOGEN™</strong></td>
<td>D160, D161, D162, D163</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>DYNAGEN™</strong></td>
<td>D020, D021, D022, D023, D150, D151, D152, D153</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>INOGEN™</strong></td>
<td>D010, D011, D012, D013, D140, D141, D142, D143</td>
<td></td>
</tr>
<tr>
<td><strong>CRT-Ds</strong></td>
<td><strong>RESONATE™</strong></td>
<td>G447</td>
<td>1.5T or 3T</td>
</tr>
<tr>
<td></td>
<td><strong>VIGILANT™</strong></td>
<td>G247</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>MOMENTUM™</strong></td>
<td>G124, G125, G138</td>
<td>1.5T</td>
</tr>
<tr>
<td></td>
<td><strong>AUTOGEN™</strong></td>
<td>G160, G161, G166, G168</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>DYNAGEN™</strong></td>
<td>G150, G151, G156, G158</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>INOGEN™</strong></td>
<td>G140, G141, G146, G148</td>
<td></td>
</tr>
</tbody>
</table>

The following leads and accessories are labeled as MR-Conditional*

- **INGEVITY™ MRI**: 7735, 7736, 7740, 7741, 7742
- **INGEVITY™ MRI**: 7731, 7732 (Not valid with ICDs or CRT-Ds)
- **FINELINE™ II**: 4469, 4470, 4471, 4472, 4473, 4474, 4479, 4480 (Not valid with VITALIO MRI.)
- **FINELINE™ II**: 4456, 4457, 4458, 4459 (Not valid with VITALIO MRI. Not valid with ICDs or CRT-Ds)
- **ENDOTAK RELIANCE™ 4-SITE™ (DF4)**: 0262, 0263, 0265, 0266, 0272, 0273, 0275, 0276, 0282, 0283, 0285, 0286, 0292, 0293, 0295, 0296
- **ENDOTAK RELIANCE™ (DF1)**: 0127, 0128, 0129, 0137, 0138, 0139, 0143, 0147, 0148, 0149, 0153, 0157, 0158, 0159, 0170, 0171, 0172, 0173, 0174, 0175, 0176, 0177, 0180, 0181, 0182, 0183, 0184, 0185, 0186, 0187
- **RELIANCE™ 4-FRONT™**: 0636, 0650, 0651, 0652, 0653, 0654, 0655, 0658, 0662, 0663, 0665, 0672, 0673, 0675, 0676, 0682, 0683, 0685, 0686, 0692, 0693, 0695, 0696
- **ACUITY™ X4**: 4671, 4672, 4674, 4675, 4677, 4678
- **EASYTRAK™ 2**: 4542, 4543, 4544
- **ACUITY™ Spiral**: 4591, 4592, 4593
- **S-ICD ELECTRODES**: 3010, 3400, 3401, 3501
- **Suture Sleeves**: 4603, 6100, 6220, 6221, 6402, 6403, 6773
- **Port Plugs**: 7145, 7148

* When conditions of use are met.

† VITALIO™ MRI is only MR-Conditional with INGEVITY™ MRI leads.

This document contains Boston Scientific CRM devices that are approved by the FDA as MR-Conditional as of August 2019. Visit [http://www.bostonscientific.com/imageready](http://www.bostonscientific.com/imageready) for additional information including cardiology/radiology checklists, conditions of use, patient resources, and the MRI Technical Guide.
Pacing Systems – ACCOLADE™, ACCOLADE™ MRI, PROPONENT™, PROPONENT™ MRI, ESSENTIO™, ESSENTIO™ MRI, ALTRUA™, FORMIO™, FORMIO™ MRI, VITALIO™

**Indications and Usage**

Boston Scientific pacemakers are indicated for treatment of the following conditions: Symptomatic paroxysmal or persistent second- and/or third-degree AV block; Symptomatic bifascicular block; Symptomatic paroxysmal or transient sinus node dysfunction with or without associated AV conduction disorders (e.g., sinus bradycardia, sinus arrest, sinoatrial [SA] block); Bradycardia-tachycardia syndrome, to prevent symptomatic bradycardia or some forms of symptomatic tachyarrhythmia; Neuromuscular (sino-vasal) syndromes or hyperthermic disorders (e.g., Marfan syndrome); Adaptive-rate pacing is indicated for patients exhibiting chronotropic incompetence of the sinus node in whom significant variability may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury or death. Always have external defibrillation equipment available during implantation.

**Contraindications**

These Boston Scientific pacemakers are contraindicated in patients who are implanted with an unipolar transvenous lead defibrillator (ICD) with transvenous leads. Use of certain pacing modes and/or features available in these Boston Scientific pacemakers is contraindicated for the circumstances listed:

- Unipolar pacing or use of the MRI Sensor with a Subcutaneous Implantable Cardiac Defibrillator (S-ICD) because it can cause inappropriate therapy or inhibition of inappropriate ICD therapy.
- Single-chamber atrial pacing in patients with an ICD
- Atrial tracking modes for patients with chronic tachyarrhythmias (atrial fibrillation or flutter), which might trigger ventricular pacing or dual-chamber pacing in single-chamber pacing with chronic atrial fibrillation or tachycardias.
- Asynchronous pacing in the presence (or likelihood) of competition between paced and intrinsic rhythms.

**Warnings**

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. Don't reuse, reprocess, or reinitialize.

- Always use external defibrillation equipment available during implantation and electrophysiologic testing. Using multipole pulse generators could cause pulse generator interaction, resulting in patient injury or death of the pulse generator or ICD therapy or inhibition of inappropriate ICD therapy.
- Single-chamber atrial pacing in patients with an ICD
- Atrial tracking modes for patients with chronic atrial fibrillation or tachycardias.
- 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. Automatic Lead Recognition should be programmed to Off before implantation for patients with an ICD. Unipolar pacing due to RAAIs is contraindicated and should be programmed off for patients with an ICD.

If programmed to a left atrial Sensitivity value of 0.15 mV or an a-fib Sensitivity value of 0.2 mV or less in a unipolar lead configuration, the pulse generator may be more susceptible to electromagnetic interference.

**Advisory patient notes**

Before beginning any medical device that could adversely affect the operation of the real-time implantable medical device, ACCOLADE™ MRI, PROPONENT™ MRI, ESSENTIO™ MRI, FORMIO™ MRI, VITALIO™, and INGENIO™ MRI devices are considered non-MR Conditional. For these devices, unless all of the MRI Conditions of Use are met, MRI scanning of the patient is not permitted. MRI scanning of the device is contraindicated for the following circumstances:

- Patients who have an implantable cardioverter-defibrillator (ICD) with transvenous leads;
- Patients who have a separate implanted cardioverter-defibrillator (ICD) with transvenous leads;
- Patients who have an ICD in place;
- Patients who have a pacemaker in place;
- Patients who have a pacemaker and an ICD in place;
- Patients who are undergoing MRI scanning.

For potential adverse events when Conditions of Use are met or not met, refer to the MRI Technical Guide. Do not subject a patient with an MRI-enabled pacemaker to MRI scanning.

**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, and home and occupational environments. Follow-up testing 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 the magnet rate in the presence of EMI. Refer to the MRI Technical Guide at www.bostonscientific.com/corporate/ Accessed before using the device. Refer to the product labeling for specific indications, contraindications, warnings, precautions, and adverse events. Rx only.

**Rev. E** 046774 A

**CR-P Systems – VISION™, VISION™ X, VALUTE™, VALUTE™ X, INTUA™, INVTIVE™**

Boston Scientific cardiac resynchronization therapy pacemakers (CRT-P) are indicated for patients with moderate to severe heart failure (NYHA Class III/IV) including left ventricular dysfunction (EF ≤ 35%) and QRS duration > 120 ms and remain asymptomatic despite stable optimal pharmacological therapy (OPT) for heart failure.

Atrial tracking modes are also indicated for patients who may benefit from maintenance of AV synchrony. Dual-chamber atrial pacing modes are specifically indicated for treatment of the following conditions: Conduction disorders that require restoration of AV synchrony, including various degrees of AV block.

**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 circumstances listed:

- Unipolar pacing or use of the MRI Sensor with a Subcutaneous Implantable Cardiac Defibrillator (S-ICD) because it can cause inappropriate therapy or inhibition of inappropriate ICD therapy.
- Single-chamber atrial pacing in patients with an ICD
- Atrial tracking modes for patients with chronic tachyarrhythmias (atrial fibrillation or flutter), which might trigger ventricular pacing or dual-chamber pacing in single-chamber pacing with chronic atrial fibrillation or tachycardias.
- Asynchronous pacing in the presence (or likelihood) of competition between paced and intrinsic rhythms.

**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 reinitialize. Use, reprocessing, or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury or death. Always have external defibrillation equipment available during implantation and electrophysiologic testing. Using multipole pulse generators could cause pulse generator interaction, resulting in patient injury or death of the pulse generator or ICD therapy or inhibition of inappropriate ICD therapy.

- Single-chamber atrial pacing in patients with an ICD
- Atrial tracking modes for patients with chronic atrial fibrillation or tachycardias.
- 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. Automatic Lead Recognition should be programmed to Off before implantation for patients with an ICD. Unipolar pacing due to RAAIs is contraindicated and should be programmed off for patients with an ICD.

If programmed to a left atrial Sensitivity value of 0.15 mV or an a-fib Sensitivity value of 0.2 mV or less in a unipolar lead configuration, the pulse generator may be more susceptible to electromagnetic interference.

**Advisory patient notes**

Before beginning any medical device that could adversely affect the operation of the real-time implantable medical device, ACCOLADE™ MRI, PROPONENT™ MRI, ESSENTIO™ MRI, FORMIO™ MRI, VITALIO™, and INGENIO™ MRI devices are considered non-MR Conditional. For these devices, unless all of the MRI Conditions of Use are met, MRI scanning of the patient is not permitted. MRI scanning of the device is contraindicated for the following circumstances:

- Patients who have an implantable cardioverter-defibrillator (ICD) with transvenous leads;
- Patients who have a separate implanted cardioverter-defibrillator (ICD) with transvenous leads;
- Patients who have an ICD in place;
- Patients who have a pacemaker in place;
- Patients who have a pacemaker and an ICD in place;
- Patients who are undergoing MRI scanning.

For potential adverse events when Conditions of Use are met or not met, refer to the MRI Technical Guide. Do not subject a patient with an MRI-enabled pacemaker to MRI scanning.

**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, and home and occupational environments. Follow-up testing 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 the magnet rate in the presence of EMI. Refer to the MRI Technical Guide at www.bostonscientific.com/corporate/ Accessed before using the device. Refer to the product labeling for specific indications, contraindications, warnings, precautions, and adverse events. Rx only.

**Rev. E** 046774 A
Patients may develop psychological intolerance to a pulse generator system and may experience the following: Dependency; Deprivation; Fear of premature battery depletion; Fear of a device malfunction.

Additionally, potential adverse events associated with the implantation of a coronary venous lead system include: Allergic reaction to contrast media; Breakage/failure of implant instruments; Prolonged exposure to fluoroscopic radiation; Renal failure from contrast media used to visualize coronary veins.

Refer to the product labeling for specific indications, contraindications, warnings/precautions and adverse events. Rx only. (Rev B) 046774 AI

Emblem™ MRI S-ICD System

INDICATIONS FOR USE

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

CONTRAINDICATIONS

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

WARNINGS

Concomitant use of the S-ICD System and implanted electromechanical devices (for example implantable neuromodulation/neurostimulation systems, 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. The S-ICD is intended as lifesaving therapy and should be seen as priority in the decision and evaluation of concomitant system implants without non-lifesaving applications. Electromagnetic (EM) or therapy delivery from the co-implanted device 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/or compromise its function. In the event of a shock delivered to a co-implanted device or the placement of all involved devices prior to any co-implant. To help prevent undesirable 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. Induction testing is recommended to ensure appropriate detection and time to therapy for the S-ICD and appropriate post-shock operation of the co-implanted device. Failure to ensure appropriate detection and time to therapy delivery of the S-ICD system could result in patient injury or death. Following completion of the interaction testing, thorough follow-up evaluation of all co-implanted devices should be performed to ensure that device functions have not been compromised. If operational settings of the co-implanted devices change or if patient conditions changes which may affect S-ICD sensing and therapy performance, re-evaluation of the co-implanted devices may be required. Do not expose a patient with an implanted S-ICD System to diathermy. EMBLEM S-ICD devices are considered MRI Conditional. Unless all MRI Conditions of Use are met, MRI scanning of the patient does not meet MR Conditional requirements for the implanted device. The Programmer is MR Unsafe and must remain outside the MRI site Zone III. During MRI Protection Mode the Tachycardia therapy is suspended. MRI scanning after ERI status has been reach may lead to premature battery depletion, a shortened device replacement window, or sudden loss of therapy. The Beeper may no longer be usable following an MRI scan.

Do not expose a patient with an implanted S-ICD System to diathermy. EMBLEM S-ICD devices are considered MRI Conditional. Unless all MRI Conditions of Use are met, MRI scanning of the patient does not meet MR Conditional requirements for the implanted system. The Programmer is MR Unsafe and must remain outside the MRI site Zone III. During MRI Protection Mode the Tachycardia therapy is suspended. MRI scanning after ERI status has been reach may lead to premature battery depletion, a shortened device replacement window, or sudden loss of therapy. The Beeper may no longer be usable following an MRI scan. The pulse generator may be more susceptible to low frequency electromagnetic interference at induced signals greater than 80 V. 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 hazards, hospital and medical environments, home and occupational environments, follow up testing, explant and disposal, supplemental precautionary information.

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 arrhythmia, adverse reaction to system or medication, bleeding, conductor fracture, cyst formation, death, delayed therapy delivery, discomfort or prolonged healing of incision, electrode deformation and/or breakage, electrode insulation failure, erosion/extrusion, failure to deliver therapy, fever, hemotoma/seroma, hemotherax, 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, injury to or pain in upper extremity, including clavicle, shoulder and arm, keloid formation, migration or dislodgement, muscle/nerve stimulation, nerve damage, pneumotherax, post-shock/post-pacem discomot, premature battery depletion, random 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 E) 046774 AI

ICD Systems – RESONATE™ HF, RESONATE™ EL, PERCIVA™ HF, PERCIVA™, VIGILANT™ EL, MOMENTUM™ EL

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 tachycardia/rhythmias may have irreversible cause, such as: digitalis intoxication, electrolyte imbalance, hypoxia, sepsis; or patients whose ventricular tachycardia/rhythmias have a transient cause, such as: acute myocardial infarction (MI), electrocution, drowning; or patients who have a unipolar pacemaker.

WARNING

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 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. Do not use this pulse generator with another pulse generator. Program the external pulse generator Tachy Mode(s) to Off during implant, explant, or posttreatment procedures to avoid inadvertent shocks. Do not test unipolar leads with bipolar devices. Do not twist, or braid the lead with other leads as doing so could cause lead insulation abrasion damage or conductor damage. 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-LLHIH or DF4-LLHDL lead terminal, other than the terminal pin, even when the lead cap is in place. Do not use atrial tracking modes in patients with chronic refractory atrial tachycardia/rhythmias. Tracking of atrial arrhythmias could result in ventricular tachyarhythmias. 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 prohibits entry by patients who have a pulse generator. RESONATE HF, RESONATE, PERCIVA HF, PERCIVA, VIGILANT and MOMENTUM devices are considered MR Conditional. For these devices, unless all of the MRI Conditions of Use are met, MRI scanning of the patient that 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. MRI scanning of devices that do not meet the Conditions of Use 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. EMBLEM S-ICD devices are considered MRI Conditional. Unless all MRI Conditions of Use are met, MRI scanning of the patient does not meet MR Conditional requirements for the implanted device. The Programmer is MR Unsafe and must remain outside the MRI site Zone III. During MRI Protection Mode the Tachycardia therapy is suspended. MRI scanning after ERI status has been reach may lead to premature battery depletion, a shortened device replacement window, or sudden loss of therapy. The Beeper may no longer be usable following an MRI scan. The pulse generator may be more susceptible to low frequency electromagnetic interference at induced signals greater than 80 V. 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 hazards, hospital and medical environments, home and occupational environments, follow up testing, explant and disposal, supplemental precautionary information.

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 arrhythmia, adverse reaction to system or medication, bleeding, conductor fracture, cyst formation, death, delayed therapy delivery, discomfort or prolonged healing of incision, electrode deformation and/or breakage, electrode insulation failure, erosion/extrusion, failure to deliver therapy, fever, hemotoma/seroma, hemotherax, 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, injury or pain in upper extremity, including clavicle, shoulder and arm, keloid formation, migration or dislodgement, muscle/nerve stimulation, nerve damage, pneumotherax, post-shock/post-pacem discomot, premature battery depletion, random 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 E) 04674 AI

For potential adverse events associated with MRI scanning, refer to the MRI Technical Guide.

Patients may develop psychological intolerance to a pulse generator system and may experience the following: Dependency; Depression; Fear of premature battery depletion; Fear of a device malfunction.

Additionally, potential adverse events associated with the implantation of a coronary venous lead system include: Allergic reaction to contrast media; Breakage/failure of implant instruments; Prolonged exposure to fluoroscopic radiation; Renal failure from contrast media used to visualize coronary veins.

Refer to the product labeling for specific indications, contraindications, warnings/precautions and adverse events. Rx only. 92436178 (Rev A)
**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 electrical 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. Do not use defibrillation pulse pads with the pulse generator system. Do not use this pulse generator with another pulse generator. Program the pulse generator Tachy Mode(s) to Off during implant, explant, or postmortem procedures. Do not kink, twist, or braid the lead with other leads. 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-LLL or DF4-LLL lead terminal, other than the terminal pin, even when the lead cap is in place. Do not contact any other portion of the LV; LV lead terminal, other than the terminal pin, even when the lead cap is in place. When implant a system that uses both a DF4-LLL or DF4-LLL and IS4-LLL lead, ensure that the leads are inserted and secured in the appropriate ports. Do not use atrial tracking modes in patients with chronic atrial tachyarrhythmias. Do not use atrial-only modes in patients with heart failure. Left ventricular lead dislodgement to a position near the atria can result in atrial oversensing and left ventricular pacing inhibition. Physicians should use medical discretion when implanting this device in patients who present with slow VT. Advise patients to seek medical guidance before entering environments that could adversely affect the operation of this implantable medical device. Advise applicable patients to have a pulse generator. RESONATE HF, RESONATE, and MOMENTUM devices except for those with an RA: 15–15; RV: 15–15/1–1. LV: LV-1 lead connection are considered MR Conditional. VIGILANT devices are considered MR Conditional. For these devices, unless all of the MRI Conditions of Use are met, MRI scanning of the patient does not meet MR Conditional requirements for the implant system, and significant harm to or death of the patient and/or damage to the implant 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 prior to sending the patient home by confirming the magnet response is programmed to Store EGM. Once the PTM feature has been triggered and the magnet response 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, hospitals and medical environments, 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**

Based on the literature and on pulse generator and/or lead implant experience, the following alphabetical list includes the possible adverse events associated with the included devices: Air emboli; Allergic reaction; Bleeding; Bradycardia; Cardiac tamponade; Chronic nerve damage; Component failure; Conductor coil fracture; Death; Electrolyte imbalance/dehydration; Elevated thresholds; Erosion; Excessive fibrotic tissue growth; Extracardiac stimulation (muscle/nerve stimulation); Failure to convert an induced arrhythmia; Fluid accumulation; Foreign body rejection phenomena; Formation of hematomas or seromas; Heart block; Inability to defibrillate or pace; Inappropriate therapy (e.g., shocks and antitachycardia pacing (ATP) where applicable, pacing); Incisional pain; Incomplete lead connection with pulse generator; Infection including endocarditis; Insulating myocardium during defibrillation with internal or external paddles; Lead dislodgement; Lead fracture; Lead insulation breakage or abrasion; Lead perforation; Lead tip deformation and/or breakage; Local tissue reaction; Loss of capture; Myocardial infarction (MI); Myocardial necrosis; Myocardial trauma (e.g., tissue damage, valve damage); Myopotential sensing; Oversensing/undersensing; Pacemaker-mediated tachycardia (PMT); Pericardial rub, effusion; Pneumothorax; Pulse generator migration; Shunting current during defibrillation with internal or external paddles; Syncope; Tachyarrhythmias, which include acceleration of arrhythmias and early, recurrent atrial fibrillation; Thrombosis/thromboemboli; Valve damage; Vasovagal response; Venous occlusion; Ventricular trauma (e.g., perforation, dissection, erosion); Worsening heart failure.

**For a list of potential adverse events associated with MRI scanning, refer to the MRI Technical Guide.**

Patients may develop psychological intolerance to a pulse generator system and may experience the following: Dependency; Depression; Fear of premature battery depletion; Fear of a device malfunction. Additionally, potential adverse events associated with the implantation of a coronary venous lead system include: Allergic reaction to contrast media; Breakage/failure of implant instruments; Prolonged exposure to fluoroscopic radiation; Renal failure from contrast media used to visualize coronary veins. For a list of potential adverse events associated with MRI scanning, refer to the MRI Technical Guide.

**CONTRAINDICATIONS**

There are no contraindications for this device.
Pacing Leads – INGEVITY™MRI
Extendable/Retractable Fixation and Tined Fixed

INDICATIONS

INGERVITY™ MRI Leads are intended for chronic pacing and sensing in the right atrium (only Preformed Atrial) with the Tined Fixed (only Straight with the Tined Fixed) 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 Fixed; 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 an optimal 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 Fixed: The safety and efficacy of the tip electrode placement in the right ventricle above midseptum has not been clinically established.

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, and follow up testing.

POTENTIAL ADVERSE EVENTS

Based on the literature and on the pulse generator and/or lead implant experience, the following alphabetical list includes the possible adverse events associated with implantation of products described in this literature:

- Air embolism
- Allergic reaction
- Arterial damage with subsequent stenosis
- Bleeding
- Bradycardia
- Breakage/failure of the implant instruments
- Cardiac perforation
- Cardiac tamponade
- Chronic nerve damage
- Component failure
- Conductor coil fracture
- Death
- Electrolyte imbalance/dehydration
- Elevated thresholds
- Erosion
- Excessive fibrotic tissue growth
- Extracardiac stimulation (muscle/nervous stimulation)
- Fluid accumulation
- Foreign body rejection phenomena
- Formation of hematomas or seromas
- Heart block
- Hemorrhage
- Hemothorax
- Inability to pace
- Inappropriate therapy (e.g., shocks and antichytracardiac pacing [ATP] where applicable, pacing)
- Incisional pain
- Incomplete lead connection with pulse generator
- Infection including endocarditis
- Lead dislodgment
- Lead fracture
- Lead insulation damage
- Lead breakage
- Lead tip deformation and/or breakage
- Malalignment and/or breakage
- Mammotoma and skin burn due to fluorescent radiation
- Myocardial trauma (e.g., tisue damage, valvular damage)
- Myopotential sensing
- Oversensing/undersensing
- Pericardial rub, effusion
- Pneumothorax
- Pulse generator and/or lead migration
- Syncope
- Tachyarrhythmias, which include acceleration of arrhythmias and early, recurrent atrial fibrillation
- Thrombosis/thromboembolism
- Valve damage
- Vasovagal response
- Venous occlusion
- Venous trauma (e.g., perforation, dissection, erosion)

For a list of potential adverse events associated with MRI scanning, refer to the ImageReady MRI Conditional Pacing System or Defibrillation System MRI Technical Guide Refer to the physician's manual(s) for specific indications, contraindications, warning/precautions and adverse events. Rx only. (Rev. C) 046774 AI

Pacing Leads – FINELINE™ II STEROX™ EZ™

INDICATIONS

The lead is intended for chronic pacing and sensing of the atrium or ventricle when used with a compatible pulse generator.

CONTRAINDICATIONS

Do not use this lead in patients with: mechanical tricuspid heart valves; a hypersensitivity to a maximum single dose of approximately 0.94 mg of dexamethasone acetate; an allergy to manniotil.

WARNINGS

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. Implant of the system cannot be performed in an MRI site Zone III (and higher). 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. Lead connector pins must be insulated from any leakage currents that may arise from line-powered equipment. Do not subject a patient with an implanted pulse generator and/or lead to diathermy since diathermy may cause fibrillation, burning of the myocardium, and irreversible damage to the pulse generator because of induced currents. Do not reuse, reprocess, or resterilize.

PRECAUTIONS

For specific information on precautions, refer to the following sections of the product labeling: general, handling, implanting.

NOTE: Use of Boston Scientific MR Conditional pulse generators and leads is required for an implanted system to be considered MRI Conditional. Refer to the appropriate ImageReady MRI Conditional Pacing System or Defibrillation System MRI Technical Guide for model numbers of pulse generators, leads, accessories, and other system components needed to satisfy the Conditions of Use for MR Conditional scanning. NOTE: Other implanted devices or patient conditions may cause a patient to be ineligible for an MRI scan, independent of the patient’s ImageReady MRI Conditional Pacing System.

POTENTIAL ADVERSE EVENTS

Based on the literature and on the pulse generator and/or lead implant experience, the following list includes the possible adverse events associated with implantation of products described in this literature:

- Air embolism
- Allergic reaction
- Arterial damage with subsequent stenosis
- Bleeding
- Bradycardia
- Breakage/failure of the implant instruments
- Cardiac perforation
- Cardiac tamponade
- Chronic nerve damage
- Component failure
- Conductor coil fracture
- Death
- Electrolyte imbalance/dehydration
- Elevated thresholds
- Erosion
- Excessive fibrotic tissue growth
- Extracardiac stimulation (muscle/nervous stimulation)
- Fluid accumulation
- Foreign body rejection phenomena
- Formation of hematomas or seromas
- Heart block
- Hemorrhage
- Hemothorax
- Inability to pace
- Inappropriate therapy (e.g., shocks and antichytracardiac pacing [ATP] where applicable, pacing)
- Incisional pain
- Incomplete lead connection with pulse generator
- Infection including endocarditis
- Lead dislodgment
- Lead fracture
- Lead insulation damage
- Lead breakage
- Lead tip deformation and/or breakage
- Malalignment and/or breakage
- Mammotoma and skin burn due to fluorescent radiation
- Myocardial trauma (e.g., tissue damage, valvular damage)
- Myopotential sensing
- Oversensing/undersensing
- Pericardial rub, effusion
- Pneumothorax
- Pulse generator and/or lead migration
- Syncope
- Tachyarrhythmias, which include acceleration of arrhythmias and early, recurrent atrial fibrillation
- Thrombosis/thromboembolism
- Valve damage
- Vasovagal response
- Venous occlusion
- Venous trauma (e.g., perforation, dissection, erosion)

For a list of potential adverse events associated with MRI scanning, refer to the ImageReady MRI Conditional Pacing System or Defibrillation System MRI Technical Guide Refer to the physician’s manual(s) for specific indications, contraindications, warning/precautions and adverse events. Rx only. (Rev. C) 046774 AI

Pacing Leads– FINELINE™ II STEROX™

INDICATIONS

FINELINE™ II STEROX™ leads are intended for chronic pacing and the ventricle (4456, 4457, 4458, 4459) or the atrium (4479, 4480) when used with a compatible pulse generator.

CONTRAINDICATIONS

Do not use these leads in patients with: mechanical tricuspid heart valves; a hypersensitivity to a maximum single dose of a 0.94 mg of dexamethasone acetate

WARNINGS

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. Implant of the system cannot be performed in an MRI site Zone III (and higher). 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. Lead connector pins must be insulated from any leakage currents that may arise from line-powered equipment. Do not subject a patient with an implanted pulse generator and/or lead to diathermy since diathermy may cause fibrillation, burning of the myocardium, and irreversible damage to the pulse generator because of induced currents. For single patient use only. Do not reuse, reprocess, or resterilize.

PRECAUTIONS

For specific information on precautions, refer to the following sections of the product labeling: general, handling, implanting.

NOTE: Use of Boston Scientific MR Conditional pulse generators and leads is required for an implanted system to be considered MRI Conditional. Refer to the appropriate ImageReady MRI Conditional Pacing System or Defibrillation System MRI Technical Guide for model numbers of pulse generators, leads, accessories, and other system components needed to satisfy the Conditions of Use for MR Conditional scanning. NOTE: Other implanted devices or patient conditions may cause a patient to be ineligible for an MRI scan, independent of the patient’s ImageReady MRI Conditional Pacing System.

POTENTIAL ADVERSE EVENTS

Based on the literature and on the pulse generator and/or lead implant experience, the following list includes the possible adverse events associated with implantation of products described in this literature:

- Air embolism
- Allergic reaction
- Arterial damage with subsequent stenosis
- Bleeding
- Bradycardia
- Breakage/failure of the implant instruments
- Cardiac perforation
- Cardiac tamponade
- Chronic nerve damage
- Component failure
- Conductor coil fracture
- Death
- Electrolyte imbalance/dehydration
- Elevated thresholds
- Erosion
- Excessive fibrotic tissue growth
- Extracardiac stimulation (muscle/nervous stimulation)
- Fluid accumulation
- Foreign body rejection phenomena
- Formation of hematomas or seromas
- Heart block
- Hemorrhage
- Hemothorax
- Inability to pace
- Inappropriate therapy (e.g., shocks and antichytracardiac pacing [ATP] where applicable, pacing)
- Incisional pain
- Incomplete lead connection with pulse generator
- Infection including endocarditis
- Lead dislodgment
- Lead fracture
- Lead insulation damage
- Lead breakage
- Lead tip deformation and/or breakage
- Malalignment and/or breakage
- Mammotoma and skin burn due to fluorescent radiation
- Myocardial trauma (e.g., tissue damage, valvular damage)
- Myopotential sensing
- Oversensing/undersensing
- Pericardial rub, effusion
- Pneumothorax
- Pulse generator and/or lead migration
- Syncope
- Tachyarrhythmias, which include acceleration of arrhythmias and early, recurrent atrial fibrillation
- Thrombosis/thromboembolism
- Valve damage
- Vasovagal response
- Venous occlusion
- Venous trauma (e.g., perforation, dissection, erosion)

For a list of potential adverse events associated with MRI scanning, refer to the ImageReady MRI Conditional Pacing System or Defibrillation System MRI Technical Guide Refer to the physician’s manual(s) for specific indications, contraindications, warning/precautions and adverse events. Rx only. (Rev. G) 046774 AI
Tachy Leads—RELIANCE 4-FRONT™

INDICATIONS AND USAGE
This Boston Scientific lead is indicated for use as follows:
- Indicated for pacing, rate-sensing, and delivery of cardioversion and defibrillation shocks when used with a compatible pulse generator.

CONTRAINDICATIONS
Use of this lead is contraindicated for the following patients:
- Patients who have a unipolar pacemaker
- Patients with a hypersensitivity to a maximum single dose of 1.1 mg demethylasone acetate
- Patients with mechanical tricuspid heart valves

WARNINGS
Tachy Leads—RELIANCE 4-FRONT™

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 equipment available during implant and electrophysiologic testing. Do not use any component of the lead system to assist in delivery of external-source rescue shocks or extensive tissue damage could occur. Ensure that an external defibrillator and medical personnel skilled in CPR are present during post-implant device testing. For DF4-LH1 or DF4-LH2 leads, only use the Connector Tool for electrical connections to pacing systems. Take care to obtain appropriate electrode position. When connecting the lead to the pulse generator, it is very important that proper connections are made.

POTENTIAL ADVERSE EVENTS
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, and follow up testing. This Boston Scientific lead is intended for pacing, rate-sensing and delivery of cardioversion and defibrillation shocks when used with a compatible pulse generator. Use of this Boston Scientific lead is intended for pacing, rate-sensing and delivery of cardioversion and defibrillation shocks when used with a compatible pulse generator.

CONTRAINDICATIONS
Use of this lead is contraindicated for the following patients: patients who have a unipolar pacemaker, patients with a hypersensitivity to a maximum single dose of 1.1 mg demethylasone 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 equipment available during implant and electrophysiologic testing. 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 as doing so could cause lead insulation abrasion damage or conductor damage. Use caution handling the lead terminal when the Connector Tool is not present on the lead. Do not contact any other portion of the lead terminal, other than the terminal pin, when the lead cap is in place. Implant of the system cannot be performed in an MRI site zone III (and higher). In order to deliver defibrillation therapy, the single-coil models must be implanted with an additional defibrillation electrode. For DF4-LH1 or DF4-LH2 leads, only use the Connector Tool for electrical connections to pacing systems. Take care to obtain appropriate electrode position. When connecting the lead to the pulse generator, it is very important that proper connections are made.

POTENTIAL ADVERSE EVENTS
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, and follow up testing. 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, and follow up testing.

POTENTIAL ADVERSE EVENTS
This Boston Scientific lead is intended for pacing, rate-sensing and delivery of cardioversion and defibrillation shocks when used with a compatible pulse generator. This Boston Scientific lead is intended for pacing, rate-sensing and delivery of cardioversion and defibrillation shocks when used with a compatible pulse generator.

CONTRAINDICATIONS
Use of this lead is contraindicated for the following patients: patients who have a unipolar pacemaker, patients with a hypersensitivity to a maximum single dose of 1.1 mg demethylasone 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 equipment available during implant and electrophysiologic testing. Do not use any component of the lead system to assist in delivery of external-source rescue shocks or extensive tissue damage could occur. 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 as doing so could cause lead insulation abrasion damage or conductor damage. Use caution handling the lead terminal when the Connector Tool is not present on the lead. Do not contact any other portion of the lead terminal, other than the terminal pin, when the lead cap is in place. Implant of the system cannot be performed in an MRI site zone III (and higher). In order to deliver defibrillation therapy, the single-coil models must be implanted with an additional defibrillation electrode. For DF4-LH1 or DF4-LH2 leads, only use the Connector Tool for electrical connections to pacing systems. Take care to obtain appropriate electrode position. When connecting the lead to the pulse generator, it is very important that proper connections are made.

POTENTIAL ADVERSE EVENTS
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, and follow up testing.
POTENTIAL ADVERSE EVENTS
Air embolism; Allergic reaction; Arterial damage with subsequent stenosis; Bleeding; Breakage/failure of the implant instruments; Cardiac perforation; Cardiac tamponade; Chronic nerve damage; Component failure; Conductor coil fracture; Death; Electrolyte imbalance/dehydration; Elevated thresholds; Erosion; Excessive fibrotic tissue growth; Extracardiac stimulation (muscle/nerve stimulation); Fluid accumulation; Foreign body rejection phenomena; Formation of hematomas or seromas; Heart block; Hemorrhage; Hemothorax; Inability to defibrillate or pace; Inappropriate therapy (e.g., shocks and anti-tachycardia pacing [ATP]) where applicable, pacing; Incisional pain; Incomplete lead connection with pulse generator; Infection including endocarditis; Lead dislodgment; Lead fracture; Lead insulation breakage or abrasion; Lead tip deformation and/or breakage; Local tissue reaction; Low amplitude VF signals; Malignancy or skin burn due to fluoroscopic radiation; Myocardial trauma (e.g., irritability, injury, tissue damage); Myopotential sensing; Oversensing/undersensing; Pericardial rub, effusion; Pneumothorax; Post-shock rhythm disturbances; Pulse generator and/or lead migration; Shunting current during defibrillation with internal or external paddles; Tachyarrhythmias, which include acceleration of arrhythmias and early, recurrent atrial fibrillation; Thrombosis/thromboemboli; Valve damage; Venous occlusion; Venous trauma (e.g., perforation, dissection, erosion)

Refer to the product labeling for specific indications, contraindications, warnings/precautions and adverse events. Rx only. (Rev. B) 046774 AI