SUMMARY

Boston Scientific pacemakers, defibrillators, and S-ICDs include an identifier in the header of the pulse generator that is visible via X-ray or fluoroscopy. The identifier is useful in determining the device manufacturer and model, allowing a clinician to determine the appropriate programmer to communicate with the device. This article includes a reference table of Boston Scientific device identifiers, and includes images of the X-ray identifier location.

Products Referenced

All referenced Boston Scientific pacemakers, ICDs, CRT-Ds, CRT-Ps, and S-ICDs

Products referenced are unregistered or registered trademarks of Boston Scientific Corporation or its affiliates. All other trademarks are the property of their respective owners.

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

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

Products referenced herein may not be approved in all geographies. Information is for the use in countries with applicable Health Authority product registrations.

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

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A Closer Look

X-ray Identification in Boston Scientific Pulse Generators

X-ray Identifier

Boston Scientific pulse generators, including pacemakers, defibrillators, and S-ICDs, have an identifier that is visible on X-ray film or under fluoroscopy. This identifier provides noninvasive confirmation of the manufacturer and consists of letters (manufacturer identification) and a number (cross-references to a programmer software application) that is required in order to communicate with the device.

The X-ray identifier is embedded in the header of the device. In general, the X-ray identifier will be visible by X-ray or fluorography at the approximate location identified in Figure 1. Note that the location may vary slightly based on the device family or the header design.

![X-Ray Identifier](image)

**Figure 1. X-ray identifier**

The tables below identify current generations of Boston Scientific pacemakers, defibrillators and S-ICDs, the programmer software application used by the device, the X-ray identifier (manufacturer letters + software identification number), and an actual X-ray image.

Identification via a Boston Scientific Programmer

The pulse generator can also be identified by interrogating it with a Boston Scientific Programmer. The model number is stored in device memory and is shown on the programmer upon interrogation. If the pulse generator is not manufactured by Boston Scientific or the model is not supported by the programmer being used, a message will be displayed when an attempt is made to interrogate the device. For example, the message displayed on the Model 3120 ZOOM™ LATITUDE™ Programmer is shown in Figure 2.

![Quick Start: PG Not Identified](image)

**Figure 2. PG Not Identified Message**
Table 1. X-ray identifier - Boston Scientific Pacemakers and CRT-Ps

Note that images below include a representative sample from each device family - the location of the X-ray identifier may vary slightly based on the device family or the design of the header.

<table>
<thead>
<tr>
<th>Device Family</th>
<th>MRI Models</th>
<th>X-ray Identifier</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACCOLADE™, PROPOSENT™, ESSENTIO™, ALTRUA™ 2 pacemakers</td>
<td>ACCOLADE MRI, PROPOSENT MRI, ESSENTIO MRI pacemakers</td>
<td>BSC012</td>
</tr>
<tr>
<td>VISIONIST™, VISIONIST™ X4, VALITUDE™, VALITUDE™ X4 CRT-Ps</td>
<td>Uses Programmer Software Application: Model 2869/3869</td>
<td>BSC012</td>
</tr>
<tr>
<td>VITALIO™, FORMIO™, INGENIO™, ADVANTIO™ pacemakers</td>
<td>VITALIO MRI, FORMIO MRI, INGENIO MRI, ADVANTIO MRI pacemakers</td>
<td>BSC011</td>
</tr>
<tr>
<td>INLIVEN™, INTUA™, INVIVE™ CRT-Ps</td>
<td>Uses Programmer Software Application: Model 2869/3869</td>
<td>BSC011</td>
</tr>
<tr>
<td>ALTRUA™ pacemakers</td>
<td>Uses Programmer Software Application: Model 2892</td>
<td>BOS003</td>
</tr>
</tbody>
</table>
Table 2. X-ray identifier - Boston Scientific ICDs and CRT-Ds
Note that images below include a representative sample from each device family - the location of the X-ray identifier may vary slightly based on the device family or the design of the header.

<table>
<thead>
<tr>
<th>ICD Family</th>
<th>X-ray Identifier</th>
</tr>
</thead>
<tbody>
<tr>
<td>RESONATE™, PERCIVA™, CHARISMA™, VIGILANT™, MOMENTUM™ ICDs</td>
<td>BSC140</td>
</tr>
<tr>
<td>RESONATE, CHARISMA, VIGILANT, MOMENTUM CRT-Ds</td>
<td></td>
</tr>
<tr>
<td>AUTOGEN™, DYNAGEN™, INOGEN™, ORIGEN™ ICDs</td>
<td></td>
</tr>
<tr>
<td>AUTOGEN, DYNAGEN, INOGEN, ORIGEN CRT-Ds</td>
<td></td>
</tr>
<tr>
<td>Uses Programmer Software Application: Model 2868/3868</td>
<td></td>
</tr>
<tr>
<td>X-ray identifier:</td>
<td>BSC140</td>
</tr>
<tr>
<td>TELIGEN™ ICD and COGNIS™ CRT-D</td>
<td></td>
</tr>
<tr>
<td>INCEPITA™, PUNCTUA™, ENERGEN™ ICDs</td>
<td></td>
</tr>
<tr>
<td>INCEPITA, PUNCTUA, ENERGEN CRT-Ds</td>
<td></td>
</tr>
<tr>
<td>Uses Programmer Software Application: Model 2868/3868</td>
<td></td>
</tr>
<tr>
<td>X-ray identifier:</td>
<td>BSC120</td>
</tr>
<tr>
<td>TELIGEN™ ICD and COGNIS™ CRT-D</td>
<td></td>
</tr>
<tr>
<td>INCEPITA™, PUNCTUA™, ENERGEN™ ICDs</td>
<td></td>
</tr>
<tr>
<td>INCEPITA, PUNCTUA, ENERGEN CRT-Ds</td>
<td></td>
</tr>
<tr>
<td>Uses Programmer Software Application: Model 2868/3868</td>
<td></td>
</tr>
<tr>
<td>X-ray identifier:</td>
<td>BSC120</td>
</tr>
</tbody>
</table>
Table 3. X-ray identifier - Boston Scientific S-ICDs

Note that images below include a representative sample from each device family - the location of the X-ray identifier may vary slightly based on the device family or the design of the header.

EMBLEM and EMBLEM MRI S-ICD
Uses Programmer Software Application: Model 2877
X-ray identifier: BSC507

SQ-RX S-ICD
Uses Programmer Software Application: Model 2877
X-ray identifier: CH1010
Contraindications

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

Pacing Systems - ACCOLADE™ MRI, ESSENTIO™ MRI, VITALIO™ MRI, INGENIO™ MRI, ADVANTIO™ MRI

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 are contraindicated for the following conditions:

- 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;
- 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 lack of therapy delivery. In response to applicable nonrecoverable or repeat fault conditions, the pulse generator will switch irreversibly to Safety Core operation. Do not kink, twist, or braid the lead with other leads. Do not use atrial tracking modes in patients with chronic refractory atrial tachyarrhythmias. Lead Safety Switch should be programmed Off for patients with an ICD. Unipolar pacing due to Lead Safety Switch is contraindicated for patients with an ICD. Unipolar pacing due to RATE is contraindicated and should be programmed off for patients with an ICD. If programmed to a fixed atrial Sensitivity value of 0.15 mV, or a fixed sensitivity value of 2.0 mV or less in a unipolar lead configuration in any chamber, the pulse generator may be more susceptible to electromagnetic interference. Advise patients to seek medical guidance before entering environments that could adversely affect the operation of the active implantable medical device. Unless all of the MRL Conditions of Use are met, MRI scanning of the patient does not meet MRL Contraindications for the implanted system, and significant harm to or death of the patient and/or damage to the implanted system may result. For potential adverse events applicable when the Conditions of Use are met or not met, refer to the MRI Technical Guide. Do not subject a patient with an implanted pulse generator and/or lead to diathermy.

Precautions

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

Adverse Effects

None known.

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

Indications and Usage

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

- Symptomatic paroxysmal or permanent second- or third-degree AV block
- Symptomatic paroxysmal or transient sinus node dysfunction with or without associated AV conduction disorders (i.e., sinus bradycardia, sinus arrest, sinoatrial [SA] block)
- Bradycardia-tachycardia syndrome, to prevent symptomatic bradycardia or some forms of symptomatic tachyarrhythmias
- Low cardiac output or congestive heart failure secondary to bradycardia

Adverse Effects

These Boston Scientific pacemakers are contraindicated for patients who have a separate implanted cardioverter defibrillator (ICD) with transvenous leads.
Refer to the product labeling for specific indications, contraindications, warnings/precautions and adverse events. Rx only. (Rev C)

**Potential Adverse Events**

Potential adverse events include, but are not limited to, the following:
- Allergic/physical/physiologic reaction, death, erosion/migration, fibillation or other arrhythmias, lead or accessory breakup (fracture/insulation/lead tip), hematoma/seroma, inappropriate or inability to provide therapy (pacing/sensing), infection, procedure related, and component failure. Patients may develop psychological intolerance to a pulse generator system and may experience fear of shocking, fear of device failure, or imagined shocking. In rare cases severe complications or device failures can occur.

**Warnings**

Read the product labeling thoroughly before implanting the pulse generator to avoid damage to the system. For single use only do not re-sterilize devices. Inappropriate sustained high-rate pacing occurred in the PULSAR™ MAX clinical study in 5 out of 130 patients with MV ON, 4 to 14 days after implant. If sustained high-rate pacing could be of concern, consider programming a reduced Max Sensor Rate or MV to Passive. These programming recommendations are intended to assure that MV calibration is evaluated and, if necessary, recalibrated 4–14 days after implantation when the pacing and sensing system have stabilized post implant. Continued monitoring of the MV sensor performance should be performed at all follow-up visits until implant stabilization has occurred.

**Precautions**

For specific information on precautions, refer to the following sections of the product labeling: MV sensor calibration at implant; clinical considerations; sterilization, storage and handling; lead evaluation and connection; implantation; programming and pacemaker operation; MV initialization; environmental and medical therapy hazards; elevated pressure; explanted pacemakers. Advise patients to avoid sources of electromagnetic interference (EMI). If the pacemaker is operating in an AC power environment, the patient may be programmed to a reduced max pacing rate or at the rate at which the EMI, moving away from the source or turning it off will usually allow the pulse generator to return to its normal mode of operation.

**Potential Adverse Events**

Potential adverse events include, but are not limited to, the following:
- Allergic/physical/physiologic reaction, death, erosion/migration, lead or accessory breakup (fracture/insulation/lead tip), hematoma/seroma, inappropriate or inability to provide therapy (pacing/sensing), infection, procedure related, and component failure. In rare cases severe complications or device failures can occur.

**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 antiarrhythmia 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 the 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 resuscitation. 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, 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 portion of the DF4-LLH4 or DF4-LLHO 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 tachyarrhythmias. Tracking of atrial arrhythmias could result in ventricular tachyarrhythmias. Advising patients to seek medical guidance before entering environments that could adversely affect the operation of the active implantable medical device, including areas protected by a warning notice that prevents entry by patients who have a pulse generator. RESONATE HF, RESONATE, PERCIVA HF, PERCIVA, and VIGILANT devices with a DF4 right ventricular lead connection are considered MR Conditional. If the patient is placed in an MR environment, the patient and/or device must be removed from the MR System. If the patient is unable to or refuses to be removed from the MR System, then, to avoid significant harm to or death of the patient and/or damage to the implanted system may result. For potential adverse events applicable when the Conditions of Use are met or not met, refer to the MRI Technical Guide. Do not subject a patient with an implanted pulse generator and/or lead to diathermy. 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 acquired, or after 60 days have elapsed from the day that 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**

Potential adverse events include, but are not limited to, the following:
- Allergic/physical/physiologic reaction, death, erosion/migration, fibillation or other arrhythmias, lead or accessory breakup (fracture/insulation/lead tip), hematoma/seroma, inappropriate or inability to provide therapy (pacing/sensing), infection, procedure related, and component failure. Patients may develop psychological intolerance to a pulse generator system and may experience fear of shocking, fear of device failure, or imagined shocking. In rare cases severe complications or device failures can occur.

**Indications and Usage**

These Boston Scientific Cardiac Resynchronization Therapy Defibrillators (CRT-Ds) are indicated for patients with heart failure who receive stable optimal pharmacologic therapy (OPT) for heart failure and who meet any one of the following classifications: Moderate to severe heart failure (NYHA Class III-IV) with EF ≤ 35% and QRS duration ≥ 120 ms or left bundle branch block (LBBB) with QRS duration ≥ 130 ms, EF ≤ 30%, and mild (NYHA Class II) ischemic or nonischemic heart failure or asymptomatic (NYHA Class I) ischemic heart failure.

ADDENDUM TO: 100000008718, Rev. B, US
Current Brief Summaries found @ www.http://www.bostonscientific.com/
April 20, 2018
Contraindications

There are no contraindications for this device.

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, resprocess, or resterilize. Always have external defibrillation equipment available during implant and electrophysiological 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 patch leads 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 IS4-LLL lead terminal, other than the terminal pin, even when the lead cap is in place. Do not contact any other portion of the IS4-LLL 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/HL or DF4-LLLH 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 refractory 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 the active implantable medical device, including areas protected by a warning notice that prevents entry by patients who have a pulse generator. RENATECH™ IV, RESONATE™, and VIGILANT devices for an IS-1/DF4 IS4 lead connection 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 implanted system, and significant harm to or death of the patient and/or damage to the implanted system may result. For potential adverse events applicable when the Conditions of Use are met or not met, refer to the MRI Technical Guide. Do not subject a patient with an implanted pulse generator and/or lead to die to therapy. If desired, enable Patient Triggered Monitor (PTM) is enabled 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, hospital and medical environments, home and occupational 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

Potential adverse events include, but are not limited to, the following: allergic/physical/physiologic reaction, death, erosion/migration, fibrillation or other arrhythmias, lead or accessory breakage (fracture/insulation/lead tip), hematoma/seroma, inappropriate or inability to provide therapy (shocks/pacing/sensing), infection, procedure related, and component failure. Patients may develop psychological intolerance to a pulse generator system and may experience fear of shocking, fear of device failure, or imagined shocking. In rare cases severe complications or device failures can occur. Refer to the product labeling for specific indications, contraindications, warnings/precautions and adverse events. Rx only (Rev B)

ICD Systems – AUTOGEN™ EL DYNAGEN™ EL, DYNAGEN™ MINI, INOGEN™ EL, INOGEN™ MINI, ORIGEN™ EL, ORIGEN™ MINI, INCEPTA™, ENERGEN™, PUNCTUA™, 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 reuse, reprocess, or resterilize. Always have external defibrillation equipment available during implant and electrophysiological 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 IS4-LLL lead terminal, other than the terminal pin, even when the lead cap is in place. Do not contact any other portion of the IS4-LLL lead terminal, other than the terminal pin, even when the lead cap is in place. When implanting a system that uses both a DF4-LLLH or DF4-LLLH 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 refractory 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 the active implantable medical device, including areas protected by a warning notice that prevents entry by patients who have a pulse generator.

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 include, but are not limited to, the following: allergic/physical/physiologic reaction, death, erosion/migration, fibrillation or other arrhythmias, lead or accessory breakage (fracture/insulation/lead tip), hematoma/seroma, inappropriate or inability to provide therapy (shocks/pacing/sensing), infection, procedure related, and component failure. Patients may develop psychological intolerance to a pulse generator system and may experience fear of shocking, fear of device failure, or imagined shocking. In rare cases severe complications or device failures can occur. Refer to the product labeling for specific indications, contraindications, warnings/precautions and adverse events. Rx only (Rev C)

CRT-D Systems – AUTOGEN™, AUTOGEN™X4, DYNAGEN™, DYNAGEN™X4, INOGEN™, INOGEN™ X4, ORIGEN™, ORIGEN™X4, INCEPTA™, ENERGEN™, PUNCTUA™, Cognis™ 100-D CRT-D

ICD Indications and Usage

These Boston Scientific Cardiac Resynchronization Therapy Defibrillators (CRT-Ds) are indicated for patients with heart failure who receive stable optimal pharmacological therapy (OPT) for heart failure and who meet any one of the following classifications: Moderate to severe heart failure (NYHA Class III–IV) with EF ≤ 35% and QRS duration ≥ 120 ms; or left bundle branch block (LBBB) with QRS duration ≥ 130 ms, EF ≥ 30%, and mild (NYHA Class II) ischemic or nonischemic heart failure or asymptomatic (NYHA Class I) ischemic heart failure.

Contraindications

There are no contraindications for this device.

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 electrophysiological 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 patch leads 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-LLLH or DF4-LLLH lead terminal, other than the terminal pin, even when the lead cap is in place. Do not contact any other portion of the IS4-LLL lead terminal, other than the terminal pin, even when the lead cap is in place. When implanting a system that uses both a DF4-LLLH or DF4-LLLH 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 refractory 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 the active implantable medical device, including areas protected by a warning notice that prevents entry by patients who have a pulse generator. RENATECH™ IV, RESONATE™, and VIGILANT devices for an IS-1/DF4-LLLt right ventricular lead connection 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 implanted 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 met or not met, refer to the MRI Technical Guide. Do not subject a patient with an implanted pulse generator and/or lead to die to therapy. If desired, enable Patient Triggered Monitor (PTM) is enabled 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, hospital and medical environments, home and occupational environments, follow-up testing, expant and disposal, supplemental precautionary information. Advise patients to avoid sources of EMI because EMI may cause the pulse generator to deliver inappropriate therapy or inhibi appropriate therapy.

Potential Adverse Events

Potential adverse events include, but are not limited to, the following: allergic/physical/physiologic reaction, death, erosion/migration, fibrillation or other arrhythmias, lead or accessory breakage (fracture/insulation/lead tip), hematoma/seroma, inappropriate or inability to provide therapy (shocks/pacing/sensing), infection, procedure related, and component failure. Patients may develop psychological intolerance to a pulse generator system and may experience fear of shocking, fear of device failure, or imagined shocking. In rare cases severe complications or device failures can occur.

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

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

Warnings and Cautions

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

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

Accelerator/induction of atrial or ventricular arrhythmia; Adverse reaction to induction testing; Allergic/adverse reaction to system or medication; Bleeding; Conductor fracture; 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; 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; Keloid formation; Migration or dislodgement; Muscle 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.

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

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

Warnings

Read the manual thoroughly before using the S-ICD System to avoid damage to the pulse generator and/or subcutaneous electrode. Such damage can result in patient injury or death. For single patient use only. Do not reuse, reprocess, or resterilize. All Boston Scientific S-ICD implantable components are designed for use with the Boston Scientific S-ICD System only. Connection of any S-ICD System components to a non-compatible component will result in failure to deliver life-saving defibrillation therapy. Always have external defibrillation equipment and medical personnel skilled in CPR available during implant and follow-up testing. Using multiple pulse generators could cause pulse generator interaction, resulting in patient injury or a lack of therapy delivery. Test each system individually and in combination to help prevent undesirable interactions. Concomitant use of the S-ICD System and implanted electromechanical devices (for example a ventricular assist device, VAD; or implantable insulin pump or drug pump) can result in interactions that could compromise the function of the S-ICD, the co-implanted device, or both. Electromagnetic (EMI) 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 compromise its functionality. 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. Handle the components of the S-ICD System with care at all times and maintain proper sterile technique. Do not modify, cut, kink, crush, stretch or otherwise damage any component of the S-ICD System. Use caution handling the subcutaneous electrode connector. Do not directly contact the connector with any surgical instruments such as forceps, hemostats, or clamps. Use appropriate anchoring techniques as described in the implant procedure to prevent S-ICD System dislodgement and/or migration. Do not implant in MRI site Zone III. Use caution when placing a magnet over the S-ICD pulse generator because it suspends arrhythmia detection and therapy response. In patients with a deep implant placement (greater distance between the magnet and the pulse generator) magnet application may fail to elicit the magnet response. Do not expose a patient with an implanted S-ICD System to diathermy. 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 MRI 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 batter depletion, a shortened device replacement window, or sudden loss of therapy. The Beeper may no longer be usable following an MRI scan. It is strongly recommended that patients are followed on LATITUDE NEXT after an MRI scan if they are not already. Advise patients to seek medical guidance before entering environments that could adversely affect the operation of the active implantable medical device, including areas protected by a warning notice that prevents entry by patients who have a pulse generator. The pulse generator may be more susceptible to low frequency electromagnetic interference at induced signals greater than 80 uV. The S-ICD System has not been evaluated for pediatric use.

Precautions

For specific information on precautions, refer to the following sections of the product labeling: clinical considerations, sterilization and storage, implantation, device programming, environmental and medical therapy hazards, hospital and medical environments, home and occupational environments, follow-up testing, expant and disposal, supplemental precautionary information. Advise patients to avoid sources of EMI because EMI may cause the pulse generator to deliver inappropriate therapy or inhibit appropriate therapy.

Potential Adverse Events

Potential adverse events related to implantation of the S-ICD System may include, but are not limited to, the following: Acceleration/induction of atrial or ventricular 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, 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.

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