

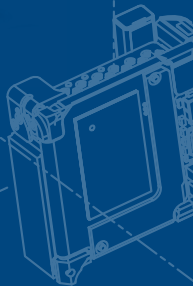


RESONATE™
Family of ICDs and CRT-Ds

More Features to Prevent Sudden Cardiac Death



**Powerful Solutions.
No Compromises.**



GOOD ENOUGH ISN'T GOOD ENOUGH.

The number one reason defibrillators are implanted is to protect patients from sudden cardiac death. Boston Scientific ICDs and CRT-Ds provide meaningful features to do just that including:

- 8 shocks in the VF zone
- Programmable shock polarity
- Automatically invert polarity in a series of shocks

While these features won't be utilized by every patient, those that do need them aren't concerned that they're in the minority. They want the assurance and functionality that only Boston Scientific devices safely provide.

Scan to learn more about what sets
Boston Scientific ICDs and CRT-Ds apart



6th Shock

Shock polarity is automatically inverted in the VT Zone

7th Shock

Additional shocks when VF conversion is difficult

8th Shock

Shock Polarity is automatically inverted in the VF Zone



RESONATE™ HF, RESONATE™, RESONATE™ X4, VIGILANT™ X4, MOMENTUM™, MOMENTUM™ X4

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 to this device.

WARNINGS Always have external defibrillation equipment available during implant and electrophysiology testing. • Ensure that an external defibrillator and medical personnel skilled in CPR are present during post-implant device testing should the patient require external resuscitation. • 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 kick, 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 usual 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 overdriving 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+I 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 EMF because EMF may cause the pulse generator to deliver inappropriate therapy or inhibit appropriate therapy. Moving away from the source of the EMF 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 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 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. **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. 9243622 (Rev. B)

RESONATE™ HF, RESONATE™ EL, PERCIVA™ HF, PERCIVA™, VIGILANT™ EL, MOMENTUM™ EL ICD

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

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

WARNINGS Read this manual thoroughly before implantation to avoid damage to the pulse generator and/or lead. For single patient use only. Do not reuse, reprocess, or sterilize. Always have external defibrillation equipment available during implant and electrophysiology testing. Ensure that an external defibrillator and medical personnel skilled in CPR are present during post-implant device testing should the patient require external resuscitation. 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 kick, 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 events 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. **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. 92436178 (Rev. B)

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