SUMMARY

Hyperbaric Oxygen Therapy (HBOT) is the medical use of oxygen at a level higher than atmospheric pressure using a pressure chamber and an oxygen-delivery system.

SCUBA (Self Contained Underwater Breathing Apparatus) is equipment used to breathe underwater while swimming or diving at elevated pressures (SCUBA diving).

This article includes a summary of Boston Scientific's elevated pressure testing of our implantable medical devices. It is not an endorsement of HBOT or SCUBA diving for patients with these implantable devices.

Products Referenced

ICMs, ICDs, CRT-Ds, S-ICDs, Pacemakers, and CRT-Ps listed in Tables 2, 3 and 4.

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

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

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

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

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

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

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
RhythmCARE
+34 919 017 279
RhythmCARE_emea@bsci.com
LATITUDE Customer Support
latitude.international@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
latitudeasiapacific@bsci.com

Elevated Pressure (HBOT/SCUBA) and Implanted Medical Devices

The International Standards Organization (ISO) has not approved a standardized pressure test for implantable pulse generators that are exposed to hyperbaric oxygen therapy (HBOT) or SCUBA diving. However, Boston Scientific developed a test protocol to evaluate device performance upon exposure to elevated atmospheric pressures (Table 1).

During laboratory testing of products listed in Table 2, all devices in a statistically significant sample continued to function as designed when exposed to more than 1,000 test cycles at pressures up to 5.0 atmospheres (ATA). Devices of the model listed in Table 3 continued to function as designed when exposed to 300 test cycles at pressures up to 3.0 ATA. Devices of the model listed in Table 4 continued to function as designed when exposed to 200 test cycles at pressures up to 3.0 ATA. Each test cycle began at ambient/room pressure, increased to a high pressure level, and then returned to ambient pressure.
Although dwell time (the amount of time under elevated pressure) may have an impact on human physiology, testing indicated dwell time did not impact performance of the implanted device.

CAUTION: Excessive pressure due to HBOT or SCUBA diving may damage the pulse generator. Laboratory testing did not characterize the impact of elevated pressure on pulse generator performance or physiological response while implanted in a human body.

Prior to SCUBA diving or starting an HBOT program, the patient's attending cardiologist or electrophysiologist should be consulted to assess the potential consequences relative to the patient's specific health condition. A Dive Medicine Specialist may also be consulted prior to SCUBA diving. In addition, more frequent device follow-up may be warranted in conjunction with HBOT or SCUBA diving. Evaluate pulse generator operation following high pressure exposure. The extent, timing, and frequency of this evaluation relative to the high pressure exposure are dependent upon current patient health.

If you would like information on Boston Scientific product families not listed in Tables 2 and 3, or have additional questions regarding the test protocol or test results specific to HBOT or SCUBA diving, please contact Boston Scientific Technical Services.

Table 1. Pressure Value Equivalencies

ATA	Sea Water* Depth (feet)	Sea Water* Depth (meters)	Pounds per Square Inch Absolute (psia)	Pounds per Square Inch Gauge (psig)†	Bar	kPa Absolute
5.0	130	40	72.8	58.1	5.0	500
3.0	65	20	42.7	28	2.9	290

Table 2. Testing Applicable to Boston Scientific Product Families and Models Listed

Please note that not all models are approved in all geographies. All devices continued to function as designed when exposed to more than 1,000 test cycles at pressures up to 5.0 atmospheres. ‡

Product Type	Product Family	Model Numbers beginning with
Pacemakers	ACCOLADE™, ACCOLADE™ MRI, PROPONENT™, PROPONENT™ MRI, ESSENTIO™, ESSENTIO™ MRI, ALTRUA™ 2, FORMIO™, FORMIO™ MRI, VITALIO™, VITALIO™ MRI, INGENIO™, INGENIO™ MRI, ADVANTIO™, ADVANTIO™ MRI, EQUIO™, ALTRUA® ‡	J, K, L, S
CRT-Ps	VISIONIST™, VISIONIST™ X4, VALITUDE™, VALITUDE™ X4, INVIVE®, INTUA™, INLIVEN™	U, V, W
ICDs and CRT-Ds	RESONATE HF™, RESONATE™, PERCIVA™, VIGILANT™, MOMENTUM™, AUTOGEN™, DYNAGEN™, INOGEN™, ORIGEN™, INCEPTA®, PUNCTUA®, ENERGEN™, TELIGEN®, COGNIS®	D, E§, F§, G, N, P

* All pressures derived assuming sea water density of 1030 kg/m^3

† Pressure as read on a gauge or dial (psia = psig + 14.7 psi)

‡IALTRUA Instructions for Use have not yet been updated to reflect engineering pressure test results.

§Testing described herein is not applicable to CONFIENT® Models E030/F030.

Table 3. Testing Applicable to Boston Scientific Product Family and Models Listed

Please note that not all models are approved in all geographies. All devices continued to function as designed when exposed to up to 300 test cycles at pressures up to 3.0 atmospheres.

Product Type	Product Family	Model Numbers beginning with
S-ICD	EMBLEM™, EMBLEM™ MRI	A

* All pressures derived assuming sea water density of 1030 kg/m^3

† Pressure as read on a gauge or dial (psia = psig + 14.7 psi)

Table 4. Testing Applicable to Boston Scientific Product Family and Models Listed

Please note that not all models are approved in all geographies. All devices continued to function as designed when exposed to up to 200 test cycles at pressures up to 3.0 atmospheres.

Product Type	Product Family	Model Numbers beginning with
ICM	Lux-Dx™, Lux-Dx II™, Lux-Dx II+™	M

* All pressures derived assuming sea water density of 1030 kg/m^3

† Pressure as read on a gauge or dial (psia = psig + 14.7 psi)

ZOOM™ LATITUDE™ Programming System from Boston Scientific

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.

Intended Use
The Programmer/Recorder/Monitor (PRM) is intended to be used as part of the ZOOM™ LATITUDE™ Programming System to communicate with Boston Scientific implantable pulse generators. The software in use controls all communication functions for the pulse generator. For detailed software application instructions, refer to the associated product literature for the pulse generator being interrogated.

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

Warnings
The use of any cables or accessories with the PRM or Zoom Wireless Transmitter (ZWT) other than those specified by Boston Scientific in this manual may result in increased emissions or decreased immunity of the PRM or ZWT. Do not simultaneously touch the patient and any accessible connector contacts on the PRM (e.g., USB, parallel port, external VGA monitor, stimulation input, analog output, and expansion port). Other equipment may interfere with the PRM and ZWT, even if that equipment complies with the International Special Committee on Radio Interference (CISPR) emission requirements. To avoid the risk of electric shock, only connect the PRM to a grounded/earthed power source. Do not use the PRM or ZWT adjacent to or stacked with other equipment. **PRM and ZWT must remain outside sterile field.** Operation of the PRM with physiological signals that are lower than the minimum detectable amplitude may cause inaccurate results. Do not simultaneously touch the patient and the parts inside the printer door. The PRM and ZWT are MR Unsafe and must remain outside the MRI site Zone III (and higher) as defined by the American College of Radiology Guidance Document for Safe MR Practices1. No modification of this equipment is allowed unless approved by Boston Scientific.

Precautions
For specific information on precautions, read the following sections of the product labeling: General, Preparation for Use, Maintenance and Handling.

Adverse Effects
None known.

Refer to the product labeling for specific indications, contraindications, warnings/precautions and adverse effects. Rx only.(92436266 Rev A)

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

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Instructions for Use/MRI Technical Guide for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.

Indications and Usage
Boston Scientific cardiac resynchronization therapy pacemakers (CRT-Ps) are indicated for patients with moderate to severe heart failure (NYHA Class III/IV) including left ventricular dysfunction (EF <=35%) and QRS duration >= 120 ms and remain symptomatic despite stable optimal pharmacological therapy (OPT) for heart failure. Atrial tracking modes are also indicated for patients who may benefit from maintenance of AV synchrony. Adaptive-rate pacing is indicated for patients exhibiting chronotropic incompetence and who would benefit from increased pacing rates concurrent with increases in minute ventilation and/or 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;
- Minute ventilation is contraindicated in patients with both unipolar atrial and ventricular leads;
- Single-chamber atrial pacing is contraindicated in patients with impaired AV nodal conduction;
- Atrial tracking modes are contraindicated in patients with chronic refractory atrial tachyarrhythmias (atrial fibrillation or flutter), which might trigger ventricular pacing;
- And asynchronous pacing is contraindicated in the presence (or likelihood) of competition between paced and intrinsic rhythms.

Warnings
• 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. Safety Core pacing may be unipolar, which may interact with an ICD. Safety Core behavior is affected by MRI Protection Mode.
• Do not kink, twist, or braid the lead with other leads as doing so could cause lead insulation abrasion damage or conductor damage.
•For leads that require the use of a Connector Tool, use caution handling the lead terminal when the Connector Tool is not present on the lead. Do not contact the lead terminal with any surgical instruments or electrical connections such as PSA (alligator) clips, ECG connections, forceps, hemostats, and clamps. This could damage the lead terminal, possibly compromising the sealing integrity and result in loss of therapy or inappropriate therapy, such as a short within the header.
• 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.
• Automatic Lead Recognition should be programmed to Off before implant with 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.
• VISIONIST X4 and VALITUDE X4 devices 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 patients with non-MR Conditional devices to MRI scanning. For potential adverse events when 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
The CRT-Ps have not been evaluated for pediatric use. 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. 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 products described in this literature:
• Air embolism
• Allergic reaction
• Bleeding
• Bradycardia
• 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 hematomas or seromas
• Heart block
• Inability to pace
• Inappropriate pacing
• Incisional pain
• Incomplete lead connection with pulse generator
• Infection including endocarditis
• Lead dislodgment
• 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 (PMT)
• Pericardial rub, effusion
• 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

Additionally, potential adverse events associated with the implantation of a coronary venous lead system include:
• Allergic reaction to contrast media
• Breakage/failure of implant instruments
• Prolonged exposure to fluoroscopic radiation
• Renal failure from contrast media used to visualize coronary veins

Refer to the product labeling for specific indications, contraindications, warnings/precautions and adverse events. Rx only. (92436229 Rev B)

Pacing Systems from Boston Scientific – ACCOLADE™, ACCOLADE™MRI, PROPONENT™, PROPONENT™ MRI, ESSENTIO™, ESSENTIO™MRI, ALTRUA™ 2, FORMIO™, FORMIO™ MRI, VITALIO™, VITALIO™MRI, INGENIO™, INGENIO™MRI, ADVANTIO™ PACEMAKER

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete “Directions for Use” for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator’s Instructions.

Intended Use
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
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 medical environments, home and occupational environments, follow up testing, explant and disposal, supplemental precautionary information,

Potential Adverse Effects
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; Conductor coil fracture; Death; Elevated thresholds; Erosion; Excessive fibrotic tissue growth; Extracardiac stimulation (muscle/nerve stimulation); Fluid accumulation; Foreign body rejection phenomena; Formation of hematomas or seromas; Heart block; Heart failure following chronic RV apical pacing; Inability to pace; Inappropriate pacing; Incisional 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 (PMT) (applies to dual-chamber devices only); Pericardial rub, effusion; 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 effects. Rx only.(92436253 Rev A)

CRT-D Systems - AUTOGEN™, AUTOGEN™X4, DYNAGEN™, DYNAGEN™X4, INOGEN™, INOGEN™ X4, ORIGEN™, ORIGEN™X4, INCEPTA™, ENERGEN™, PUNCTUA™. COGNIS™ 100-D

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete “Instructions for Use/MRI Technical Guide” for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator’s Instructions.

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
- Always have external defibrillation equipment available during implant and electrophysiologic testing.
- Ensure that an external defibrillator and medical personnel skilled in CPR are present during post-implant device testing should the patient require external rescue.
- Do not use defibrillation patch leads with the pulse generator system,
- Do not use this pulse generator with another pulse generator.
- Program the pulse generator Tachy Mode(s) to Off during implant, explant, or postmortem procedures
- Do not kink, twist, or braid the lead with other leads as doing so could cause lead insulation abrasion damage or conductor damage.
- For leads that require the use of a Connector Tool, use caution handling the lead terminal when the Connector Tool is not present on the lead. Do not directly contact the lead terminal with any surgical instruments or electrical connections such as PSA (alligator) clips, ECG connections, forceps, hemostats, and clamps. This could damage the lead terminal, possibly compromising the sealing integrity and result in loss of therapy or inappropriate therapy, such as a short within the header.
- 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.
- When implanting a system which uses both a DF4-LLHH/LLHO and IS4-LLLL lead, ensure that the leads are inserted and secured in the appropriate ports. Inserting a lead into an incorrect port will result in unanticipated device behavior (potentially leaving the patient without effective therapy).
- 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. Programming therapy for slow monomorphic VT may preclude CRT delivery at faster rates if these rates are in the tachyarrhythmia zones.
- 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.
- AUTOGEN and DYNAGEN devices except for those with an LV: LV-1 lead connection are considered MR Conditional. INOGEN and ORIGEN devices 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 manual are not MR conditional. Do not expose patients with non-MR Conditional devices to MRI scanning. Strong magnetic fields may damage the pulse generator and/or lead system, possibly resulting in injury to or death of the patient.
- 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 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 Magnet Response programming automatically will be set to Inhibit Therapy. When this happens, the patient should not apply the magnet because tachyarrhythmia therapy could be inhibited.

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
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 products described in this literature:
- Air embolism
- Allergic reaction
- Bleeding
- Bradycardia
- 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)
- Failure to convert an induced arrhythmia
- Fluid accumulation
- Foreign body rejection phenomena
- Formation of hematomas or seromas
- Heart block
- 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
- Insulating myocardium during defibrillation with internal or external paddles
- Lead dislodgment
- 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 (PMT)
- Pericardial rub, effusion
- 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 ImageReady MR Conditional Defibrillation System 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 shocking while conscious
- Fear that shocking capability may be lost
- Imagined shocking
- Fear of device malfunction

Additionally, potential adverse events associated with the implantation of a coronary venous lead system include:
- Allergic reaction to contrast media
- Breakage/failure of implant instruments
- Prolonged exposure to fluoroscopic radiation
- Renal failure from contrast media used to visualize coronary veins

Refer to the product labeling for specific indications, contraindications, warnings/precautions and adverse events. Rx only.(92436228 Rev B)

ICD Systems – AUTOGEN™ EL, DYNAGEN™ EL, DYNAGEN™ MINI, INOGEN™ EL, INOGEN™ MINI, ORIGEN™ EL, ORIGEN™ MINI, INCEPTA™, ENERGEN™, PUNCTUA™, TELIGEN™100

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete “Directions for Use” for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator’s Instructions.

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
Based on the literature and on pulse generator and/or lead implant experience, the following alphabetical list includes the possible adverse evets associated with the included devices: Air embolism; Allergic reaction; Bleeding; Bradycardia; Cardiac tamponade; Chronic nerve damage; Component failure; Conductor coil fracture; Death; Elevated thresholds; Erosion; Excessive fibrotic tissue growth; Extracardiac stimulation (muscle/nerve stimulation); Failure to convert an induced arrhythmia; Fluid accumulation; Foreign body rejection phenomena; Formation of hematomas or seromas; Heart block; Heart failure following chronic RV apical pacing; 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 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 (PMT)(Applies to dual-chamber devices only); Pericardial rub, effusion; 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 ImageReady MR Conditional Defibrillation System 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 shocking while conscious; Fear that shocking capability may be lost; Imagined shocking; Fear of a device malfunction.

Refer to the product labeling for specific indications, contraindications, warnings/precautions and adverse events. Rx only. (92436232 Rev A)

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete “Instructions for Use”and MRI Technical Guide for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator’s Instructions.

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

Warnings
• Concomitant use of the S-ICD System and implanted electro-mechanical devices (for example implantable neuromodulation/neurostimulation systems, 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. The S-ICDis intended as lifesaving therapy and should be seen as priority in the decision and evaluation of concomitant system implants over non-lifesaving applications. 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/or compromise its functionality. Verify sensing configuration, operation modes, surgical considerations and existing placement of all involved devices prior to any co-implant. 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 coimplanted device. Induction testing is recommended to ensure appropriate detection and time to therapy for the S-ICD and appropriate post-shock operation of the co-implanted device. Failure to ensure appropriate detection and time to therapy delivery of the S-ICD system could result in patient injury or death.
• Following completion of the interaction testing, thorough follow-up evaluation of all co-implanted devices should be performed to ensure that device functions have not been compromised. If operational settings of the co-implanted devices change or if patient conditions changes which may affect S-ICD sensing and therapy performance, re-evaluation of the co-implanted devices may be required.
• 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 has not been tested and could 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. If not terminated in a timely fashion, an induced ventricular tachyarrhythmia can result in the patient’s death.
• 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. Refer to "S-ICD System and Pacemaker Interaction" on page 73 for more information.
• Attention is required to placement of the arm ipsilateral to the device implant to avoid injury of the ulnar nerve and brachial plexus while the patient is in the supine position during device implantation and before VF induction or shock delivery. The patient should be positioned with the arm abducted to an angle of no more than 60° with the hand in a supinated (palm up) position during the implant phase of the procedure. Securing the arm to an arm board is standard practice to maintain positioning of the arm during device implantation. Do not strap the arm too tightly during defibrillation testing. Elevation of the torso through use of a wedge may also add stress to the shoulder joint and should be avoided during defibrillation testing.
• Use appropriate anchoring techniques as described in the implant procedure to prevent S-ICD System dislodgement and/or migration. Dislodgement and/or migration of the S-ICD System may result in an inappropriate shock or failure to deliver therapy to the patient.
• Use caution when placing a magnet over the S-ICD pulse generator because it suspends arrhythmia detection and therapy response. Removing the magnet resumes 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. In this case the magnet cannot be used to inhibit therapy.
• 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.
• High shocking electrode impedance may reduce VT/VF conversion success.
• When positioning the electrode and pulse generator, avoid excessive tension on the electrode, particularly if the electrode body extends over the pulse generator. This could cause structural damage, abrasion, and/or conductor discontinuity.
• Although pliable, the electrode is not designed to tolerate excessive flexing, tight radius bending, kinking, or twisting. This could cause structural damage, conductor discontinuity, electrode migration, and/or dislodgement.
• Electrode fracture, abrasion, under-insertion of the electrode connector into the pulse generator connector port, or a loose setscrew connection may result in compromised sensing, loss of therapy, or inappropriate therapy.
• Following any sensing parameter adjustment or any modification of the subcutaneous electrode, always verify appropriate sensing.
• Determine if the device and programmed parameters are appropriate for patients with SVTs because SVTs can initiate unwanted device therapy.
• During a device software update, tachycardia therapy is suspended. Always monitor the patient and have external defibrillation equipment available during interrogation.
• Do not expose a patient with an implanted S-ICD System to diathermy.
• EMBLEM S-ICD devices are considered MR Conditional. Unless all MRI Conditions of Use are met, MRI scanning of the patient does not meet MR Conditional requirements for the implanted system.
• The Programmer is MR Unsafe and must remain outside the MRI site Zone III (and higher) as defined by the American College of Radiology Guidance Document on MR Safe Practices.
• During MRI Protection Mode the Tachycardia therapy is suspended.
• MRI scanning after ERI status has been reached may lead to premature battery depletion, a shortened device replacement window, or sudden loss of therapy.
• The Beeper may no longer be usable following an MRI scan.
• The pulse generator may be more susceptible to low frequency electromagnetic interference at induced signals greater than 80 uV.
• Immersion in saltwater and similar conductive fluid environments (i.e. ocean, saltwater pools) may divert some defibrillation shock energy away from the patient’s heart into the surrounding conductive fluid (as evidenced by a lower-than-normal shock impedance). This may reduce VT/VF conversion success, especially in patients with low BMI.

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.
• 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 antitachycardia pacing (ATP).
• When implanting the S-ICD system in a patient with sternal wires, ensure that there is no contact between the sternal wires and the distal and proximal sense electrodes (for example, by using fluoroscopy). Compromised sensing can occur if metal-to-metal contact occurs between a sense electrode and a sternal wire. If necessary, re-tunnel the electrode to ensure sufficient separation between the sense electrodes and the sternal wires.
• Implanting a replacement device in a subcutaneous pocket that previously housed a larger device may result in pocket air entrapment, migration, erosion, or insufficient grounding between the device and tissue. Irrigating the pocket with sterile saline solution decreases the possibility of pocket air entrapment and insufficient grounding. Suturing the device in place reduces the possibility of migration and erosion.

Electromagnetic Interference (EMI) Precautions
• Avoid electromagnetic interference (EMI). Advise patients to avoid sources of EMI because EMI may cause the pulse generator to deliver inappropriate therapy or inhibit appropriate therapy.
• Moving away from the source of the EMI or turning off the source usually allows the pulse generator to return to normal operation.
• Examples of potential EMI sources are:
    - o Electrical power sources
    - o Arc welding or resistance welding equipment (should remain at least 24 inches from the implant)
    - o Robotic jacks
    - o High voltage power distribution lines
    - o Electrical smelting furnaces
    - o Large RF transmitters such as radar
    - o Radio transmitters, including those used to control toys
    - o Electronic surveillance (antitheft) devices
    - o An alternator on a car that is running
    - o Medical treatments and diagnostic tests in which an electrical current is passed through the body, such as TENS, electrocautery, electrolysis/thermolysis, electrodiagnostic testing, electromyography, or nerve conduction studies
    - o Any externally applied device that uses an automatic lead detection alarm system (e.g., an EKG machine)
• Home appliances. Home appliances that are in good working order and properly grounded do not usually produce enough EMI to interfere with pulse generator operation. There have been reports of pulse generator disturbances caused by electric hand tools or electric razors used directly over the pulse generator implant site.
• Electronic Article Surveillance (EAS) and security systems. Advise patients how to avoid impact to cardiac device function due to antitheft and security gates, tag deactivators, or tag readers that include radio frequency identification (RFID) equipment. These systems may be found at the entrances and exits of stores, at checkout counters, in public libraries, and in point-of-entry access control systems. Patients should avoid lingering near or leaning against antitheft and security gates and tag readers. In addition, patients should avoid leaning against checkout counter-mounted and handheld tag deactivation systems. Antitheft gates, security gates, and entry control systems are unlikely to affect cardiac device function when patients walk through them at a normal pace. If the patient is near an electronic antitheft, security, or entry control system and experiences symptoms, they should promptly move away from nearby equipment and inform their doctor.
• Cellular phones. Patients should not carry a cellular phone within 15 cm (6 inches) of the implanted device in order to avoid interaction which may cause the pulse generator to deliver inappropriate therapy or inhibit appropriate therapy. Advise patients to hold cellular phones to the ear opposite the side of the implanted device, and to avoid storing a cellular phone within 15 cm (6 inches) of the implanted device. Examples of storage locations to be avoided include a breast or other shirt pocket, on a belt, or in a handbag held near the implant location.

• Static magnetic fields. Advise patients that extended exposure to strong (greater than 10 gauss or 1 mTesla) magnetic fields may suspend arrhythmia detection. Examples of permanent magnet—containing sources to be aware of include:
    - o Industrial motors if held within 60 cm (24 inches) of the pulse generator
    - o MRI scanners
    - o Large stereo speakers if held within 60 cm (24 inches) of the pulse generator
    - o Telephone receivers if held within 1.27 cm (0.5 inches) of the pulse generator
    - o Magnetic wands such as those used for airport security and in the Bingo game
    - o Cellular phones, ear buds, or headphones, if held within 15 cm (6 inches) of the pulse generator
    - o Magnetically attached charging port or cable, such as used in laptops or cellular phones, if held within 15 cm (6 inches) of the pulse generator
    - o Be aware of other body-worn items which may contain magnets, such as wrist bands, jewelry, clothing, nametags, CPAP masks, etc.

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
• Injury to or pain in upper extremity, including clavicle, shoulder, and arm
• Keloid formation
• Migration or dislodgement
• Muscle/nerve stimulation
• Nerve damage
• Organ injury or perforation
• Pneumothorax
• Post-shock/post-pace discomfort
• Premature battery depletion
• Random component failures
• Stroke
• Subcutaneous emphysema
• Surgical revision or replacement of the system
• Syncope
• Tissue damage
• Tissue redness, irritation, numbness or necrosis
• Vessel injury or perforation

Transient procedural adverse events are expected in some patients. These include, but are not limited to, discomfort, pain and other systemic symptoms that might be related to medications or other interventions performed during implant.
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. (92436235 Rev. B)

ICD System from Boston Scientific CRM - RESONATE™ HF, RESONATE™ EL, PERCIVA™ HF, PERCIVA™, VIGILANT™ EL, MOMENTUM™ EL ICD

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete “Directions for Use” for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator’s Instructions.

INDICATIONS AND USAGE
Boston Scientific implantable cardioverter defibrillators (ICDs) are intended to provide ventricular antitachycardia pacing (ATP) and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias.
CONTRAINDICATIONS
Use of these Boston Scientific pulse generators are contraindicated for the following: patients whose ventricular tachyarrhythmias may have reversible cause, such as: digitalis intoxication, electrolyte imbalance, hypoxia, sepsis; or patients whose ventricular tachyarrhythmias have a transient cause, such as: acute myocardial infarction (MI), electrocution, drowning; or patients who have a unipolar pacemaker.
WARNINGS
Read this manual thoroughly before implantation to avoid damage to the pulse generator and/or lead. For single patient use only. Do not reuse, reprocess, or resterilize. Always have external defibrillation equipment available during implant and electrophysiologic testing. Ensure that an external defibrillator and medical personnel skilled in CPR are present during post-implant device testing should the patient require external rescue. Do not use this pulse generator with another pulse generator. Program the pulse generator Tachy Mode(s) to Off during implant, explant, or postmortem procedures to avoid inadvertent high voltage shocks. Do not kink, twist, or braid the lead with other leads as doing so could cause lead insulation abrasion damage or conductor damage. For leads that require the use of a Connector Tool, use caution handling the lead terminal when the Connector Tool is not present on the lead. Do not directly contact the lead terminal with any surgical instruments or electrical connections such as PSA (alligator) clips, ECG connections, forceps, hemostats, and clamps. Do not contact any other portion of the DF4–LLHH or DF4–LLHO lead terminal, other than the terminal pin, even when the lead cap is in place. Do not use atrial tracking modes in patients with chronic refractory atrial tachyarrhythmias. Tracking of atrial arrhythmias could result in ventricular tachyarrhythmias. Advise patients to seek medical guidance before entering environments that could adversely affect the operation of the active implantable medical device, including areas protected by a warning notice that prevents entry by patients who have a pulse generator. RESONATE HF, RESONATE, PERCIVA HF, PERCIVA, VIGILANT and MOMENTUM devices are considered MR Conditional. For these devices, unless all of the MRI Conditions of Use are met, MRI scanning of the patient does not meet MR Conditional requirements for the implanted system, and significant harm to or death of the patient and/or damage to the implanted system may result. Do not expose patients 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 MRI Technical Guide. Do not subject a patient with an implanted pulse generator and/or lead to diathermy. If desired, ensure that Patient Triggered Monitor is enabled prior to sending the patient home. Once the Patient Triggered Monitor feature has been triggered by the magnet and an EGM has been stored, or after 60 days have elapsed from the day that Store EGM was enabled, the patient should not apply the magnet.

PRECAUTIONS
For specific information on precautions, refer to the following sections of the product labeling: clinical considerations, sterilization and storage, implantation, device programming, environmental and medical therapy hazards, hospital and medical environments, home and occupational environments, follow up testing, explant and disposal, supplemental precautionary information.
POTENTIAL ADVERSE EVENTS
Based on the literature and on pulse generator and/or lead implant experience, the following alphabetical list includes the possible adverse evets associated with the included devices: Air embolism; Allergic reaction; Bleeding; Bradycardia; Cardiac tamponade; Chronic nerve damage; Component failure; Conductor coil fracture; Death; Elevated thresholds; Erosion; Excessive fibrotic tissue growth; Extracardiac stimulation (muscle/nerve stimulation); Failure to convert an induced arrhythmia; Fluid accumulation; Foreign body rejection phenomena; Formation of hematomas or seromas; Heart block;

Heart failure following chronic RV apical pacing; 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; Insulating myocardium during defibrillation with internal or external paddles; 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 (PMT); Pericardial rub, effusion; 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 a device malfunction.

Refer to the product labeling for specific indications, contraindications, warnings/precautions and adverse events. Rx only. (92436178 Rev. B)

CRT-D System from Boston Scientific CRM - RESONATE™HF, RESONATE™, RESONATE™X4, VIGILANT™, VIGILANT™X4, MOMENTUM™, MOMENTUM™ X4

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete “Instructions for Use/MRI Technical Guide” for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator’s Instructions.

Content
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
- Always have external defibrillation equipment available during implant and electrophysiologic testing.
- Ensure that an external defibrillator and medical personnel skilled in CPR are present during post-implant device testing should the patient require external rescue.
- Do not use defibrillation patch leads with the pulse generator system.
- Do not use this pulse generator with another pulse generator.
- Program the pulse generator Tachy Mode(s) to Off during implant, explant, or postmortem procedures.
- Do not kink, twist, or braid the lead with other leads as doing so could cause lead insulation abrasion damage or conductor damage.
- For leads that require the use of a Connector Tool, use caution handling the lead terminal when the Connector Tool is not present on the lead. Do not contact the lead terminal with any surgical instruments or electrical connections such as PSA (alligator) clips, ECG connections, forceps, hemostats, and clamps. This could damage the lead terminal, possibly compromising the sealing integrity and result in loss of therapy or inappropriate therapy, such as a short within the header.
- 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.
- When implanting a system that uses both a DF4–LLHH or DF4–LLHO and IS4–LLLL lead, ensure that the leads are inserted and secured in the appropriate ports. Inserting a lead into an incorrect port will result in unanticipated device behavior (potentially leaving the patient without effective therapy).
- 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. Programming therapy for slow monomorphic VT may preclude CRT delivery at faster rates if these rates are in the tachyarrhythmia zone.
- 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.
- All devices except for those with an LV: LV-1 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. Do not expose patients with non-MR Conditional devices to MRI scanning. Strong magnetic fields may damage the pulse generator and/or lead system, possibly resulting in injury to or death of the patient.
- For potential adverse events applicable when the Conditions of Use are met or not met, refer to the MRI Technical Guide.
- Do not subject a patient with an implanted pulse generator and/or lead to diathermy.
- If desired, ensure that Patient Triggered Monitor (PTM) is enabled prior to sending the patient home by confirming the magnet response is programmed to Store EGM.
- 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 Magnet Response programming automatically will be set to Inhibit Therapy. When this happens, the patient should not apply the magnet because tachyarrhythmia therapy could be inhibited.

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. Advise patients to avoid sources of EMI because EMI may cause the pulse generator to deliver inappropriate therapy or inhibit appropriate therapy. Moving away from the source of the EMI or turning off the source usually allows the pulse generator to return to normal operation.
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 products described in this literature:
- Air embolism
- Allergic reaction
- Bleeding
- Bradycardia
- 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)
- Failure to convert an induced arrhythmia
- Fluid accumulation
- Foreign body rejection phenomena
- Formation of hematomas or seromas
- Heart block
- 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
- Insulating myocardium during defibrillation with internal or external paddles
- Lead dislodgment
- 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 (PMT)
- Pericardial rub, effusion
- 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 ImageReady MR Conditional Defibrillation System MRI Technical Guide.

Patients may develop psychological intolerance to a pulse generator system and may experience the following:
- Dependency
- Depression
- Fear of shocking while conscious
- Fear that shocking capability may be lost
- Imagined shocking
- Fear of premature battery depletion
- Fear of device malfunction

Additionally, potential adverse events associated with the implantation of a coronary venous lead system include:
- Allergic reaction to contrast media
- Breakage/failure of implant instruments
- Prolonged exposure to fluoroscopic radiation
- Renal failure from contrast media used to visualize coronary veins

Refer to the product labeling for specific indications, contraindications, warnings/precautions and adverse events. Rx only (92436222 Rev B)

LUX-Dx™ Insertable Cardiac Monitor System

Indications
The LUX-Dx™ Insertable Cardiac Monitor (ICM) is intended to monitor and record subcutaneous electrocardiogram (S-ECG). The recorded S-ECG is used for the clinical evaluation and diagnosis of cardiac arrhythmias. The LUX-Dx is indicated for use in patients that have a known heart condition and are at risk of developing an abnormal heart rhythm, or have symptoms that may suggest a cardiac arrhythmia, such as dizziness, palpitations, syncope, chest pain, and/or shortness of breath.
The LUX-Dx has not been tested specifically for pediatric use.

Contraindications
There are no known contraindications for the insertion of the LUX-Dx insertable cardiac monitor. However, the patient's particular medical condition may dictate whether or not they can tolerate a subcutaneous, chronically- inserted device.
LATITUDE Clarity is contraindicated for use with any device other than a compatible Boston Scientific device.

Warnings
General
• Co-implanted device interaction. Concomitant use of the ICM system and implanted electro-mechanical devices [for example implantable neuromodulation/neurostimulation systems, ventricular assist device (VAD), or implantable insulin pump or drug pump] can result in interactions that could compromise the function of the ICM, the co-implanted device, or both. Electromagnetic interference (EMI) or therapy delivery from the co-implanted device can interfere with ICM sensing and/or rate assessment, resulting in failure to monitor or record when needed. Verify sensing configuration, operation modes, surgical considerations and existing placement of all involved devices prior to any co-implant. To help prevent undesirable interactions, test the ICM system when used in combination with the co-implanted device.
Following completion of the interaction testing, thorough follow-up evaluation of all co-implanted devices should be performed to ensure that device functions have not been compromised. If operational settings of the co-implanted devices change or if patient conditions change which may affect ICM sensing, re-evaluation of the co-implanted devices may be required.
• **Labeling knowledge**. Read this manual thoroughly before using the ICM system to avoid damage to the device. Such damage can result in patient injury or death.
• **For single patient use only.** Do not reuse, reprocess, or resterilize the insertable cardiac monitor or insertion tools. Reuse, reprocessing, or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness, or death. Reuse, reprocessing, or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from onepatient to another. Contamination of the device may lead to injury, illness, or death of the patient. The medical professional may reposition or re-insert the device within a single procedure.
• **Sharp object.** Incision tool is sharp. Take precautions to ensure that it is handled properly. Dispose of incision tool directly into a sharps disposal container labeled with a biological hazard symbol. Sharps waste should be safely disposed of using available sharps waste channels in accordance with hospital, administrative, and/or local government policy.
Insertion
• **Tunneling.** The insertion tool is intended to be used in the subcutaneous space. Always be aware of the location of the tool tip relative to the patient anatomy. Hold the insertion tool at a narrow angle while tunneling. Unintended tissue damage may result if the device is inserted at a large angle.
• **Incision tool blade placement.** Always be aware of the location of the incision tool blade relative to the patient anatomy. Unintended tissue damage may result if the incision tool is inserted beyond the blade.
Post Insertion
• **Diathermy**. Do not expose a patient with an ICM system to diathermy. The interaction of diathermy therapy with an insertable cardiac monitor can damage the device and cause patient injury.
• **Firmware update must be completed.** Once a firmware update begins, the patient will not be monitored until the update is completed. If the firmware update is skipped, the patient is still monitored.
• Interrogate device, save data, and check device function. The influence of medical equipment on implanted devices varies considerably according to the type of unit and energy levels employed. In situations where the risks are known, always interrogate the device and save data before the procedure, and check device function afterwards.
• **Magnet compatibility.** Magnet model 6386 has been tested for use with the ICM system. Use of any other magnets has not been tested and could result in failure to initiate communication with the device.
• **Magnet use**. The magnet provided with the ICM system may cause interference with devices sensitive to magnetic fields such as hearing aids, pacemakers, and other implanted devices. It can also permanently disable some magnetic strip cards. Keep the magnet at least 15 cm (6 inches) away from items sensitive to magnetic fields, including the ICM device when the magnet is not being used to initiate communication between the device and the patient or clinic app.
• **Mobile devices and magnet are MR Unsafe**. The mobile devices and magnet are MR Unsafe and must remain outside the MRI site Zone III (and higher) as defined by the American College of Radiology Guidance Document on MR Safe Practices1. Under no circumstances should the mobile device or magnet be brought into the MRI scanner room, the control room, or the MRI site Zone III or IV areas.
• **MR conditional requirements.** Unless all of the MRI Conditions of Use are met, MRI scanning of the patient does not meet MR Conditional requirements for the inserted device, and significant harm to or death of the patient and/or damage to the inserted device may result.
• **Scanning with other devices**. Scanning patients who have other MR Conditional devices is acceptable if all the MR Conditional requirements for each of the implanted devices are met. Do not conduct an MRI scan if any conditions or implants prohibit it.
• **Protected environments.** 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.

Precautions
For specific information on precautions, refer to the following sections of the product labeling: General, Clinical Considerations, Sterilization and Storage, Insertion, Magnet, Device Programming, Environmental and Medical Hazards, Follow-up, Device Removal and Disposal.

Potential Adverse Events
Insertion and usage of this product may result in adverse events which may lead to injury, death, or other serious adverse reactions. If any adverse events occur, invasive corrective action and/or ICM system modification or removal may be required.

Potential adverse events related to insertion of the device may include, but are not limited to, the following:

- Device migration
- Erosion
- Foreign body rejection phenomena
- Formation of hematomas or seromas
- Infection
- Local tissue reaction
- Tissue damage

Potential adverse events related to device operation may include, but are not limited to, the following:

- Premature battery depletion
- Sensing issues
- Error codes
- Loss of telemetry

Transient procedural adverse events are expected in some patients. These include, but are not limited to discomfort, pain, anxiety, and other systemic symptoms that might be related to medications or other interventions performed during implant.

For a list of potential adverse events associated with MRI scanning, refer to the MRI Technical Guide at www.bostonscientific-elabeling.com.

Any serious incident that occurs in relation to this device should be reported to Boston Scientific and to the relevant local regulatory authority.

Refer to the product labeling for specific indications, contraindications, warnings/precautions and adverse events. Rx only (92496928 Rev C)