

SUMMARY

The magnet feature allows use of a donut magnet to control certain device functions. This quick-reference provides a summary of device behavior expected upon magnet application.

Products Referenced

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

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-elabeling.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.

CRT-D: Cardiac Resynchronization Therapy Defibrillator
 CRT-P: Cardiac Resynchronization Therapy Pacemaker
 ICD: Implantable Cardioverter Defibrillator
 S-ICD: Subcutaneous Implantable Defibrillator

Contact Information

www.bostonscientific.com

Americas

Technical Services LATITUDE™ Customer Support

1.800.CARDIAC (227.3422)

+1.651.582.4000

Patient Services

1.866.484.3268

Europe, Middle East, Africa Technical Services

+32 2 416 7222

intltechservice@bsci.com

LATITUDE Customer Support

latitude.europe@bsci.com

Japan

Technical Services

japantechservice@bsci.com

LATITUDE Customer Support

japan.latitude@bsci.com

Asia Pacific

Technical Services

+61 2 8063 8299

aptechservice@bsci.com

LATITUDE Customer Support

latitude.asiapacific@bsci.com

© 2016 by Boston Scientific Corporation or its affiliates. All Rights Reserved.

Expected Magnet Response of Boston Scientific Pacemakers and Defibrillators

The magnet feature allows certain device functions to be triggered when a model 6860 or model 4730 donut magnet is placed over the pulse generator. Devices are designed to return to normal function once the magnet is removed. Please refer to device *Instructions for Use* for complete magnet use instructions.

Table 1 lists the expected magnet responses of Boston Scientific's implantable cardiac devices, assuming nominal programming (see black column header). If the described magnet response is not observed, please contact Technical Services.

IMPORTANT: A small subset of Boston Scientific devices, listed in this box, includes an additional magnet function which can be used to toggle Tachycardia Therapy between 'Off' and 'Monitor + Therapy'. Contact Technical Services for additional magnet use information prior to magnet application if the device model is:

- T135
- Unknown
- Not listed in Table 1

Table 1. Expected Magnet Response with Programming Noted.

Family	Model Number(s)	Expected Magnet Response
Implantable Cardioverter Defibrillators (ICDs)		
Magnet Response Programming - Inhibit Therapy: Device is in a temporary <i>Monitor Only</i> mode. No shocks or anti-tachycardia pacing will be delivered as long as magnet is in place. Device is designed to return to normal function once magnet is removed.		
AUTOGEN™	D044, D045, D046, D047, D174, D175, D176, D177	<ul style="list-style-type: none"> • Inhibit tachy therapy during magnet application • Beeping tones: once per second • No change to pacing therapy
DYNAGEN™	D020, D021, D022, D023, D150, D151, D152, D153	
INOGEN™	D010, D011, D012, D013, D140, D141, D142, D143	
ORIGEN™	D000, D001, D002, D003, D050, D051, D052, D053	
INCEPTA™	E160, E161, E162, E163, F160, F161, F162, F163	
ENERGEN™	E140, E141, E142, E143, F140, F141, F142, F143	
PUNCTUA™	E050, E051, E052, E053, F050, F051, F052, F053	
TELIGENT™	E102, E103, E110, E111, F102, F103, F110, F111	<ul style="list-style-type: none"> • Inhibit tachy therapy during magnet application • Beeping tones: R-wave synchronous • No change to pacing therapy
CONFIENT	E030, F010, F030	
VITALITY®	1870, 1871, 1872, T165, T167, T175, T177, T180 *(model T135, see box above)	
Subcutaneous Implantable Cardioverter Defibrillators (S-ICDs)		
Magnet Response is not programmable. When therapy is programmed On, device responds to magnet application by entering a temporary <i>Monitor Only</i> mode. No shocks will be delivered as long as magnet is in place. No ATP or pacing available. Device is designed to return to normal function once magnet is removed.		
EMBLEM™	A209	<ul style="list-style-type: none"> • Inhibit tachy therapy during magnet application • Beeping tones: one beep upon magnet detection, then R-wave synchronous per sensed event for up to 60 s at which point beeping stops.
SQ-RX™*	1010	

Cardiac Resynchronization Therapy - Defibrillators (CRT-Ds)

Magnet Response Programming - Inhibit Therapy: Device is in a temporary *Monitor Only* mode. No shocks or anti-tachycardia pacing will be delivered as long as magnet is in place. The device is designed to return to normal function once the magnet is removed.

Family	Model Number(s)	Expected Magnet Response
AUTOGEN™	G160, G161, G166, G168, G172, G173, G175, G177, G179	<ul style="list-style-type: none"> Inhibit tachy therapy during magnet application Beeping tones: once per second No change to pacing therapy
DYNAGEN™	G150, G151, G154, G156, G158	
INOGEN™	G140, G141, G146, G148	
ORIGEN™	G050, G051, G056, G058	
INCEPTA™	N160, N161, N162, N163, N164, N165, P162, P163, P165	
ENERGEN™	N140, N141, N142, N143, P142, P143	
PUNCTUA™	N050, N051, N052, N053, P052, P053	
COGNIS™	N106, N107, N108, N118, N119, P106, P107, P108	<ul style="list-style-type: none"> Inhibit tachy therapy during magnet application Beep on paced and/or sensed R-waves No change to pacing therapy
LIVIAN™	H220, H225, H227, H229, H240, H245, H247, H249	

Pacemakers

Magnet Response Programming - Pace Async: Device will pace at Magnet Rate when the magnet is applied. The device is designed to return to normal function once the magnet is removed.

Family	Model Number(s)	Expected Magnet Response
ESSENTIO™, PROponent™, ACCOLADE™, ALTRUA™ 2	L100, L101, L110, L111, L121, L131, L200, L201, L209, L210, L211, L221, L231, L300, L301, L310, L311, L321, L331, S701, S702, S722	<ul style="list-style-type: none"> Asynchronous pacing at 100, 90, or 85 ppm 85 ppm indicates device is nearing replacement. Consider contacting patient's device-following physician.
FORMIO™	J278, J279, K278, K288, K289	
VITALIO™	J272, J273, J274, J275, J276, J277, K272, K273, K274, K275, K277, K282, K283, K284, K285, K286, K287	
INGENIO™	J172, J173, J174, J175, J176, J177, J178, K172, K173, K174, K182, K183, K184, K185, K186, K187, K188	
ADVANTIO™	J062, J063, J064, J065, J066, J067, K062, K063, K064, K065, K066, K067, K082, K083, K084, K085, K086, K087	
ALTRUA™ (20, 40, 50, 60)	S201, S202, S203, S204, S205, S206, S207, S208, S209, S401, S402, S403, S404, S501, S502, S503, S504, S508, S601, S602, S603, S606	
INSIGNIA™	1190, 1290, 1291, 1195, 1198, 1294, 1295, 1296, 1194, 1297, 1298	

Cardiac Resynchronization Therapy - Pacemakers (CRT-Ps)

Magnet Response Programming - Pace Async: Device will pace at Magnet Rate when the magnet is applied. The device is designed to return to normal function once the magnet is removed.

Family	Model Number(s)	Expected Magnet Response
VISIONIST™, VALITUDE™	U225, U226, U228, U125, U128	<ul style="list-style-type: none"> Asynchronous pacing at 100, 90, or 85 ppm 85 ppm indicates device is nearing replacement. Consider contacting patient's device-following physician.
INLIVEN™	V284, V285, W274, W275	
INTUA™	V272, V273, W272, W273	
INVIVE™	V172, V173, V182, V183, W172, W173	
CONTAk™ RENEWAL™ TR 2	H140, H145	<ul style="list-style-type: none"> Asynchronous pacing at 100 or 85 ppm 85 ppm indicates device is nearing replacement. Consider contacting patient's device-following physician.
CONTAk™ RENEWAL™ TR	H120, H125	

More detailed information may be found in the product manual and in the following ACL articles:

- Magnet Use with Boston Scientific Pacemakers and CRT-Ps
- Using a Magnet to Inhibit Tachy Therapy in Boston Scientific ICDs and CRT-Ds
- Using a Magnet to Temporarily Inhibit S-ICD Therapy

INDICATIONS AND USAGE

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

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

Adaptive-rate pacing is indicated for patients exhibiting chronotropic incompetence and who may benefit from increased pacing rates concurrent with increases in minute ventilation and/or level of physical activity. Dual-chamber and atrial tracking modes are also indicated for patients who may benefit from maintenance of AV synchrony. Dual chamber modes are specifically indicated for treatment of the following:

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

CONTRAINDICATIONS

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

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

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

WARNINGS

General

Read this manual thoroughly before implantation to avoid damage to the pulse generator and/or lead. Such damage can result in patient injury or death. For single patient use only. Do not reuse, reprocess, or resterilize. Always have external defibrillation equipment available during implant and electrophysiologic testing. Using multiple pulse generators could cause pulse generator interaction, resulting in patient injury or a lack of therapy delivery. In response to applicable nonrecoverable or repeat fault conditions, the pulse generator will switch irreversibly to Safety Core operation. Do not kink, twist, or braid the lead with other leads. Do not use atrial tracking modes in patients with chronic refractory atrial tachyarrhythmias. Lead Safety Switch should be programmed Off for patients with an ICD. Unipolar pacing due to Lead Safety Switch is contraindicated for patients with an ICD. Unipolar pacing due to RAAT is contraindicated and should be programmed off for patients with an ICD. If programmed to a fixed atrial Sensitivity value of 0.15 mV, or a fixed sensitivity value of 2.0 mV or less in a unipolar lead configuration in any chamber, the pulse generator may be more susceptible to electromagnetic interference. Advise patients to seek medical guidance before entering environments that could adversely affect the operation of the active implantable medical device. Unless all of the MRI Conditions of Use are met, MRI scanning of the patient does not meet MR Conditional requirements for the implanted system, and significant harm to or death of the patient and/or damage to the implanted system may result. For potential adverse events applicable when the Conditions of Use are met or not met, refer to the MRI Technical Guide. Do not subject a patient with an implanted pulse generator and/or lead to diathermy.

PRECAUTIONS

For specific information on precautions, refer to the following sections of the product labeling: clinical considerations; sterilization and storage; implantation; device programming; environmental and medical therapy hazards; hospital and medical environments; home and occupational environments; follow-up testing; explant and disposal; supplemental precautionary information. Advise patients to avoid sources of EMI. The pulse generator may inhibit pacing due to oversensing, or may switch to asynchronous pacing at the programmed pacing rate or at the magnet rate in the presence of EMI. These pulse generators are compatible for use with a Subcutaneous Implantable Cardioverter Defibrillator (S-ICD) when implanted with bipolar leads and programmed to a bipolar pacing configuration.

POTENTIAL ADVERSE EVENTS

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

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

CRT-P Systems from Boston Scientific - VALITUDE™, VALITUDE X4™, INTUA™, INVIVE™

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 QRS duration >= 120 ms and remain symptomatic 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:

- In patients who have a separate implanted cardioverter defibrillator (ICD) with transvenous leads;
- Unipolar pacing or use of the 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;
- 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;
- And 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. Such damage 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. 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 contact any other portion of the IS4—LLLL 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. 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. Unipolar pacing due to RAAT is contraindicated and should be programmed off for patients with an ICD. Left ventricular lead dislodgement to a position near the atria can result in atrial oversensing and left ventricular pacing inhibition. 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. Do not expose a patient to MRI scanning. Do not subject a patient with an implanted pulse generator and/or lead to diathermy.

Precautions

For specific information on precautions, refer to the following sections of the product labeling: clinical considerations; sterilization and storage; implantation; device programming; environmental and medical therapy hazards; hospital and medical environments; 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

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

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

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 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 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 DF4–LLHH 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. Advise patients to seek medical guidance before entering environments that could adversely affect the operation of the active implantable medical device, including areas protected by a warning notice that prevents entry by patients who have a pulse generator. Do not expose a patient to MRI scanning. Do not subject a patient with an implanted pulse generator 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 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, 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 A)

CRT-D Systems from Boston Scientific – DYNAGEN™, DYNAGEN™X4, INOGEN™, INOGEN™X4, ORIGEN™, ORIGEN™X4, INCEPTA™, ENERGEN™, PUNCTUA™, COGNIS™100-D CRT-D

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 \leq 35% and QRS duration \geq 120 ms; or left bundle branch block (LBBB) with QRS duration \geq 130 ms, EF \leq 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 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 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–LLLL or DF4–LLHH or DF4–LLHO lead terminal, other than the terminal pin, even when the lead cap is in place. Do not contact any other portion of the IS4–LLLL lead terminal, other than the terminal pin, even when the lead cap is in place. When implant a system that uses both a DF4–LLHH or DF4–LLHO and IS4–LLLL 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. Do not expose a patient to MRI scanning. Do not subject a patient with an implanted pulse generator and/or lead to diathermy. If desired, ensure that Patient Triggered Monitor (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)

S-ICD™ System from Boston Scientific CRM

Indications for Use

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

Contraindications

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

Warnings and Cautions

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

General

- External defibrillation equipment should be available for immediate use during the implantation procedure and follow-up.
- Placing a magnet over the SQ-RX Pulse Generator suspends arrhythmia detection and therapy response. Removing the magnet resumes arrhythmia detection and therapy response.
- Battery depletion will eventually cause the SQ-RX Pulse Generator to stop functioning. Defibrillation and excessive numbers of charging cycles shorten the battery longevity.
- The S-ICD System has not been evaluated for pediatric use.
- The S-ICD System does not provide long-term bradycardia pacing, Cardiac Resynchronization Therapy (CRT) or Anti-Tachycardia Pacing (ATP).

Potential Adverse Events related to implantation of the S-ICD System may include, but are not limited to, the following:

Acceleration/induction of atrial or ventricular arrhythmia; Adverse reaction to induction testing; Allergic/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; 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 from Boston Scientific CRM

Indications for Use

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

Contraindications

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

Warnings

Read the manual thoroughly before using the S-ICD System to avoid damage to the pulse generator and/or subcutaneous electrode. Such damage can result in patient injury or death. For single patient use only. Do not reuse, reprocess, or resterilize. All Boston Scientific S-ICD implantable components are designed for use with the Boston Scientific S-ICD System only. Connection of any S-ICD System components to a non-compatible component will result in failure to deliver 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 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 reached 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. It is strongly recommended that patients are followed on LATITUDE NXT 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, explant and disposal and 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)
