Boston Scientific
Advancing science for life™

Device replacement comes with risk

PATIENTS ARE GETTING DEVICES **EARLIER, LIVING LONGER AND NEED LONGER LASTING DEVICES**[1]

35-40%
OF PATIENTS WITH AN ICD OR CRT-D
< 65 YEARS OLD[2]

80%
OF MILDLY SYMPTOMATIC HF CRT-D PATIENTS ARE **LIVING 7 YEARS POST-IMPLANT**[3]

40%
OF ICD PATIENTS ARE **LIVING 10 YEARS POST-IMPLANT**[4]

IN AN INDEPENDENT STUDY **OF 2,635 PATIENTS,** 451 HAD REPLACEMENTS[5]:

9.1% HAD **COMPLICATIONS**[5]

of those with complications...

66% EXPERIENCED A **MAJOR COMPLICATION** AND NEEDED REOPERATION[5]

of those requiring re-operation...

37% **REQUIRED AN EXTRACTION**[5]

of those requiring an extraction...

20% **DIED**[5]

DEVICE INFECTIONS WERE **ASSOCIATED WITH:**

- LONGER HOSPITAL STAYS[6]
- HIGHER COSTS[6]
- INCREASED MORTALITY[6]

BOSTON SCIENTIFIC'S EL ICDs AND X4 CRT-Ds WITH **ENDURALIFE™ BATTERY TECHNOLOGY** ARE OUTLASTING THE COMPETITION.[7-14]

Discover why **longer battery life** gives defibrillator patients **more.**

Get the Facts. Cut the Risk.

Sources

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10 Ellis C, Markus T, Dickerman D, Orton J, Hassan S, Good E, Okabe T, Greenspon A. Ampere Hour as a Predictor of CRT ICD Pulse Generator Longevity: A Multi-Center Study. Presented at HFSA 2014. http://www.onlinejcf.com/article/S1071-9164(14)00337-6/fulltext. Ampere Hour (Ah) as a Predictor of CRT ICD Pulse Generator Battery Longevity Study. The five major institutions performing the study include, at Vanderbilt University, Eastside Cardiovas-cular Medicine, University of Michigan, Thomas Jefferson University, Robert Wood Johnson University Hospital, Cooper Health System and North Ohio Research. Boston Scientific = 266 patients, Medtronic = 542 patients, St. Jude Medical = 149 patients. Five-year survival rate calculated using device replacements for battery depletion as indicated by ERI.

11 Landolina M, Curnis A, Morani G, Vado A, Ammendola E, D'onofrio A, Stabile G, Crosato M, Petracci B, Ceriotti C, Bontempi L, Morosato M, Ballari GP, Gasparini M. Longevity of implant Cardioverter-defibrillators for cardiac resynchronization therapy in current clinical practice: an analysis according to influencing factors, device generation, and manufacturer. Europace (2015) doi: 10.1093/eurospace/euv109. First published online: May 14, 2015. Medtronic = 798 patients, Boston Scientific = 608 patients, St. Jude Medical = 172 patients, Biotronik = 49 patients, Sorin = 99. Five-year survival rate calculated using device replacements for battery depletion as indicated by ERI.

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14 Boston Scientific CRM Product Performance Report, Data on file. Medtronic CRM Product Performance Report, C154DWK Concerto CRT-D DR, 2014 CDRM Product Performance eSource, data February 9, 2015. St. Jude Medical Product Performance Report, Promote RF CRT-D, 60069901 REV_A, page 41, Last updated May 5, 2015.

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

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

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

Warnings Read this manual thoroughly before implantation to avoid damage to the pulse generator and/or lead. For single patient use only. Do not reuse, reprocess, or resterilize. Program the pulse generator Tachy Mode(s) to Off during implant, explant, or postmortem procedures to avoid inadvertent high voltage shocks. Always have external defibrillation equipment available during implant and electrophysiologic testing. Ensure that an external defibrillator and medical personnel skilled in CPR are present during post-implant device testing should the patient require external rescue. Patients should seek medical guidance before entering environments that could adversely affect the operation of the active implantable medical device, including areas protected by a warning notice that prevents entry by patients who have a pulse generator. Do not expose a patient to MRI scanning. Do not subject a patient with an implanted pulse generator and/or lead to diathermy. If desired, ensure that Patient Triggered Monitor is enabled prior to sending the patient home. Once the Patient Triggered Monitor feature has been triggered by the magnet and an EGM has been stored, or after 60 days have elapsed from the day that Store EGM was enabled, the patient should not apply the magnet.

For leads that require the use of a Connector Tool, use caution handling the lead terminal when the Connector Tool is not present on the lead. Do not directly contact the lead terminal with any surgical instruments or electrical connections such as PSA (alligator) clips, ECG connections, forceps, hemostats, and clamps. Do not contact any other portion of the DF4-LLHH or DF4-LLHO lead terminal, other than the terminal pin, even when the lead cap is in place. Do not use this pulse generator with another pulse generator. This combination could cause pulse generator interaction, resulting in patient injury or a lack of therapy delivery. Do not kink, twist, or braid the lead with other leads as doing so could cause lead insulation abrasion damage or conductor damage. Do not use atrial tracking modes in patients with chronic refractory atrial tachyarrhythmias. Tracking of atrial arrhythmias could result in ventricular tachyarrhythmias.

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

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

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

CRT-D Systems from Boston Scientific — DYNAGEN™, INOGEN™, and ORIGEN™

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

Contraindications There are no contraindications for this device.

Warnings Read this manual thoroughly before implantation to avoid damage to the pulse generator and/or lead. For single patient use only. Do not reuse, reprocess, or resterilize. 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. Advise patients to seek medical guidance before entering environments that could adversely affect the operation of the active implantable medical device, including areas protected by a warning notice that prevents entry by patients who have a pulse generator. Do not expose a patient to MRI scanning. Do not subject a patient with an implanted pulse generator and/or lead to diathermy. Do not use atrial tracking modes in patients with chronic refractory atrial tachyarrhythmias. Do not use atrial-only modes in patients with heart failure. Left ventricular lead dislodgement to a position near the atria can result in atrial oversensing and left ventricular pacing inhibition. Physicians should use medical discretion when implanting this device in patients who present with slow VT. Do not kink, twist, or braid the lead with other leads. Do not use defibrillation patch leads with the pulse generator system. Do not use this pulse generator with another pulse generator. Ensure that Patient Triggered Monitor (PTM) is enabled prior to sending the patient home by confirming the magnet response is programmed to Store EGM. Once the PTM feature has been triggered and the magnet response set to Inhibit therapy the patient should not reapply the magnet.
For DF4-LLHH or DF4-LLHO leads, use caution handling the lead terminal when the Connector Tool is not present on the lead and do not directly contact the lead terminal with any surgical instruments or electrical connections such as PSA (alligator) clips, ECG connections, forceps, hemostats, and clamps. Do not contact any other portion of the DF4-LLHH or DF4-LLHO lead terminal, other than the terminal pin, even when the lead cap is in place. Do not contact any other portion of the IS4-LLLL lead terminal, other than the terminal pin, even when the lead cap is in place.

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

Potential Adverse Events Potential adverse events from implantation of the CRT-D system include, but are not limited to, the following: air embolism, allergic reaction, bleeding, 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, tachyarrhythmias, which include acceleration of arrhythmias and early, recurrent atrial fibrillation, thrombosis/thromboemboli, valve damage, venous occlusion, venous trauma (e.g., perforation, dissection, erosion), worsening heart failure, 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.
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