The following accessories may be used as part of an MR-Conditional system:

- Suture Sleeves: 4603, 6220, 6221, 6402
- Port Plugs: 7145, 7148

* When conditions of use are met.

The table above contains all Boston Scientific CRM devices that are approved by the FDA as MR-Conditional as of July 2018. Visit http://www.bostonscientific.com/imageready for additional information including an MRI lookup tool, conditions of use, patient resources, and the MRI technical manual.
Pacing Systems – ACCOLADE™, ACCOLADE™ MRI, PROPONENT™, PROPONENT™ MRI, ESSENTIO™, ESSENTIO™ MRI, ALTRUA™ 2, FORMIO™, FORMIO™ MRI, VITALIO™, VITALIO™ MRI, INGENIO™, INGENIO™ MRI, 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, sinusal [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
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. Automatic Lead Recognition should be programmed to Off before implant for patients with an ICD. Unipolar pacing due to RAAT is contraindicated and should be programmed off for patients with an ICD. If programmed to a fixed atrial Sensitivity value of 0.15 mV, or a fixed sensitivity value of 2.0 mV or less in a unipolar lead configuration in any chamber, the pulse generator may 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. ACCOLADE MRI, PROPONENT MRI, ESSENTIO MRI, FORMIO MRI, VITALIO MRI and INGENIO MRI devices are considered MRI Conditional. For these devices, unless all of the MRI Conditions of Use are met, MRI scanning of the patient does not meet MR Conditional requirements for the implanted system. Significant harm to or death of the patient and/or damage to the implanted system may result. All other devices covered by this statement are not MR Conditional. For potential adverse events applicable when the Conditions of Use are met or not met, refer to the MRI Technical Guide. Do not subject a patient with an implanted pulse generator and/or lead to diathermy.

Precautions
For specific information on precautions, refer to the following sections of the product labeling: clinical considerations; sterilization and storage; implantation; device programming; environmental and medical therapy hazards; hospital and 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. Refer to the MRI Technical Guide at www.bostonscientific-elabeling.com for a comprehensive list of Warnings and Precautions, and Conditions of Use that are applicable to MRI scanning of patients implanted with an ImageReady MR Conditional Pacing System. These pulse generators are compatible for use with a Subcutaneous Implantable Cardioverter Defibrillator (S-ICD) when implanted with bipolar leads and programmed to a bipolar pacing configuration.

Potential Adverse Events
Based on the literature and on pulse generator and/or lead implant experience, the following alphabetical list includes the possible adverse events associated with implantation of the included devices: Air embolism; Allergic reaction; Bleeding; Bradycardia; Cardiac tamponade; Chronic nerve damage; Component failure; Conductode failure; Deafness; Elevated thresholds; Erosion; Excessive fibrotic tissue growth; Extracardiac stimulation (muscle/nerve stimulation); Fluid accumulation; Foreign body rejection phenomena; Formation of hematoma or seroma; Heart block; Heart failure following chronic RV apical pacing; Inability to pace; Inappropriate pacing; Incisural pain; Incomplete lead connection with pulse generator; Infection including endocarditis; Lead dislodgement; Lead fracture; Lead insulation breakage or abrasion; Lead perforation; Lead tip deformation and/or breakage; Local tissue reaction; Loss of capture; Myocardial infarction (MI); Myocardial necrosis; Myocardial trauma (e.g., tissue damage, valve damage); Myopotential sensing; Oversensing/Undersensing; Pacemaker-mediated tachycardia (PMI); Applies to dual-chamber devices only; Pericardial rub; Pneumothorax; Pulse generator migration; Shunting current during defibrillation with internal or external paddles; Syncope; Tachyarrhythmias, which include acceleration of arrhythmias and early, recurrent atrial fibrillation; Thrombosis/thromboemboli; Valve damage; Vasovagal response; Venous occlusion; Venous trauma (e.g., perforation; dissection; erosion); Worsening heart failure. For a list of potential adverse events associated with MRI scanning, refer to the MRI Technical Guide. Patients may develop psychological intolerance to a pulse generator system and may experience the following: Dependency; Depression; Fear of premature battery depletion; Fear of device malfunction. Refer to the product labeling for specific indications, contraindications, warnings/precautions and adverse events.

Rx only. (Rev. D) 046774 AF
Potential Adverse Events:

These pulse generators are compatible for use with a Subcutaneous Implantable Cardiac Defibrillator (S-ICD) when implanted with bipolar leads and programmed to a bipolar pacing configuration.

Contraindications:

For specific information on precautions, refer to the following sections of the product labeling: clinical considerations, sterilization and storage, implantation, device programming, environmental and material hazards, hospital and medical environments, home and occupational environments, follow-up testing, explant and disposal, supplemental precautionary information. Refer to the MRI Technical Guide at www.bostonscientific-mls.com for a comprehensive list of Warnings and Precautions, and Conditions of Use that are applicable to MRI scanning of patients implanted with an ImageReady MRI Conditional Pacing System.

For specific information on precautions, refer to the following sections of the product labeling: clinical considerations, sterilization and storage, implantation, device programming, environmental and material hazards, hospital and medical environments, home and occupational environments, follow-up testing, explant and disposal, supplemental precautionary information. Refer to the MRI Technical Guide at www.bostonscientific-mls.com for a comprehensive list of Warnings and Precautions, and Conditions of Use that are applicable to MRI scanning of patients implanted with an ImageReady MRI Conditional Pacing System.

For specific information on precautions, refer to the following sections of the product labeling: clinical considerations, sterilization and storage, implantation, device programming, environmental and material hazards, hospital and medical environments, home and occupational environments, follow-up testing, explant and disposal, supplemental precautionary information. Refer to the MRI Technical Guide at www.bostonscientific-mls.com for a comprehensive list of Warnings and Precautions, and Conditions of Use that are applicable to MRI scanning of patients implanted with an ImageReady MRI Conditional Pacing System.

For specific information on precautions, refer to the following sections of the product labeling: clinical considerations, sterilization and storage, implantation, device programming, environmental and material hazards, hospital and medical environments, home and occupational environments, follow-up testing, explant and disposal, supplemental precautionary information. Refer to the MRI Technical Guide at www.bostonscientific-mls.com for a comprehensive list of Warnings and Precautions, and Conditions of Use that are applicable to MRI scanning of patients implanted with an ImageReady MRI Conditional Pacing System.

For specific information on precautions, refer to the following sections of the product labeling: clinical considerations, sterilization and storage, implantation, device programming, environmental and material hazards, hospital and medical environments, home and occupational environments, follow-up testing, explant and disposal, supplemental precautionary information. Refer to the MRI Technical Guide at www.bostonscientific-mls.com for a comprehensive list of Warnings and Precautions, and Conditions of Use that are applicable to MRI scanning of patients implanted with an ImageReady MRI Conditional Pacing System.

For specific information on precautions, refer to the following sections of the product labeling: clinical considerations, sterilization and storage, implantation, device programming, environmental and material hazards, hospital and medical environments, home and occupational environments, follow-up testing, explant and disposal, supplemental precautionary information. Refer to the MRI Technical Guide at www.bostonscientific-mls.com for a comprehensive list of Warnings and Precautions, and Conditions of Use that are applicable to MRI scanning of patients implanted with an ImageReady MRI Conditional Pacing System.

For specific information on precautions, refer to the following sections of the product labeling: clinical considerations, sterilization and storage, implantation, device programming, environmental and material hazards, hospital and medical environments, home and occupational environments, follow-up testing, explant and disposal, supplemental precautionary information. Refer to the MRI Technical Guide at www.bostonscientific-mls.com for a comprehensive list of Warnings and Precautions, and Conditions of Use that are applicable to MRI scanning of patients implanted with an ImageReady MRI Conditional Pacing System.

For specific information on precautions, refer to the following sections of the product labeling: clinical considerations, sterilization and storage, implantation, device programming, environmental and material hazards, hospital and medical environments, home and occupational environments, follow-up testing, explant and disposal, supplemental precautionary information. Refer to the MRI Technical Guide at www.bostonscientific-mls.com for a comprehensive list of Warnings and Precautions, and Conditions of Use that are applicable to MRI scanning of patients implanted with an ImageReady MRI Conditional Pacing System.

For specific information on precautions, refer to the following sections of the product labeling: clinical considerations, sterilization and storage, implantation, device programming, environmental and material hazards, hospital and medical environments, home and occupational environments, follow-up testing, explant and disposal, supplemental precautionary information. Refer to the MRI Technical Guide at www.bostonscientific-mls.com for a comprehensive list of Warnings and Precautions, and Conditions of Use that are applicable to MRI scanning of patients implanted with an ImageReady MRI Conditional Pacing System.

For specific information on precautions, refer to the following sections of the product labeling: clinical considerations, sterilization and storage, implantation, device programming, environmental and material hazards, hospital and medical environments, home and occupational environments, follow-up testing, explant and disposal, supplemental precautionary information. Refer to the MRI Technical Guide at www.bostonscientific-mls.com for a comprehensive list of Warnings and Precautions, and Conditions of Use that are applicable to MRI scanning of patients implanted with an ImageReady MRI Conditional Pacing System.

For specific information on precautions, refer to the following sections of the product labeling: clinical considerations, sterilization and storage, implantation, device programming, environmental and material hazards, hospital and medical environments, home and occupational environments, follow-up testing, explant and disposal, supplemental precautionary information. Refer to the MRI Technical Guide at www.bostonscientific-mls.com for a comprehensive list of Warnings and Precautions, and Conditions of Use that are applicable to MRI scanning of patients implanted with an ImageReady MRI Conditional Pacing System.

For specific information on precautions, refer to the following sections of the product labeling: clinical considerations, sterilization and storage, implantation, device programming, environmental and material hazards, hospital and medical environments, home and occupational environments, follow-up testing, explant and disposal, supplemental precautionary information. Refer to the MRI Technical Guide at www.bostonscientific-mls.com for a comprehensive list of Warnings and Precautions, and Conditions of Use that are applicable to MRI scanning of patients implanted with an ImageReady MRI Conditional Pacing System.

For specific information on precautions, refer to the following sections of the product labeling: clinical considerations, sterilization and storage, implantation, device programming, environmental and material hazards, hospital and medical environments, home and occupational environments, follow-up testing, explant and disposal, supplemental precautionary information. Refer to the MRI Technical Guide at www.bostonscientific-mls.com for a comprehensive list of Warnings and Precautions, and Conditions of Use that are applicable to MRI scanning of patients implanted with an ImageReady MRI Conditional Pacing System.

For specific information on precautions, refer to the following sections of the product labeling: clinical considerations, sterilization and storage, implantation, device programming, environmental and material hazards, hospital and medical environments, home and occupational environments, follow-up testing, explant and disposal, supplemental precautionary information. Refer to the MRI Technical Guide at www.bostonscientific-mls.com for a comprehensive list of Warnings and Precautions, and Conditions of Use that are applicable to MRI scanning of patients implanted with an ImageReady MRI Conditional Pacing System.

For specific information on precautions, refer to the following sections of the product labeling: clinical considerations, sterilization and storage, implantation, device programming, environmental and material hazards, hospital and medical environments, home and occupational environments, follow-up testing, explant and disposal, supplemental precautionary information. Refer to the MRI Technical Guide at www.bostonscientific-mls.com for a comprehensive list of Warnings and Precautions, and Conditions of Use that are applicable to MRI scanning of patients implanted with an ImageReady MRI Conditional Pacing System.

For specific information on precautions, refer to the following sections of the product labeling: clinical considerations, sterilization and storage, implantation, device programming, environmental and material hazards, hospital and medical environments, home and occupational environments, follow-up testing, explant and disposal, supplemental precautionary information. Refer to the MRI Technical Guide at www.bostonscientific-mls.com for a comprehensive list of Warnings and Precautions, and Conditions of Use that are applicable to MRI scanning of patients implanted with an ImageReady MRI Conditional Pacing System.
ICD Systems – RESONATE™ HF, RESONATE™ EL, PERCIVA™, VIGILANT™ EL, MOMENTUM™ EL

Indications for Use: 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: digitals intoxication, electrolyte imbalance, hypoxia, sepsis, or patients whose ventricular tachyarrhythmias have a transient cause, such as: acute myocardial infarction (MI), electrolytically, drowning, or patients who have a unipolar pacemaker.

Warnings: It is strongly recommended that the patient does not undergo implantation before 30 days of …

Potential Adverse Events: May include, but are not limited to, the following: allergic/physical/physiologic reaction, death, erosion/migration, fibillation or other arrhythmias, lead or accessory brake (fracture/insulation/lead tip), hematoma/seoma, inappropriately or inability to provide therapy (shocks/pacing/sensing), infection, injection, procedure related, and component failure.

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

Revised (Rev B) 04/6774 AF

CRT-D Systems –RESONATE™ HF, RESONATE™ EL, PERCIVA™, VIGILANT™, VIGILANT™ X4, MOMENTUM™, MOMENTUM™ X4

Indications for Use: 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 II) ischemic heart failure.

Contraindications: There are no contraindications for this device.

Potentially Adverse Events: May include, but are not limited to, the following: allergic/physical/physiologic reaction, death, erosion/migration, fibillation or other arrhythmias, lead or accessory brake (fracture/insulation/lead tip), hematoma/seoma, inappropriately or inability to provide therapy (shocks/pacing/sensing), infection, injection, procedure related, and component failure.

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

Revised (Rev C) 04/6774 AF
CR-T Systems – AUTOGEN™, AUTOGEN™X4, DYNAGEN™, DYNAGEN™X4, INOGEN™, INOGEN™X4, ORIGEN™, ORIGEN™X4, INCEPTA™, ENERGEN™, PUNCUTA™, COGNIS™ 100-D CR-T

Indications for Use:
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 of the following classifications: Moderate to severe heart failure (NYHA Class III-IV) with EF ≤ 35% and ORS duration ≥ 130 ms, or left bundle branch block (LBBB) with ORS 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. Do not use defibrillation patch leads with the pulse generator system. Do not use the lead with another pulse generator, programmer, or pacing implant system. Do not kink, twist, or braid the lead with other leads. For leads that require the use of a Connector Tool, use caution handling the lead terminal when the Connector Tool is not present on the lead. Do not directly contact the lead terminal with any surgical instruments or electrical connections such as PSA (alligator) clips, ECG connections, forceps, hemostats, and clamps. Do not contact any other portion of the DF4–LLLH or DF4–LLHO lead terminal, other than the terminal pin, even when the lead cap is in place. Do not connect the terminal pin when the lead cap is in place. When implanting a system that uses both a DF4–LLLH or DF4–LLHO and DF4–LLO and IS4–LLL lead, ensure that the leads are inserted and secured in the appropriate ports. Do not use atrial tracking modes in patients with chronic refractory atrial tachyarrhythmias. Do not use atrial-only modes in patients with heart failure. Left ventricular lead dislodgement to a position near the atria can result in atrial oversensing and left ventricular pacing inhibition. Physicians should use medical discretion when implanting this device in patients who present with slow VT. Advise patients to seek medical advice if patients (or the active implantable medical device, including areas protected by a warning notice that prevents entry by patients who have a pulse generator. DYNAGEN, INOGEN, and ORIGEN devices with an IS-1/DF4/IS4 right ventricular lead connection are considered MR Conditional. For these devices, unless all of the MRI Conditions of Use are met, MRI scanning of the patient does not meet MR Conditional requirements for the implanted system. Significant harm to or death of the patient and/or damage to the implanted system may result. All other devices covered by this statement are not MR Conditional. Do not expose a patient with non-MR Conditional devices to MRI scanning. For potential adverse events applicable when the Conditions of Use are met or not met, refer to the ImageReady MR Conditional Defibrillation System MRI Technical Guide. Do not subject a patient with an implanted pulse generator and/or lead to diathermy. If desired, ensure that Patient Triggered Monitor (PTM) is enabled prior to sending the patient home by confirming the magnet response is programmed to Store EGM. Once the PTM feature has been triggered and the magnet response set to Inhibit therapy the patient should not reapply the magnet.

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

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

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

(Rev D) 04/07/74 AF

Pacing Leads – INGevity™MRI
Extendable/Retractable Fixation and Tined Fixation

Indications:
INGevity™ MRI Leads are intended for chronic pacing and sensing in the right atrium (only preformed atrial J with the Tined Fixation) and/or right ventricle (only straight with the tined fixation) when used with a compatible pulse generator.

Contraindications:
The use of these leads is contraindicated in patients with a hypersensitivity to a nominal single dose dexamethasone acetate: 0.61 mg for Tined Fixation, 0.91 mg for Extendable Retractable Fixation; and patients with mechanical tricuspid heart valves.

Warnings:
Always refer to the product labeling before implanting the lead 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. Lead fracture, dislodgement, abrasion, or an incomplete connection can cause a periodic or continual loss of pacing or sensing or both. Do not rotate the terminal pin clockwise or counterclockwise more than the recommended maximum number of turns indicated in the specifications. Continuing to rotate the terminal pin once the helix is fully extended or retracted (as indicated by fluoroscopy) can damage the lead, cause a conductor coil break mechanism during helix extension or retraction. Do not rotate the terminal pin clockwise or counterclockwise more than the recommended maximum number of turns indicated in the specifications. Continuing to rotate the terminal pin once the helix is fully extended or retracted (as indicated by fluoroscopy) can damage the lead, cause a conductor coil break mechanism during helix extension or retraction, cause lead dislodgment, tissue trauma, and/or cause acute pacing threshold to rise.

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) 04/07/74 AF

Pacing Leads – FINELINE™ II STEROX EZ™

Indications:
The lead is intended for chronic pacing and sensing of the atrium or ventricle when used with a compatible pulse generator.

Contraindications:
Do not use this lead in patients with: mechanical tricuspid heart valves; a hypersensitivity to a maximum single dose of approximately 0.94 mg of dexamethasone acetate; an allergy to mannitol.

Warnings:
Unless all of the MRI Conditions of Use are met, MRI scanning of the patient does not meet MR Conditional requirements for the implanted system, and significant harm to or death of the patient and/or damage to the implanted system may result. For potential adverse events applicable when the Conditions of Use are met or not met, refer to the MRI Technical Guide. Implant of the system cannot be performed in an MRI site Zone III (and higher). Take care to obtain appropriate electrode position. Failure to do so may result in suboptimal lead measurements. Unless all of the MRI Conditions of Use (as described in the MRI Technical Guide) are met, MRI scanning of the patient does not meet MR Conditional requirements of the implanted system. Refer to the MRI Technical Guide for potential adverse events applicable when Conditions of Use are met or not met, as well as a complete list of MRI-related Warnings and Precautions. Do not subject a patient with an implanted pulse generator and/or lead to diathermy. For Extendable/Retractable Fixation: The safety and efficacy of the tip electrode placement in the right ventricle above midseptum has not been clinically established.

Precautions:
Refer to the implant product labeling for cautions specific to clinical considerations, sterilization and storage, handling, implantation, hospital and medical environments, and follow up testing of 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, dislodgement, abrasion, or an incomplete connection can cause a periodic or continual loss of pacing or sensing or both. Do not rotate the terminal pin clockwise or counterclockwise more than the recommended maximum number of turns indicated in the specifications. Continuing to rotate the terminal pin once the helix is fully extended or retracted (as indicated by fluoroscopy) can damage the lead, cause a conductor coil break mechanism during helix extension, cause lead dislodgment, tissue trauma, and/or cause acute pacing threshold to rise.

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. In rare cases severe complications or device failures can occur.

For a list of potential adverse events associated with MRI scanning, refer to the MRI Technical Guide.

Refer to the physician’s manual(s) for specific indications, contraindications, warnings/precautions and adverse events. Rx only.

(Rev. A) 04/07/74 AF
Pacing Leads– FINELINE™ II STEROX

Indications: FINELINE™ II STEROX Leads are intended for chronic pacing and sensing of the ventricle (4456, 4457, 4458, 4459) or the atrium (4479, 4480) when used with a compatible pulse generator.

Contraindications: Do not use these leads in patients with: mechanical tricuspid heart valves; a hypersensitivity to a maximum single dose of approximately 0.94 mg of dexamethasone acetate.

Warnings: Unless all of the MRI Conditions of Use are met, MRI scanning of the patient does not meet MR Conditional requirements for the implanted system, and significant harm to or death of the patient and/or damage to the implanted system may result. For potential adverse events applicable when the Conditions of Use are met or not met, refer to the MRI Technical Guide. Implant of the system cannot be performed in an MRI site zone III (and higher). 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. Lead connector pins must be insulated from any leakage currents that may arise from line-powered equipment. Do not subject a patient with an implanted pulse generator and/or lead to diathermy since diathermy may cause fibrillation, burning of the myocardium, and irreversible damage to the pulse generator because of induced currents. For single patient use only. Do not reuse, reprocess, or resterilize.

Precautions: Use of Boston Scientific MR Conditional pulse generators and leads is required for an implanted system to be considered MR Conditional. Other implanted devices or patient conditions may cause a patient to be ineligible for an MRI scan, independent of the patient’s ImageReady MR Conditional Pacing System. Prior to implantation of this lead, confirm lead/pulse generator compatibility. Defibrillating equipment should be kept nearby during the implant procedure. It has not been determined whether the warnings, precautions, or complications usually associated with injectable dexamethasone acetate apply to the use of this lead. Refer to the PDR for potential adverse effects. Refer to the lead product labeling for cautions specific to handling and implanting the lead.

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 manuals for specific indications, contraindications, warning/precautions and adverse events. Rx only.

(Rev. E) 046774 AF

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

Indications: This Boston Scientific lead is intended for pacing, rate-sensing and delivery of cardioversion and defibrillation shocks when used with a compatible pulse generator.

Contraindications: Use of this lead is contraindicated for the following patients: patients who have a unipolar pacemaker, patients with a hypersensitivity to a maximum single dose of 1.1 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. Use caution handling the lead terminal when the Connector Tool is not present on the lead. Do not contact any other portion of the lead terminal, other than the terminal pin even when the lead cap is in place. Implant of the system cannot be performed in an MRI site zone III (and higher). 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. For DF4-LLHH or DF4-LLHO leads, only use the Connector Tool for electrical connections to pacing system analyzers or similar monitors. Take care to obtain appropriate electrode position. When connecting the lead to the pulse generator, it is very important that proper connections are made. Unless all of the MRI Conditions of Use are met, MRI scanning of the patient does not meet MR Conditional requirements for the implanted system, and significant harm to or death of the patient and/or damage to the implanted system may result. For potential adverse events applicable when the Conditions of Use are met or not met, refer to the MRI Technical Guide. Do not subject a patient with an implanted pulse generator and/or lead to diathermy.

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

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. D) 046774 AF

ICD Leads

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. Certain 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 pacing or 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 valvar valve disease may be exacerbated by the presence of a lead. Use medical judgment when deciding to place a lead in a patient with tricuspid valvar 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) 046774 AF
**Left Ventricular Pace/Sense Leads—ACUITY X4™**

**Indications:** This Boston Scientific lead is indicated for use as follows: Intended for chronic, left-ventricular pacing and sensing via the coronary venous system when used in conjunction with a compatible pulse generator. The Boston Scientific ACUITY X4™ is a steroid-eluting (dexamethasone acetate) IS4 quadrupolar lead.

**Contraindications:** Use of this Boston Scientific lead is contraindicated for the following patients: Patients with a hypersensitivity to a maximum single dose of 0.54 mg dexamethasone acetate. 

**Warnings:** Read the 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 additional defibrillation equipment available during implant and electrophysiologic testing. Do not use any component of the lead system to deliver defibrillation therapy. The single-coil models must be implanted with an additional defibrillation electrode. 

**Potential Adverse Events:**
- **Vasovagal response**
- **Venous occlusion**
- **Venous trauma (e.g., perforation, dissection, erosion)**
- **Breakage/failure of the implant instruments**
- **Cardiac perforation**
- **Cardiac tamponade**
- **Chronic nerve damage**
- **Component failure**
- **Conductor coil fracture**
- **Death** associated with implantation of products described in this literature
- **Air embolism**
- **Allergic reaction**
- **Arterial damage with subsequent stenosis**
- **Bleeding**
- **Bradycardia**

Potential Adverse Events in conjunction with this left coronary venous pace/sense 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. Although pliable, the lead is not designed to tolerate excessive flexing, bending, or tension. Do not kink, twist, or braid the lead with other leads as doing so could cause lead insulation abrasion damage or conductor damage. 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 lead terminal, other than the terminal pin, even when the lead cap is in place. When implanting a system which uses both a DF4-LLH/LLHO and IS4-LLLL lead, ensure that the leads are inserted and secured in the appropriate ports. Implant of the system cannot be performed in an MRI site zone III (and higher). Only use the Connector Tool for electrical connections to pacing system analyzers or similar monitors. Take care to obtain appropriate electrode position. When connecting the lead to the pulse generator, it is very important that proper connections are made. Unless all of the MRI Conditions of Use are met, MRI scanning of the patient does not meet MR Conditional requirements for the implanted system, and significant harm to or death of the patient and/or damage to the implanted system may result. For potential adverse events applicable when the Conditions of Use are met or not met, refer to the MRI Technical Guide. Do not subject a patient with an implanted pulse generator and/or lead to diathermy since diathermy may cause fibrillation, burning of the myocardium, and irreversible damage to the pulse generator because of induced currents.

**Precautions:** Refer to the lead product labeling for cautions specific to clinical considerations, sterilization and storage, handling, implantation, hospital and medical environments, and follow-up testing. 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/serosa, 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.  

**RELIANCE 4–FRONT™ Pace/Sense and Defibrillation Lead**

**Indications and Usage** This Boston Scientific lead is indicated for use as follows:
- Intended for pacing, rate-sensing, and delivery of cardioversion and defibrillation shocks when used with a compatible pulse generator.

**Contraindications:** Use of this Boston Scientific lead is contraindicated for the following patients:
- Patients who have a unipolar pacemaker
- Patients with a hypersensitivity to a maximum single dose of 1.1 mg dexamethasone acetate
- Patients with mechanical tricuspid valve 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 additional defibrillation equipment available during implant and electrophysiologic testing. Do not use any component of the lead system to deliver defibrillation therapy. The single-coil models must be implanted with an additional defibrillation electrode. 

**Potential Adverse Events:**
- **Breakage/failure of the implant instruments**
- **Cardiac perforation**
- **Cardiac tamponade**
- **Chronic nerve damage**
- **Component failure**
- **Conductor coil fracture**
- **Death**
- **Electrolyte imbalance/dehydration**
- **Elevated thresholds**
- **Erosion**
- **Excessive fibrotic tissue growth**
- **Extracardiac stimulation (muscle/nerve stimulation)**
- **Fluid accumulation**
- **Foreign body rejection phenomena**
- **Formation of hematoma or seromas**
- **Heart block**
- **Hemorrhage**
- **Hemothorax**
- **Inability to defibrillate or pace**
- **Inappropriate therapy** (e.g., shocks and antitachycardia pacing (ATP) where applicable, pacing, Incisional pain**
- **Incomplete lead connection with pulse generator**
- **Infection including endocarditis**
- **Lead dislodgment**
- **Lead fracture**
- **Lead insulation breakage or abrasion**
- **Lead tip deformation and/or breakage**
- **Local tissue reaction**
- **Low amplitude VF signals**
- **Malignancy or skin burn due to fluoroscopic radiation**
- **Myocardial trauma (e.g., irritability, injury, tissue damage)**
- **Myopotential sensing**
- **Oversensing/undersensing**
- **Pericardial rub, effusion**
- **Pneumothorax**
- **Post-shock rhythm disturbances**
- **Pulse generator and/or lead migration**
- **Shunting current during defibrillation with internal or external paddles**
- **Syncope**
- **Tachyarrhythmias**, which include acceleration of arrhythmias and early, recurrent atrial fibrillation
- **Thrombosis/thromboembolus**
- **Valve damage**
- **Vasovagal response**
- **Venous occlusion**
- **Venous trauma (e.g., perforation, dissection, erosion)**

For a list of potential adverse events associated with MRI scanning, refer to the ImageReady MR Conditional Defibrillation System MRI Technical Guide. 

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

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