Connecting Leads to Boston Scientific Pacemakers, Defibrillators, and S-ICDs

SUMMARY

This article summarizes steps for a successful lead connection to Boston Scientific Pacemakers, Defibrillators, and S-ICDs referenced herein, including those with connections systems that meet DF-4 and IS-4 International Standards*. For complete lead connection instructions, reference the applicable product's Physician's Technical Manual.

**International standard ISO 27186:2010.*

Products Referenced

All Boston Scientific Pacemakers, CRT-Ps, ICDs, CRT-Ds, S-ICDs, leads, and electrodes.

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

Boston Scientific lead/electrode terminals include an IS-1, IS-4, DF-4, or SQ-1 connector. During implant, follow instructions for use provided in the applicable manuals for devices and implant accessories. The steps summarized in this article may be helpful in achieving a successful connection with any of the connection types.

To connect the electrode or lead(s) to the implanted device, use only the tools provided in the sterile tray or accessory kit. Failure to use the supplied tools (connector tool and torque wrench) may result in damage to the setscrews, seal plugs, connector threads in the device header, or the terminal pin/electrode tip.

WARNING: For DF-4 and IS-4 leads, use caution handling the lead terminal when the EZ-4™ or ACUITY X4™ Connector Tool is not present on the lead. Do not directly contact the lead terminal rings with any surgical instruments or electrical connections such as PSA (alligator) clips, ECG connections, forceps, hemostats, and clamps. This could damage the lead terminal rings, possibly compromise the sealing integrity, and result in loss of therapy or inappropriate therapy.

Steps for Lead/Electrode Connection Success

STEP 1: Prior to insertion, look into lead ports to ensure that:

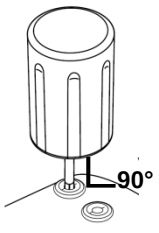
- the ports are clear
  Check for the presence of blood or body fluids on the lead terminal/electrode tip and in header ports. Clean as necessary with sterile water.
- the setscrews are retracted sufficiently for insertion
  Use the torque wrench to retract the setscrew if necessary. Verify that the stylet and any terminal pin accessories are removed prior to connecting the lead/electrode.

No setscrews or fluid visible in ports

STEP 2: Insert the torque wrench at a **90° angle** before inserting the lead/electrode.

- Gently insert the torque wrench at a 90° angle through the visible pre-slit center depression of the seal plug.
  This provides a pathway to release air or fluid trapped in the port as the lead/electrode is inserted, mitigating potential pressure build-up in the lead barrel.

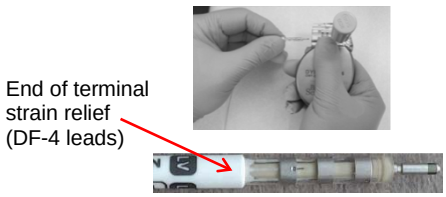
***NOTE:** Failure to properly insert the torque wrench in the pre-slit depression of the seal plug may result in damage to the plug and its sealing properties. Do not implant the device if any seal plugs appear to be damaged.*



STEP 3: Grip the lead/electrode near the proximal end of the terminal.

Once the torque wrench is in place, grip the terminal as close as possible to the proximal end of the terminal. DF-4 leads have a white terminal strain relief.

Gripping the terminal as proximally as possible will reduce lead bending and increase force during insertion.



STEP 4: Fully insert the lead or electrode. Ensure that the terminal pin/electrode is clearly visible beyond the connector block.

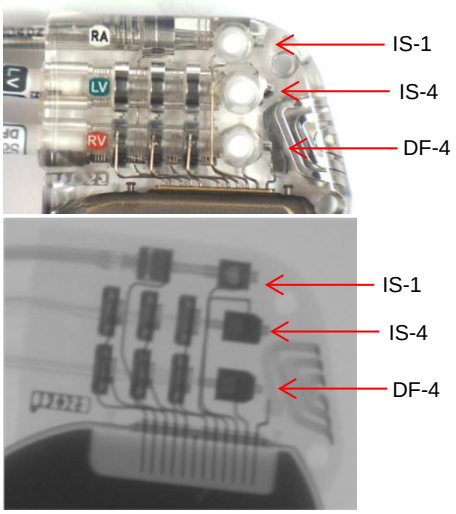
With the torque wrench in place, fully insert the terminal into the lead/electrode port. If necessary, and as directed in product-specific labeling, lubricate connectors sparingly with sterile water or sterile mineral oil to make insertion easier.

When fully inserted, the terminal pin will be clearly visible beyond the connector block when viewed through the header. If the inserted torque wrench prevents viewing of the terminal pin, flip the device to the opposite side to confirm the terminal pin extends beyond the setscrew block. It is not possible to over-insert a lead or electrode.

PRECAUTION: Insert the lead/electrode terminal straight into the port. Do not bend the lead near the lead-header interface; do not fold the lead and then press against the fold. Improper insertion can cause insulation or conductor damage.

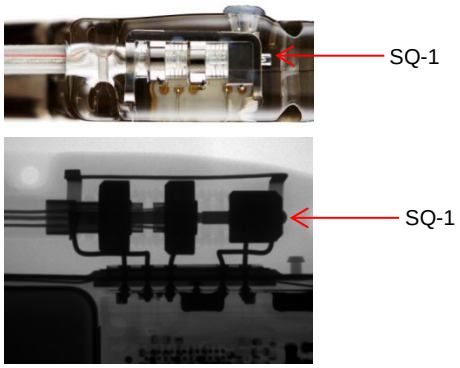
IS-1, IS-4, and DF-4

Leads are clearly visible beyond the connector block



SO-1

Electrode is clearly visible beyond the connector block

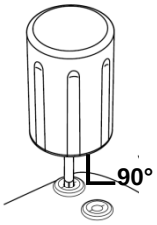


STEP 5: Tighten the setscrew(s).

Ensure that the torque wrench is seated perpendicular (90º) to the connector block throughout this step.

Apply gentle downward pressure on the torque wrench until the blade is fully engaged within the setscrew cavity.

While maintaining pressure on the lead to ensure that it remains fully inserted, tighten the setscrew by ***slowly*** rotating the torque wrench clockwise until it ratchets (clicks) once. The torque wrench is preset to apply the proper amount of force to the setscrew; additional downward force and rotation are unnecessary.



STEP 6: Remove the wrench by pulling it straight out of the connector block, maintaining a 90° angle
Remove the wrench **before** applying gentle traction to each lead terminal (Step 7). In the event that the setscrew is accidentally loosened during wrench removal, this will help ensure that it will be detected by the terminal pull test.
STEP 7: Verify that the lead is secure.
After removing the torque wrench, verify lead connection integrity by applying gentle traction to *each lead terminal separately*. Do not pull on the yoke or on more than one lead terminal at a time. If a lead terminal is not secure, reinsert the torque wrench, loosen the setscrew by rotating the wrench counterclockwise until the lead is loose, and then repeat the steps above.
STEP 8: Ensure that *all* impedances (pacing/shocking) are stable and within recommended ranges.
Evaluate the electrical performance of each lead after connecting to the pulse generator to confirm proper connection. Verify that the baseline atrial and RV/LV channels are free of artifacts. An improper connection could result in loss of therapy or unneeded therapy. **TIP:** Evaluate each electrode of a rate sensing lead by programming and testing suitable pace/sense vectors from the **Lead Settings Screen**. If a high lead impedance measurement is observed for ***any one electrode***, consider further investigation. If necessary, disconnect the lead and repeat the connection steps above. If reconnection does not eliminate the high impedance, contact Boston Scientific Technical Services for further assistance.

Pacing Systems from Boston Scientific – ACCOLADE™, ESSENTIO™, VITALIO™, INGENIO™, ADVANTIO™

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. Do not expose a patient to MRI scanning. Do not subject a patient with an implanted pulse generator and/or lead to diathermy.

Precautions

For specific information on precautions, refer to the following sections of the product labeling: clinical considerations; sterilization and storage; implantation; device programming; environmental and medical therapy hazards; hospital and medical environments; home and occupational environments; follow-up testing; explant and disposal; supplemental precautionary information. Advise patients to avoid sources of 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. A)

Pacing Systems from Boston Scientific – ALTRUA™ and INSIGNIA™

Indications

Pacemaker indications include: 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; 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 who may benefit from increased pacing rates concurrent with increases in minute ventilation and/or level of physical activity. Pacemakers' dual-chamber and atrial tracking modes are also indicated for patients who may benefit from maintenance of AV synchrony. Dual-chamber modes are specifically indicated for: conduction disorders that require restoration of AV synchrony, including varying degrees of AV block; VVI intolerance (eg, pacemaker syndrome) in the presence of persistent sinus rhythm.

Contraindications

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

Warnings

Read the product labeling thoroughly before implanting the pulse generator to avoid damage to the system. For single use only-do not resterilize 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 →ON) when the patient and pacing 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 electric or magnetic interference (EMI). If the pacemaker inhibits or reverts to asynchronous operation at the programmed pacing rate or at the magnet rate while in the presence of 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 breakage (fracture/insulation/lead tip), hematoma/seroma, inappropriate or inability to provide therapy (pacing/sensing), infection, procedure related, and component failure. In rare cases severe complications or device failures can occur.

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

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

Indications

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;
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- 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 limited to, the following: allergic/physical/physiologic reaction, death, erosion/migration, fibrillation or other arrhythmias, lead or accessory breakage (fracture/insulation/lead tip), hematoma/seroma, inappropriate or inability to provide therapy (pacing/sensing), infection, procedure related, and component failure. Patients may develop psychological intolerance to a pulse generator system and may experience fear of shocking, fear of device failure, or imagined shocking. In rare cases severe complications or device failures can occur.

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

CRT-P System from Boston Scientific - CONTAK RENEWAL™ TR

Indications
The CONTAK RENEWAL™ TR Pulse Generator is indicated for patients who have 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 heart failure drug therapy (as defined in the clinical trials section in the System Guide). These devices provide atrial-ventricular tracking modes to help preserve AV synchrony and adaptive-rate pacing for patients who would benefit from adjusted pacing rates concurrent with physical activity.

Contraindications
These devices are contraindicated in patients who have a separate implanted cardioverter-defibrillator (ICD). Single-chamber atrial pacing is contraindicated in patients with impaired AV nodal conduction. Atrial tracking modes are contraindicated for patients with chronic refractory atrial tachyarrhythmias (atrial fibrillation or flutter), which might trigger ventricular pacing. Asynchronous pacing is contraindicated in the presence (or likelihood) of competition between paced and intrinsic rhythms.

Warnings
Read the product labeling thoroughly before implanting the pulse generator to avoid damage to the system. For single patient use only. Do not reuse, reprocess, or resterilize. Such damage can result in patient injury or death. Do not expose a patient to MRI device scanning. Do not expose a patient with an activated implanted pulse generator to diathermy. Do not use atrial-only modes in patients with heart failure. The clinical outcomes for patients with chronic refractory atrial tachyarrhythmias are not fully known. Safety and effectiveness studies have not been conducted. If a chronic refractory atrial tachyarrhythmia develops in a patient with these devices, do not use dual-chamber or single-chamber atrial pacing. Left ventricular (LV) lead dislodgment to a position near the atria can result in atrial oversensing and LV pacing inhibition.

Precautions
For specific information on precautions, refer to the following sections of the product labeling: clinical considerations; sterilization, storage and handling; implantation and device programming; pulse generator explant and disposal; environmental and medical therapy hazards. Advise patients to avoid sources of electromagnetic interference (EMI) because EMI may cause the pulse generator to deliver inappropriate therapy or inhibit appropriate therapy.

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

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

ICD Systems from Boston Scientific – PUNCTUA™, ENERGEN™, and INCEPTA™

ICD Indications and Usage
PUNCTUA™, ENERGEN™, and INCEPTA™ ICDs are intended to provide ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias.

Contraindications
Use of these ICD systems are contraindicated in: Patients whose ventricular tachyarrhythmias may have reversible cause, such as 1) digitalis intoxication, 2) electrolyte imbalance, 3) hypoxia, or 4) sepsis, or whose ventricular tachyarrhythmias have a transient cause, such as 1) acute myocardial infarction, 2) electrocution, or 3) drowning. Patients who have a unipolar pacemaker.

Warnings
Read the product labeling thoroughly before implanting the pulse generator to avoid damage to the ICD system. For single patient use only. Do not reuse, reprocess, or resterilize. Program the pulse generator ventricular Tachy Mode to Off during implant, explant or post-mortem procedures. Always have external defibrillator protection available during implant and electrophysiologic testing. Ensure that an external defibrillator and medical personnel skilled in cardiopulmonary resuscitation (CPR) are present during post-implant device testing. Patients should seek medical guidance before entering environments that could adversely affect the operation of the active implantable medical device, including areas protected by a warning notice that prevents entry by patients who have a pulse generator. Do not expose a patient to MRI scanning. Do not subject a patient with an implanted pulse generator to diathermy. Do not use atrial tracking modes in patients with chronic refractory atrial tachyarrhythmias. Do not use this pulse generator with another pulse generator. Do not kink, twist or braid lead with other leads. For Patient Triggered Monitor (PTM) feature, make sure the feature is enabled prior to sending the patient home with a magnet. Once the PTM feature has been triggered and the magnet response programming is set to inhibit therapy, the patient should not reapply the magnet. For DF4-LLHH or DF4-LLHO leads, use caution handling the lead terminal when the Connector Tool is not present on the lead and do not directly contact the lead terminal with any surgical instruments or electrical connections such as PSA (alligator) clips, ECG connections, forceps, hemostats, and clamps. Do not contact any other portion of the DF4-LLHH or DF4-LLHO lead terminal, other than the terminal pin even when the lead cap is in place.

Precautions
For specific information on precautions, refer to the following sections of the product labeling: clinical considerations; sterilization and storage; implantation; device programming; environmental and medical therapy hazards; hospital and medical environments; home and occupational environments follow-up testing; explant and disposal; supplemental precautionary information. Advise patients to avoid sources of electromagnetic interference (EMI).

Potential Adverse Events
Potential adverse events from implantation of the ICD system include, but are not limited to, the following: allergic/physical/physiologic reaction, death, erosion/migration, fibrillation or other arrhythmias, lead or accessory breakage (fracture/insulation/lead tip), hematoma/seroma, inappropriate or inability to provide therapy (shocks/pacing/sensing), infection, procedure related, psychologic intolerance to an ICD system – patients susceptible to frequent shocks despite antiarrhythmic medical management/imagined shocking, and component failure. In rare cases severe complications or device failures can occur.

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

ICD Systems from Boston Scientific –TELIGEN™

ICD Indications and Usage
ICDs are intended to provide ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias. ICDs (i.e. Vitality AVT) with atrial therapies are also intended to provide atrial antitachycardia pacing and atrial defibrillation treatment in patients who have or are at risk of developing atrial tachyarrhythmias.

Contraindications
Use of ICD systems are contraindicated in: Patients whose ventricular tachyarrhythmias may have reversible cause, such as 1) digitalis intoxication, 2) electrolyte imbalance, 3) hypoxia, or 4) sepsis, or whose ventricular tachyarrhythmias have a transient cause, such as 1) acute myocardial infarction, 2) electrocution, or 3) drowning. Patients who have a unipolar pacemaker.

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

Precautions
For specific information on precautions, refer to the following sections of the product labeling: clinical considerations; sterilization and storage; implantation; device programming; environmental and medical therapy hazards; hospital and medical environments; home and occupational environments follow-up testing; explant and disposal; supplemental precautionary information. Advise patients to avoid sources of electromagnetic interference (EMI).

Potential Adverse Events
Potential adverse events from implantation of the ICD system include, but are not limited to, the following: allergic/physical/physiologic reaction, death, erosion/migration, fibrillation or other arrhythmias, lead or accessory breakage (fracture/insulation/lead tip), hematoma/seroma, inappropriate or inability to provide therapy (shocks/pacing/sensing), infection, procedure related, psychologic intolerance to an ICD system – patients susceptible to frequent shocks despite antiarrhythmic medical management/imagined shocking, and component failure. In rare cases severe complications or device failures can occur.

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

ICD Systems from Boston Scientific – DYNAGEN™ EL ICD, DYNAGEN™ MINI ICD, INOGEN™ EL ICD, INOGEN™ MINI ICD, ORIGEN™ EL ICD, ORIGEN™ MINI ICD

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

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

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

Precautions For specific information on precautions, refer to the following sections of the product labeling: clinical considerations, sterilization and storage, implantation, device programming, environmental and medical therapy hazards, hospital and medical environments, home and occupational environments, follow-up testing, explant and disposal, supplemental precautionary information

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/INOGEN/ORIGEN

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

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. 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. 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. Do not kink, twist, or braid the lead with other leads. Do not use defibrillation patch leads with the pulse generator system. Do not use this pulse generator with another pulse generator. 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.
For DF4–LLHH or DF4–LLHO leads, use caution handling the lead terminal when the Connector Tool is not present on the lead and do not directly contact the lead terminal with any surgical instruments or electrical connections such as PSA (alligator) clips, ECG connections, forceps, hemostats, and clamps. Do not contact any other portion of the DF4–LLHH or DF4–LLHO lead terminal, other than the terminal pin, 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.

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

Potential Adverse Events
Potential adverse events 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 – PUNCTUA™, ENERGEN™, and INCEPTA™

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

Contraindications
There are no contraindications for this device.

Warnings
Read the product labeling thoroughly before implanting the pulse generator to avoid damage to the system. For single patient use only. Do not reuse, reprocess, or resterilize. Program the pulse generator Tachy Mode to Off during implant, explant or postmortem procedures. Always have external defibrillator protection available during implant and electrophysiologic testing. Ensure that an external defibrillator and medical personnel skilled in CPR are present during post-implant device testing. Advise patients to seek medical guidance before entering environments that could adversely affect the operation of the active implantable medical device, including areas protected by a warning notice that prevents entry by patients who have a pulse generator. Do not expose a patient to MRI scanning. Do not subject a patient with an implanted pulse generator to diathermy, Do not use atrial-tracking modes in patients with chronic refractory atrial tachyarrhythmias. Do not use atrial-only modes in patients with heart failure. LV lead dislodgment to a position near the atria can result in atrial oversensing and LV pacing inhibition. Physicians should use medical discretion when implanting this device in patients who present with slow VT. Do not kink, twist or braid the lead with other leads. Do not use defibrillation patch leads with the CRT-D system. Do not use this pulse generator with another pulse generator. For Patient Triggered Monitor (PTM) feature, make sure the feature is enabled prior to sending the patient home with a magnet. Once the PTM feature has been triggered and the magnet response programming is set to inhibit therapy, the patient should not reapply the magnet. For DF4-LLHH or DF4-LLHO leads, use caution handling the lead terminal when the Connector Tool is not present on the lead and do not directly contact the lead terminal with any surgical instruments or electrical connections such as PSA (alligator) clips, ECG connections, forceps, hemostats, and clamps. Do not contact any other portion of the DF4-LLHH or DF4-LLHO lead terminal, other than the terminal pin even when the lead cap is in place.

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

Potential Adverse Events
Potential adverse events from implantation of the CRT-D system include, but are not limited to, the following: allergic/physical/physiologic reaction, death, erosion/migration, fibrillation or other arrhythmias, lead or accessory breakage (fracture/insulation/lead tip), hematoma/seroma, inappropriate or inability to provide therapy (shocks/pacing/sensing), infection, procedure related, and component failure. 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 System from Boston Scientific - COGNIS™
Indications and Usage
These Boston Scientific Cardiac Resynchronization Therapy Defibrillators (CRT-Ds) are indicated for patients with heart failure who receive stable optimal pharmacologic therapy (OPT) for heart failure and who meet any one of the following classifications:
• Moderate to severe heart failure (NYHA Class III-IV) with EF ≤ 35% and QRS duration ≥ 120 ms
• Left bundle branch block (LBBB) with QRS ≥ 130 ms, EF ≤ 30%, and mild (NYHA Class II) ischemic or nonischemic heart failure or asymptomatic (NYHA Class I) ischemic heart failure

Contraindications
There are no contraindications for this device.

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

Precautions
For specific information on precautions, refer to the following sections of the product labeling: clinical considerations; sterilization, storage and handling; implant and device programming; follow-up testing; explant and disposal; environmental and medical therapy hazards; hospital and medical environments; home and occupational environments. Advise patients to avoid sources of electromagnetic interference (EMI) because EMI may cause the pulse generator to deliver inappropriate therapy or inhibit appropriate therapy.

Potential Adverse Events
Potential adverse events from implantation of the CRT-D system include, but are not limited to, the following: allergic/physical/physiologic reaction, death, erosion/migration, fibrillation or other arrhythmias, lead or accessory breakage (fracture/insulation/lead tip), hematoma/seroma, inappropriate or inability to provide therapy (shocks/pacing/sensing), infection, procedure related, and component failure. 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. S)

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

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

Warnings and Cautions
The S-ICD System contains sterile products for single use only. Do not resterilize. Handle the components of the S-ICD System with care at all times and maintain proper sterile technique. All Cameron Health implantable components are designed for use with the Cameron Health 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. D)

S-ICD System from Boston Scientific - EMBLEM™
Indications and Usage
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 this 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 or Cameron Health 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 it's 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. 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. Do not expose a patient to MRI scanning. Advise patients to seek medical guidance before entering environments that could adversely affect the operation of the active implantable medical device, including areas protected by a warning notice that prevents entry by patients who have a pulse generator. The pulse generator may be more susceptible to low frequency electromagnetic interference at induced signals greater than 80 uV. The S-ICD System has not been evaluated for pediatric use.

Precautions
For specific information on precautions, refer to the following sections of the product labeling: clinical considerations; sterilization, storage and handling; implant and device programming; follow-up testing; explant and disposal; environmental and medical therapy hazards; hospital and medical environments; home and occupational environments. Advise patients to avoid sources of electromagnetic interference (EMI) because EMI may cause the pulse generator to deliver inappropriate therapy or inhibit appropriate therapy.

Potential Adverse Events
Potential adverse events 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. A)

LATITUDE™ NXT Patient Management System from Boston Scientific CRM
Intended Use
The LATITUDE™ NXT Patient Management System is intended for use to remotely communicate with a compatible pulse generator from Boston Scientific CRM and transfer data to a central database. The LATITUDE NXT System provides patient data that can be used as part of the clinical evaluation of the patient.

Contraindications
The LATITUDE NXT Patient Management System is contraindicated for use with any implanted device other than a compatible Boston Scientific implanted device. Not all Boston Scientific implanted devices are compatible with the LATITUDE NXT System. For contraindications for use related to the implanted device, refer to the System Guide for the Boston Scientific implanted device being interrogated.

Precautions
Alerts may appear on the LATITUDE NXT website on a daily basis. Primary notification of alert conditions is through the View Patient List page on the LATITUDE NXT website. The clinician needs to log onto the LATITUDE NXT website in order to receive alerts. Although secondary notification through email and SMS
text messages is available, these reminders are dependent on external systems and may be delayed or not occur. The secondary notification feature does not eliminate or reduce the need to check the website. Implanted device data and alerts are typically available for review on the LATITUDE NXT website within 15 minutes of a successful interrogation. However, data uploads may take significantly longer (up to 14 days). If the Communicator is unable to interrogate the implanted device or if the Communicator is unable to contact the LATITUDE NXT server to upload data, up to two weeks may elapse before the LATITUDE NXT server detects these conditions and informs the clinic user that monitoring is not occurring. If both of these conditions occur at the same time, this notification could take up to 28 days. Implanted device data and alert notification may be delayed or not occur at all under various conditions, which include but are not limited to the following: System limitations; the Communicator is unplugged; the Communicator is not able to connect to the LATITUDE NXT server through the configured phone system; the implanted device and the Communicator cannot establish and complete a telemetry session; the Communicator is damaged or malfunctions; the patient is not compliant with prescribed use or is not using the
LATITUDE NXT System as described in the patient manual; if subscribed to the LATITUDE Cellular Data Plan, missing two or more payments discontinues the subscription; the clinic user can identify any patients that are not being monitored as described above by using the Not Monitored filter on the View Patient List.

Adverse Effects: None known.

System Limitations:
The LATITUDE NXT System does not provide continuous real-time monitoring. As a remote monitoring system, the LATITUDE NXT System provides periodic patient monitoring based on clinician configured settings. There are many internal and external factors that can hinder, delay, or prevent acquisition and delivery of implanted device, sensor, and patient information as intended by the clinician. These factors include: implanted device clock; patient environment; cellular data service; telephone system; communicator memory capacity; clinic environment; schedule/configuration changes; or data processing.

Refer to the product labeling for specific instructions for use. Rx only. (Rev. C)

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

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

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

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

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

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

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

Extending/Retracting the Fixation Helix
In the event of previous handling or repositioning of the lead, more than the minimum number of rotations may be necessary to fully extend or retract the helix. Full helix extension should always be verified through fluoroscopy.

Chronic Repositioning
It is generally recommended that a chronically implanted endocardial lead not be explanted. Chronic repositioning or removal of active fixation leads may be difficult due to the presence of blood or fibrotic tissue in the helix. If it becomes necessary to remove the lead without successfully retracting the fixation helix, the lead should be rotated counter-clockwise during withdrawal in order to minimize the risk of endothelial laceration. If it becomes necessary to abandon a lead, the connector pin should be capped to prevent the transmission of electrical signals to the heart.

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

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

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

Left Ventricular Pacing Leads from Boston Scientific – ACUITY™ Spiral

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

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

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

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

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

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

Left Ventricular Pacing Leads from Boston Scientific – ACUITY™ Steerable and EASY TRAK™ 3

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

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

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

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

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

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

Left Ventricular Pacing Leads from Boston Scientific – EASYTRAK® 2+ IS-1 Lead

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

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

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

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

Potential Adverse Events
Potential adverse events include, but are not limited to the following: allergic/physical/physiologic reaction, death, erosion/migration, fibrillation or other arrhythmias, lead or accessory breakage (fracture/insulation /lead tip) hematoma/seroma, inappropriate or inability to provide therapy (pacing/sensing), infection, procedure-related, and component failure. In rare cases severe complications or device failures can occur. *Refer to the product labeling for specific indications, contraindications, warnings/precautions and adverse events. Rx only. (Rev. A)*

Pacing Leads from Boston Scientific – FINELINE™ II and FLEXTEND™

Indications
FINELINE™ II and FLEXTEND™ Leads are intended for chronic pacing and sensing of the atrium and/or ventricle when used with a compatible pulse generator.

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

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

Precautions
Refer to the implant product labeling for cautions specific to handling, implanting and testing the lead. Failure to observe these cautions could result in incorrect lead implantation, lead damage/dislodgment, or harm to the patient. Prior to implantation of this lead, confirm lead/pulse generator compatibility. Lead fracture, dislodgment, abrasion, or an incomplete connection can cause a periodic or continual loss of pacing or sensing or both. Defibrillation equipment should be kept nearby during the implant procedure. .

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

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

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

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

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

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

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

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

Potential Adverse Events
Potential adverse events from implantation of the ICD lead system include, but are not limited to, the following: allergic/physical/physiologic reaction, death, erosion/migration, fibrillation or other arrhythmias, lead or accessory breakage (fracture/insulation/lead tip), hematoma/seroma, inappropriate or inability to provide therapy (shocks/pacing/sensing), infection, procedure related, and component failure. In rare cases severe complications or device failures can occur.

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

ICD Leads from Boston Scientific

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

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

Warnings
Do not attempt to use the lead system with any device other than a commercially available ICD with which it has been tested and demonstrated safe and effective. Potential adverse consequences include, but are not limited to, undersensing of cardiac activity and failure to deliver necessary therapy. The safety and efficacy of the tip electrode placement above midseptum has not been clinically established (extendable retractable helix leads). Lead fracture, dislodgment, abrasion and/or incomplete connection can cause a periodic or continual loss of rate-sensing, possibly resulting in inappropriate delivery of a PG shock or inadequate delivery of conversion energy. The lead is not designed to tolerate excessive flexing, bending or tension. This could cause structural weakness, conductor discontinuity and/or lead dislodgment. Failure to obtain appropriate electrode position may result in higher defibrillation thresholds or may render lead unable to defibrillate a patient whose tachyarrhythmia(s) might otherwise be convertible by an ICD system. In order to deliver defibrillation therapy, the single-coil lead must be implanted with a separate defibrillation electrode. Boston Scientific CRM recommends using the single-coil lead with a pectorally implanted device that uses the metallic housing as a defibrillation electrode. When connecting the lead to ECD cables and/or the ICD PG it is very important that proper connections are made. Damage to the heart could result if a high-voltage defibrillating pulse were to be delivered through the pace/sense tip electrode. Use of any component of the lead system to assist in the delivery of external-source rescue shocks could cause extensive tissue damage. Do not kink, twist, or braid the lead terminals as doing so could cause lead insulation abrasion damage.

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

Potential Adverse Events
Potential adverse events from implantation of the ICD lead system include, but are not limited to, the following: allergic/physical/physiologic reaction, death, erosion/migration, fibrillation or other arrhythmias, lead or accessory breakage (fracture/insulation/lead tip), hematoma/seroma, inappropriate or inability to provide therapy (shocks/pacing/sensing), infection, procedure related, and component failure. In rare cases severe complications or device failures can occur.

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