SUMMARY
The magnet feature allows the use of a magnet to control certain device functions. This reference describes how to use a magnet to activate these functions and provides a summary of the expected behavior when a magnet is detected by a Boston Scientific cardiac implantable electronic device (pacemakers, cardiac resynchronization therapy devices, transvenous and subcutaneous implantable cardioverter defibrillators).

Products Referenced
All Boston Scientific products referenced in Table 1 of this article.

For comprehensive information on device operation, reference the full instructions for use or found at: www.bostonscientific-elabeling.com.

CAUTION: US Federal law restricts this device to sale by or on the order of a physician.

All graphics produced by Boston Scientific Corporation, unless otherwise noted.

A Closer Look
Magnet Response of Boston Scientific Cardiac Implantable Electronic Devices

The magnet feature allows certain device functions to be modified when a donut magnet is placed over the pulse generator. When using nominal programming, all products listed in Table 1 are designed to respond to magnet application and return to normal function once the magnet is removed.

Table 1. Boston Scientific Cardiac Implantable Electronic Devices

<table>
<thead>
<tr>
<th>Product Type</th>
<th>Product Family Names</th>
<th>Model Numbers Beginning with</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pacemakers</td>
<td>ACCOLADE™, ACCOLADE MRI, PROONENT™, PROONENT MRI, ESSENTIO™, ESSENTIO MRI, ALTRUA™ 2, FORMIO™, FORMIO MRI, VITALIO™, VITALIO MRI, INGENIO™, INGENIO MRI, ADVANTIO™, ADVANTIO MRI, EQUIO™, ALTRUA (20, 40, 50, 60)</td>
<td>J, K, L, S</td>
</tr>
<tr>
<td></td>
<td>INSIGNIA™/NEXUS™</td>
<td>11xx, 12xx, 13xx, 14xx</td>
</tr>
<tr>
<td>Cardiac Resynchronization Therapy Pacemakers (CRT-P)</td>
<td>VISIONIST™, VISIONIST X4, VALITUDE™, VALITUDE X4, INLIVEN™, INTUA™, INVIVE™, CONTAK RENEWAL TR/TR2</td>
<td>U, V, W, H</td>
</tr>
<tr>
<td>Implantable Cardioverter Defibrillators (ICD)</td>
<td>RESONATE™ HF, RESONATE EL, PERCIVA™ HF, PERCIVA, CHARISMA™ EL, VIGILANT™ EL, MOMENTUM™ EL, AUTOGEN™, DYNAGEN™, INOGEN™, ORIGEN™, INCEPTA™, ENERGEN™, PUNCTUA™, TELIGEN™</td>
<td>D, E, F</td>
</tr>
<tr>
<td>Cardiac Resynchronization Therapy Defibrillators (CRT-D)</td>
<td>RESONATE HF, RESONATE, RESONATE X4, CHARMA, CHARISMA X4, VIGILANT, VIGILANT X4, MOMENTUM, MOMENTUM X4, AUTOGEN, DYNAGEN, INOGEN, ORIGEN, INCEPTA, ENERGEN, PUNCTUA, COGNIS™</td>
<td>G, N, P</td>
</tr>
<tr>
<td>Subcutaneous Implantable Cardioverter Defibrillators (S-ICD)</td>
<td>EMBLEM™</td>
<td>A</td>
</tr>
<tr>
<td></td>
<td>SQ-RX™</td>
<td>1010</td>
</tr>
</tbody>
</table>

Note that magnet application will elicit a different response for each of the product types listed in Table 1 above. Table 2 provides a summary of the nominal magnet feature programming and associated device functions that will be modified when a donut magnet remains in place over the pulse generator. As noted above, all devices will return to normal function once the magnet is removed. Please refer to each product’s Physician Technical Manual and Reference Guide for additional magnet-related information, including other magnet feature programming options and complete magnet use instructions. If the expected magnet response is not observed upon magnet application, reposition the magnet as recommended in Table 3 below. If the expected magnet response is still not observed, contact a Boston Scientific representative or Boston Scientific’s Technical Services for assistance.
Table 2: Nominal Magnet Feature Programming and Expected Magnet Response

<table>
<thead>
<tr>
<th>Product Type</th>
<th>Nominal Programming</th>
<th>Expected Magnet Response</th>
</tr>
</thead>
</table>
| Pacemakers                                           | Pace Async         | • Asynchronous pacing at 100, 90, or 85 ppm (depending on current battery status) with an AV Delay of 100 ms.  
• 85 ppm indicates device has reached the replacement battery status. Consider contacting patient's device-following physician.  
• The third pulse during the Pace Async Magnet Response will be issued at 50% of the programmed Pulse Width. If loss of capture is observed at the third beat after magnet application, consider re-assessing the pacing energy safety margin. |
| Cardiac Resynchronization Therapy Pacemakers (CRT-P)  | Pace Async         | • Asynchronous pacing at 100, 90, or 85 ppm (depending on current battery status) with an AV Delay of 100 ms.  
• 85 ppm indicates device has reached the replacement battery status. Consider contacting patient's device-following physician.  
• The third pulse during the Pace Async Magnet Response will be issued at 50% of the programmed Pulse Width. If loss of capture is observed at the third beat after magnet application, consider re-assessing the pacing energy safety margin. |
| Implantable Cardioverter Defibrillators (ICD)         | Inhibit Therapy    | • Device is in a temporary Monitor Only mode. No shocks or anti-tachycardia pacing will be delivered as long as the magnet remains in place.  
• Beeping tones will be emitted once per second².  
• There is no change to pacing therapy. |
| Cardiac Resynchronization Therapy Defibrillators (CRT-D) | Inhibit Therapy    | • Device is in a temporary Monitor Only mode. No shocks or anti-tachycardia pacing will be delivered as long as the magnet remains in place.  
• Beeping tones will be emitted once per second².  
• There is no change to pacing therapy. |
| Subcutaneous Implantable Cardioverter Defibrillators (S-ICD) | Not programmable   | • Arrhythmia detection is suspended, and shock therapy is inhibited. No shocks will be delivered as long as the magnet remains in place.  
• R-wave synchronous tones will be emitted for each sensed event for up to 60 seconds². After 60 seconds, the beeping will stop, but therapy will continue to be inhibited as long as the magnet remains in place. |

¹CONTAK RENEWAL TR/TR2 CRT-P devices will deliver asynchronous pacing at 100 or 85 bpm only.
²Note that the beeper will no longer be usable following an MRI scan. Please refer to each product’s IMAGEREADY™ MR Conditional labeling for additional information regarding beeper function and associated patient management recommendations following an MRI scan.

To active the magnet feature in Boston Scientific devices, position the donut magnet as described in Table 3.

Table 3: Proper Magnet Position and Proximity to Activate the Magnet Feature

<table>
<thead>
<tr>
<th>Product Type</th>
<th>Proper Magnet Position to Activate the Magnet Feature</th>
<th>Recommended Proximity Between Magnet and Pulse Generator¹</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pacemaker, CRT-P, ICD, CRT-D</td>
<td>Proper Magnet Position to Activate the Magnet Feature</td>
<td>1.2 in (3.0 cm)</td>
</tr>
<tr>
<td>Product Type</td>
<td>Proper Magnet Position to Activate the Magnet Feature</td>
<td>Recommended Proximity Between Magnet and Pulse Generator</td>
</tr>
<tr>
<td>----------------------------------</td>
<td>------------------------------------------------------</td>
<td>--------------------------------------------------------</td>
</tr>
<tr>
<td>Subcutaneous Implantable Cardioverter Defibrillators (S-ICD)</td>
<td>Model Numbers Beginning with the Letter “A”:</td>
<td></td>
</tr>
<tr>
<td>Model Number 1010:</td>
<td></td>
<td>Magnet 1.5 in (3.8 cm)</td>
</tr>
</tbody>
</table>

*Boston Scientific’s donut magnet has a minimum field strength of 90 gauss when measured at 1.5 inches (3.8 cm) from the magnet surface.

*Advise patients that extended exposure to strong (greater than 10 gauss or 1 m Tesla) magnetic fields may trigger the magnet feature.*
Pacing Systems - ACCOLADE™, ACCOLADE™ MRI, PROPONENT™, PROPONENT™ MRI, ESSENTIO™, ESSENTIO™ MRI, ALTRUA™ 2, FORMIO™, FORMIO™ MRI, VITALIO™, VITALIO™ MRI, INGENIO™, INGENIO™ MRI, ADVANTIO™ Pacermaker

INDICATIONS AND USAGE

Boston Scientific pacemakers are indicated for treatment of the following conditions:

- Single-chamber or bi-chamber or permanent second- or third-degree AV block
- Symptomatic bilateral bundle branch block
- Symptomatic paroxysmal or transient sinus node dysfunction with or without associated AV conduction disorders (i.e., sinus bradycardia, sinus arrest, sinoatrial [SA] block)
- Ventricular fibrillation or tachycardia, to prevent symptomatic bradycardia or some form of symptomatic tachyarrhythmias
- Neurovascular (vaso-vagal) syndromes or hypersensitive carotid sinus syndromes

Adaptive-rate pacing is indicated for patients exhibiting chronotropic incompetence and who may benefit from increased pacing rates concurrent with increases in minute ventilation or level of physical activity.

Dual-chamber and atrial tracking modes are also indicated for patients who may benefit from maintenance of AV synchrony.

Dual chamber modes are specifically indicated for treatment of the following conditions:

- Conduction disorders that require restoration of AV synchrony, including varying degrees of AV block
- VVI intolerance (i.e., pacemaker syndrome) in the presence of persistent sinus rhythm
- Low cardiac output or congestive heart failure secondary to bradycardia

CONTRAINDICATIONS

These Boston Scientific pacemakers are contraindicated in patients who have a separate implanted cardioverter defibrillator (ICD) with transvenous leads.

Use of certain pacing modes and/or features in these Boston Scientific pacemakers is contraindicated for the following patients under the circumstances listed:

- Unipolar pacing or use of the MV Sensor with a Subcutaneous Implantable Cardioverter Defibrillator (S-ICD) because it may cause inappropriate therapy or inhibition of appropriate S-ICD therapy
- Minute Ventilation in patients with both unipolar atrial and ventricular leads
- Single-chamber atrial pacing in patients with impaired AV nodal conduction
- Adaptive-rate pacing in patients with chronic refractory atrial tachyarrhythmias (atrial fibrillation or flutter), which might trigger ventricular pacing
- Dual-chamber and single-chamber atrial pacing in patients with chronic refractory atrial tachyarrhythmias
- Asynchronous pacing in the presence (or likelihood) of competition between paced and intrinsic rhythms

WARNINGS

Read this manual thoroughly before implantation to avoid damage to the pulse generator and/or lead. Such damage can result in patient injury or death. For single patient use only. Do not reuse, reprocess, or resterilize. Always have external defibrillation equipment available during implant and electrophysiologic testing. Using multiple pulse generators could cause pulse generator interaction, resulting in patient injury or a lack of therapy delivery. In response to applicable nonrecoverable or repeat fault conditions, the pulse generator will switch irreversibly to Safety Core operation. Do not kink, twist, or bruise the leads. Do not use patients with chronic refractory atrial tachyarrhythmias. Lead Safety Switch should be programmed to Off during the implant procedure 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 implant 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, the pulse generator may sense medical guidance before electromagnetic interference. Advise patients to seek medical guidance before entering environments that could adversely affect the operation of the active implantable medical device. ACCOLADE MRI, PROPONENT MRI, ESSENTIO MRI, FORMIO MRI, VITALIO MRI and INGENIO MRI devices are considered MRI 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 implanted system. Significant reductions in the magnetic field or the signal to noise ratio may be noted in patients and/or the implanted system may result. For potential adverse events applicable when the Conditions of Use are met or not met, refer to the MRI Technical Guide. Do not subject a patient with an implanted pulse generator and/or lead to diathermy.

PRECAUTIONS

For specific information on precautions, refer to the following sections of the product labeling: clinical considerations; sterilization and storage; implantation; device programming; environmental and medical therapy hazards; hospital and medical environments; home and occupational environments; follow-up testing; explant and disposal; supplemental precautionary information. These pulse generators are contraindicated in patients who have a separate implanted cardioverter defibrillator (ICD) with transvenous leads.

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 embolism; Allergic reaction; Bleeding; Bradycardia; Cardiac tamponade; Chronic nerve damage; Component failure; Conductor coil fracture; Death; 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; Heart failure following chronic RV apical pacing; Heart failure following appropriate pacing; Housing generator; Infection including endocarditis; Lead dislodgement; Lead fracture; Lead insulation breakdown 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) (applies to dual-chamber devices only); Pericardial rub, effusion; Pneumothorax; Pulse generator interaction and resetting; Hunting 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; Venous 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 device malfunction. CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator’s Instructions. (2240625 Rev. A)

CRP Systems – VISIONIST™, VISIONIST™ X4, VALITUDE™, VALITUDE™ X4, INTUA™, INVIVE™ CRP-T

Indications and Usage

Boston Scientific cardiac resynchronization therapy pacemakers (CRT-Ps) are indicated for patients with moderate to severe heart failure (NYHA Class III/IV) including left ventricular dysfunction (EF <35%) and clinical symptoms and remains 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.

Adaptive-rate pacing is indicated for patients exhibiting chronotropic incompetence and who would benefit from increased pacing rates concurrent with increases in physical activity.

Contraindications

These Boston Scientific pulse generators have the following contraindications:

- All patients who have a separate implanted cardioverter defibrillator (ICD) with transvenous leads;
- Unipolar pacing or use of the MV/Respiratory Sensor with a Subcutaneous Implantable Cardioverter Defibrillator (S-ICD) is contraindicated because it may cause inappropriate therapy or inhibition of appropriate S-ICD therapy;
- Unipolar pacing is contraindicated in patients with both unipolar atrial and ventricular leads;
- Single-chamber atrial pacing is contraindicated in patients with impaired AV nodal conduction;
- Atrial tracking modes are contraindicated in 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 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. Reuse, 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, illness, or death. Always have external defibrillation equipment available during implant and electrophysiologic testing. Using multiple pulse generators could cause pulse generator interaction, resulting in patient injury or a lack of therapy delivery. In response to applicable nonrecoverable or repeat fault conditions, the pulse generator will switch irreversibly to Safety Core operation. Safety Core pacing may be unipolar, which may interact with an ICD. Safety Core behavior is affected by MRI Protection Mode. Do not kink, 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 Catheter Handling Kit or a Wire Guide how the lead may be handled to avoid lead injury. Do not use atrial tracking modes in patients with chronic refractory atrial tachyarrhythmias. Do not use atrial-only modes in patients with heart failure. 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 implant 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 sense medical guidance before electromagnetic interference. Advise patients to seek medical guidance before entering environments that could adversely affect the operation of the active implantable medical device. VISIONIST X4 and VALITUDE X4 devices are considered MRI 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 implanted system. Significant reductions in the magnetic field or the signal to noise ratio may be noted in patients and/or the implanted system may result. For potential adverse events applicable when the Conditions of Use are met or not met, refer to the MRI Technical Guide. Do not subject a patient with an implanted pulse generator and/or lead to diathermy.

Precautions

For specific information on precautions, refer to the following sections of the product labeling: clinical considerations; sterilization and storage; implantation; device programming; environmental and medical therapy hazards; hospital and medical environments; home and occupational environments; follow up testing; explant and disposal; supplemental precautionary information. These pulse generators are compatible for use with a Subcutaneous Implantable Cardioverter Defibrillator (S-ICD) when implanted with bipolar leads and programmed to a bipolar pacing configuration.

Potential Adverse Events

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 embolism; 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); Fluid accumulation; Foreign body rejection phenomena; Formation of hematomas or seromas; Heart block; Inability to...
pace; Inappropriate pacing; Incisional pain; Incomplete lead connection with pulse generator; Infection including endocarditis; Lead dislodgement; Lead fracture; Lead insulation breakage or abrasion; Lead perforation; Lead tip deformation and/or breaching; Local tissue reaction; Loss of capture; Myocardial infarction (MI); Myocardial necrosis; Myocardial trauma (e.g., tissue damage, valve damage); Myopotential sensing; Myopotential undersensing; Local tissue edema; Syncope; Tachyarrhythmias, which include acceleration of arrhythmias and early, recurrent atrial fibrillation; Thrombosis/thromboemboli; Valve damage; Vasovagal response; Venous occlusion; Venous 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.

**CAUTION:** Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator’s Instructions. (92436232 Rev. A)

**ICD Systems – AUTOGEN™ EL, DYNAGEN™ EL, DYNAHEN™ MINI, INOGEN™ EL, INOGEN™ MINI, ORIGEN™ EL, ORIGEN™ MINI, INCEPTA™, ENERGEN™, PUNCTA™, TELIGEN™100 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 re-use, reprocess, or resterilize. Always have external defibrillation equipment available during implant and electrophyslogic 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 pulse generator Tachy Mode(s) to OFF during implant, explant, or postmortem procedures to avoid inadvertent high voltage shocks. Do not kink, 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 D4-LLH or D4-LLO lead terminal, other than the terminal pin, even when the lead cap is in place. Do not use atraul tracking modes in patients with chronic refractory atrial tachyarrhythmias. Tracking of atrial arrhythmias could result in ventricular tachyarrhythmias. Advise patients to stop taking medications before entering fluoroscopy, medical devices, including areas protected by a warning notice that prevents entry by patients who have a pulse generator. AUTOGEN, DYNAHEN, INOGEN, and ORIGEN devices are considered MR Conditional. For these devices, unless all of the MRI Conditions of Use are met, do not perform MRI in patients who have an implantable cardioverter defibrillator system. 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 not met, refer to the MRI Technical Guide. All other devices covered by this statement are not MR Conditional. Do not expose a patient with non-MR-conditional devices 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 day Store EGM was enabled, the patient should not apply 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, follow-up testing, explant and disposal, supplemental precautionary information.

**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 embolism; Allergic reaction; Bleeding; Bradycardia; Cardiac tamponade; Chronic nerve damage; Component failure; Coagulation coil fracture; Death; Elevated thresholds; Erosion; Excessive fibrotic tissue growth; Extracardial stimulation (muscle/nerve stimulation); Failure to convert an induced arrhythmia; Fluid accumulation; Foreign body reaction phenomena; Formation of hematomas or seromas; Heart block; Heart failure; Hypoxia; Intracardiac thrombosis; Intraoperative injury (e.g., burns, shock and antitachycardia pacing (ATP) where applicable, pacing); Incisional pain; Incomplete lead connection with pulse generator; Infection including endocarditis; Lead dislodgement; Lead fracture; Lead insulation breakage or abrasion; Lead perforation; Lead tip deformation and/or breaching; Local tissue reaction; Loss of capture; Myocardial infarction (MI); Myocardial necrosis; Myocardial trauma (e.g., tissue damage, valve damage); Myopotential sensing; Myopotential undersensing; Pacemaker-mediated tachycardia (PMT); Pericardium; rhythm, effusion; Pneumothorax; Pulse generator migration; Shocking 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; Venous 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.

**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 re-use, reprocess, or resterilize. Always have external defibrillation equipment available during implant and electrophyslogic 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 pulse generator Tachy Mode(s) to OFF during implant, explant, or postmortem procedures to avoid inadvertent high voltage shocks. Do not kink, 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 D4-LLH or D4-LLO lead terminal, other than the terminal pin, even when the lead cap is in place. Do not use atraul tracking modes in patients with chronic refractory atrial tachyarrhythmias. Tracking of atrial arrhythmias could result in ventricular tachyarrhythmias. Advise patients to stop taking medications before entering fluoroscopy, medical devices, including areas protected by a warning notice that prevents entry by patients who have a pulse generator. AUTOGEN, DYNAHEN, INOGEN, and ORIGEN devices are considered MR Conditional. For these devices, unless all of the MRI Conditions of Use are met, do not perform MRI in patients who have an implantable cardioverter defibrillator system. 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 not met, refer to the MRI Technical Guide. All other devices covered by this statement are not MR Conditional. Do not expose a patient with non-MR-conditional devices 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 day Store EGM was enabled, the patient should not apply 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, follow-up testing, explant and disposal, supplemental precautionary information.

**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 embolism; Allergic reaction; Bleeding; Bradycardia; Cardiac tamponade; Chronic nerve damage; Component failure; Coagulation coil fracture; Death; Elevated thresholds; Erosion; Excessive fibrotic tissue growth; Extracardial stimulation (muscle/nerve stimulation); Failure to convert an induced arrhythmia; Fluid accumulation; Foreign body reaction phenomena; Formation of hematomas or seromas; Heart block; Heart failure; Hypoxia; Intracardiac thrombosis; Intraoperative injury (e.g., burns, shock and antitachycardia pacing (ATP) where applicable, pacing); Incisional pain; Incomplete lead connection with pulse generator; Infection including endocarditis; Lead dislodgement; Lead fracture; Lead insulation breakage or abrasion; Lead perforation; Lead tip deformation and/or breaching; Local tissue reaction; Loss of capture; Myocardial infarction (MI); Myocardial necrosis; Myocardial trauma (e.g., tissue damage, valve damage); Myopotential sensing; Myopotential undersensing; Pacemaker-mediated tachycardia (PMT); Pericardium; rhythm, effusion; Pneumothorax; Pulse generator migration; Shocking 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; Venous 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.
CONTRAINdicATIONS 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 II-IV) with EF ≤ 35% and QRS duration ≥ 130 ms; or ≤ 30% and QRS duration ≥ 130 ms; or ≤ 30% and mild and/or moderate (NYHA Class II) ischemic or nonischemic heart failure or asymptomatic (NYHA Class I) ischemic heart failure.

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 embolism; Allergic reaction; Cardiac tamponade; Chronic nerve damage; Compartment failure; Conducting coil fracture; Death; Electroeel imbalance/dehydration; Elevated thresholds; Erision; Extraocular tissue damage; Exposure to fluoroscopic radiation; Renal failure from contrast media used to visualize coronary veins. 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; Vasovagal response; Venous occlusion; Venous stasis (e.g., perforation, dissection, erosion); Worsening heart failure.

For a list of adverse events associated with MRI conditions, 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; Vasovagal response; Venous occlusion; Venous stasis (e.g., perforation, dissection, erosion); Worsening heart failure.

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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 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 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 coconcurrent system implants over 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 coimplanted device and/or compromise its functionality. Verify sensing configuration, operation modes, surgical considerations and existing 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 coimplanted 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 MR 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. Do not expose a patient with an implanted S-ICD System to diathermy. EMBLEM S-ICD devices are considered MR 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 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 hazards, hospital and medical environments, home and occupational environments, follow-up testing, explant and disposal and 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 induction testing, allergic/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, hematoma/seroma, hemothorax, 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, pneumothorax, post-shock/post-pace discomfort, 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.

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete “Directions for Use” for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions. (92436235 Rev. A)