

SUMMARY

Boston Scientific has introduced ICDs, CRT-Ds, and leads with connection systems that meet DF-4 and IS-4 International Standards*. Only one setscrew is required to secure an electrical connection for four conductors per lead. This article summarizes steps for a successful connection between Boston Scientific DF-4 and IS-4 leads and Boston Scientific ICDs and CRT-Ds. For complete lead connection instructions, reference the applicable Physician's Technical Manual. *International standard ISO 27186:2010.

Products Referenced

ENERGEN™, INCEPTA™, PUNCTUA™, DYNAGEN™, INOGEN™, and ORIGEN™ ICDs and CRT-Ds
 RELIANCE™ 4-FRONT Leads with DF44-LLHH and DF4-LLHO connectors
 ACUITY™ X4 Leads with IS4 four-pole connectors

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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

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Connecting DF-4 and IS-4 Leads to DF-4 and IS-4 Defibrillators

Lead Connection Tips

- Ensure the port is clear and setscrew is retracted prior to lead insertion.
- Insert the torque wrench **before** the lead.
- Grip the lead close to the proximal end of the white terminal strain relief.
- Ensure the terminal pin is clearly visible beyond the connector block.
- Ensure that **all** pacing/shock impedances are within the recommended range.

Steps for Lead Connection Success

Verify ports are clear. Check for the presence of any blood or other body fluids on the lead terminal and within pulse generator header ports. Clean as necessary with sterile water. Look down the lead ports to visually verify that the setscrew is sufficiently retracted to allow lead 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 to the pulse generator.

Verify that setscrews are not visible in lead ports.



To connect leads to the pulse generator, use only the tools provided in the pulse generator 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 lead terminal.

WARNING: For DF4 and IS4 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 compromising the sealing integrity and result in loss of therapy or inappropriate therapy, such as a high voltage short within the header.

Insert torque wrench. Gently insert the torque wrench blade into the setscrew by passing it through the pre-slit, center depression of the seal plug at a 90° angle. This will open up the seal plug, relieving any potential pressure build-up from the lead port by providing a pathway to release trapped fluid or air as the lead is inserted.

Inserting the torque wrench before the lead allows pressure to equalize



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 pulse generator if the seal plugs appear to be damaged.

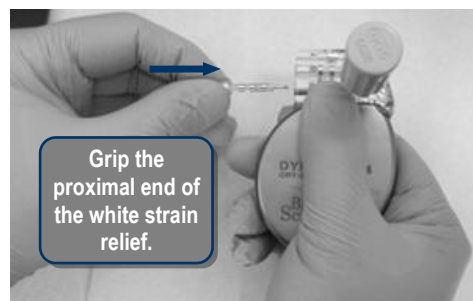
Fully insert the lead. With the torque wrench in place, fully insert the lead terminal into the lead port. To ease insertion, grip the terminal as close as possible to the proximal end of the white terminal strain relief. When fully inserted, the lead terminal pin will be clearly visible beyond the connector block when viewed through the pulse generator header, and for DF4/IS4 leads there will only be small gap between the proximal end of the white terminal strain relief and the colored header bore labels. It is not possible to over-insert a DF4 or IS4 lead. The lead is designed to hard stop in the header bore when fully inserted. 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.

TIP: Full lead insertion can be verified by observing the lead terminal pin as it passes beyond the connector block into the lead terminal pin cavity.

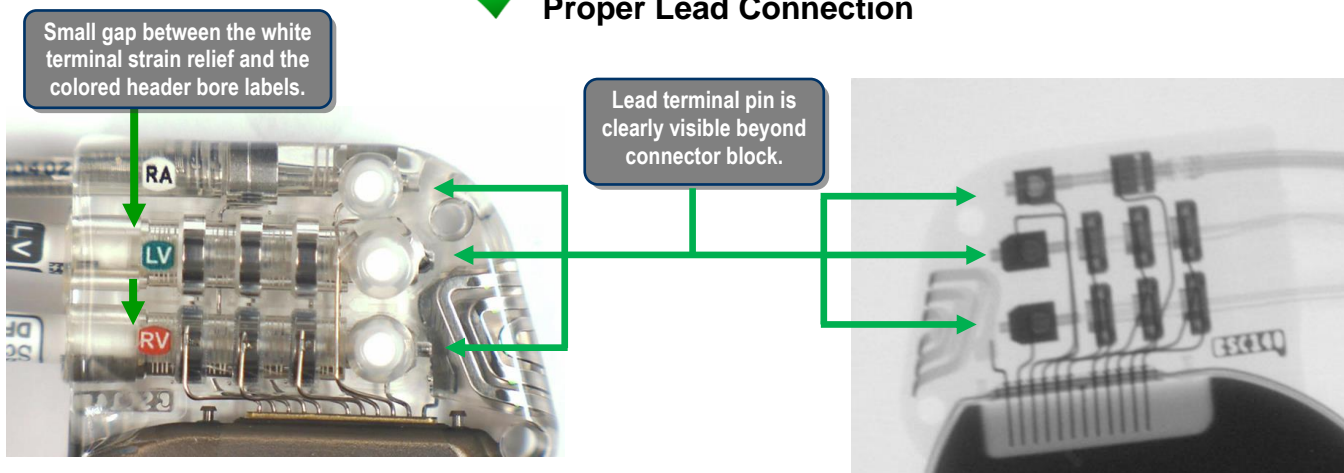
NOTE: If necessary, lubricate the lead connectors sparingly with sterile water to make lead insertion easier.

PRECAUTION: Insert the lead terminal straight into the lead port. Do not bend the lead near the lead-header interface. Improper insertion can cause insulation or connector damage.

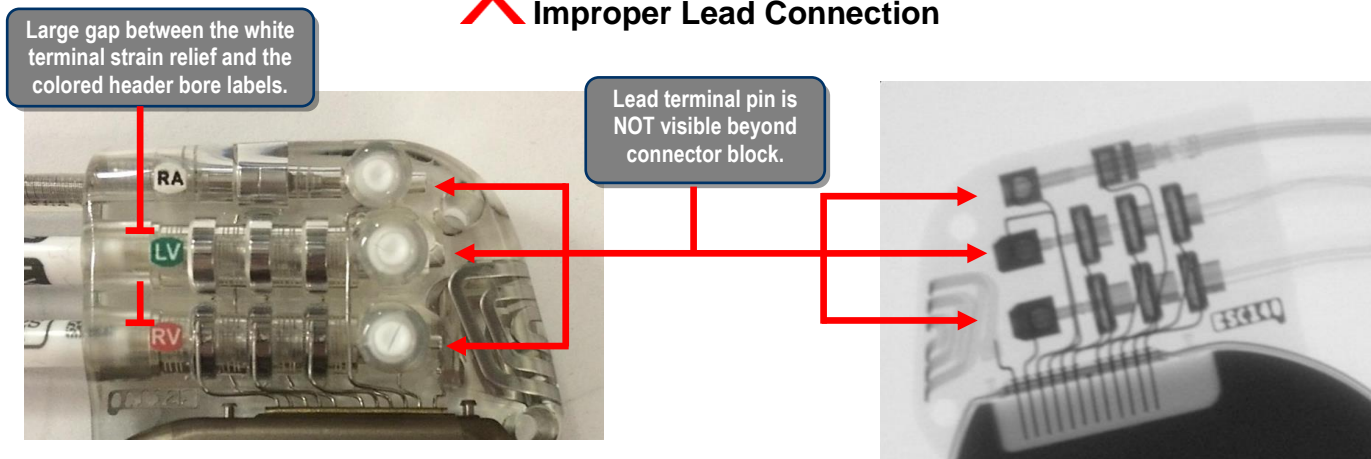
NOTE: Minor, inadvertent bending is acceptable during lead insertion, but do not fold lead and then press against the fold.



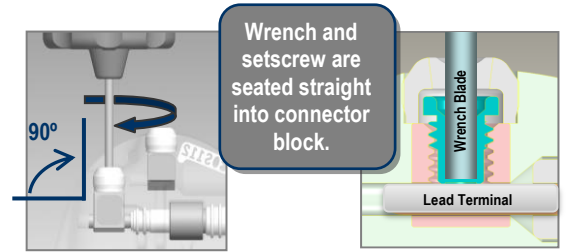
✓ Proper Lead Connection



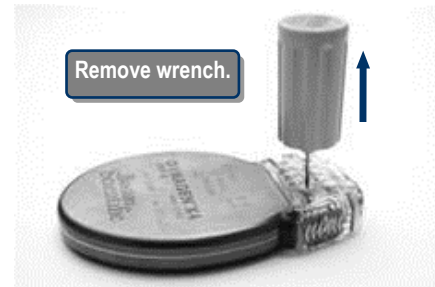
✗ Improper Lead Connection



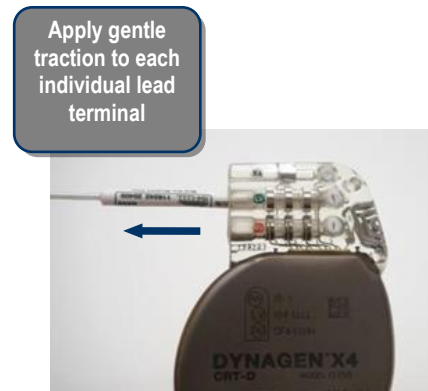
Tighten setscrew. Apply gentle downward pressure on the torque wrench until the blade is fully engaged within the setscrew cavity, taking care to avoid damage to the seal plug. Ensure the torque wrench is seated perpendicular (90°) to the connector block. While maintaining pressure on the lead to ensure that it remains fully inserted, tighten the setscrew by **slowly** rotating the torque wrench clockwise until it ratchets (clicks) once, keeping the torque wrench perpendicular to the connector block while tightening. The torque wrench is preset to apply the proper amount of force to the setscrew; additional rotation and downward force is unnecessary.



Remove wrench. Remove the torque wrench by pulling it straight out of the connector block.

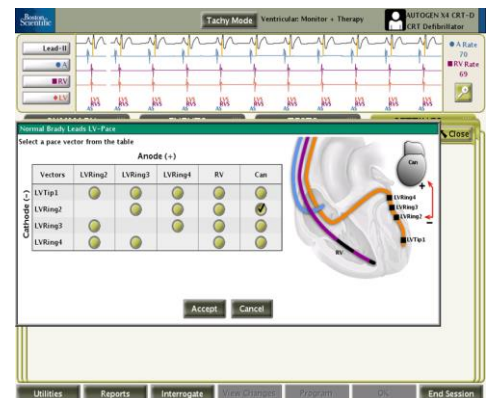


Verify lead is secure. Apply gentle traction to the lead to ensure a secure connection. If the lead terminal is not secure, reinsert the torque wrench as described above, and loosen the setscrew by slowly turning the wrench counterclockwise, until the lead is loose. Then repeat the steps above.



Evaluate Lead Signals. Evaluate the electrical performance of each lead after connecting to the pulse generator to provide final confirmation of a proper connection. Ensure the baseline atrial and RV/LV channels are free of artifacts. An improper connection could result in loss of therapy or inappropriate therapy.

TIP: Evaluate each electrode of the IS4 lead by programming and testing suitable pace/sense vectors from the **Lead Settings Screen**. If a high (>2000 ohms) 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.



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 \leq 35% and QRS duration \geq 120 ms
- Left bundle branch block (LBBB) with QRS \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 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)

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

ICD Indications and Usage

PUNCTUA™, ENERGEN™, and INCEPTA™ ICDs are intended to provide ventricular anti-tachycardia 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)

CRT-D Systems from Boston Scientific – DYNAGEN™, INOGEN™, and 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 \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. 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 dislodgment 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)

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

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)