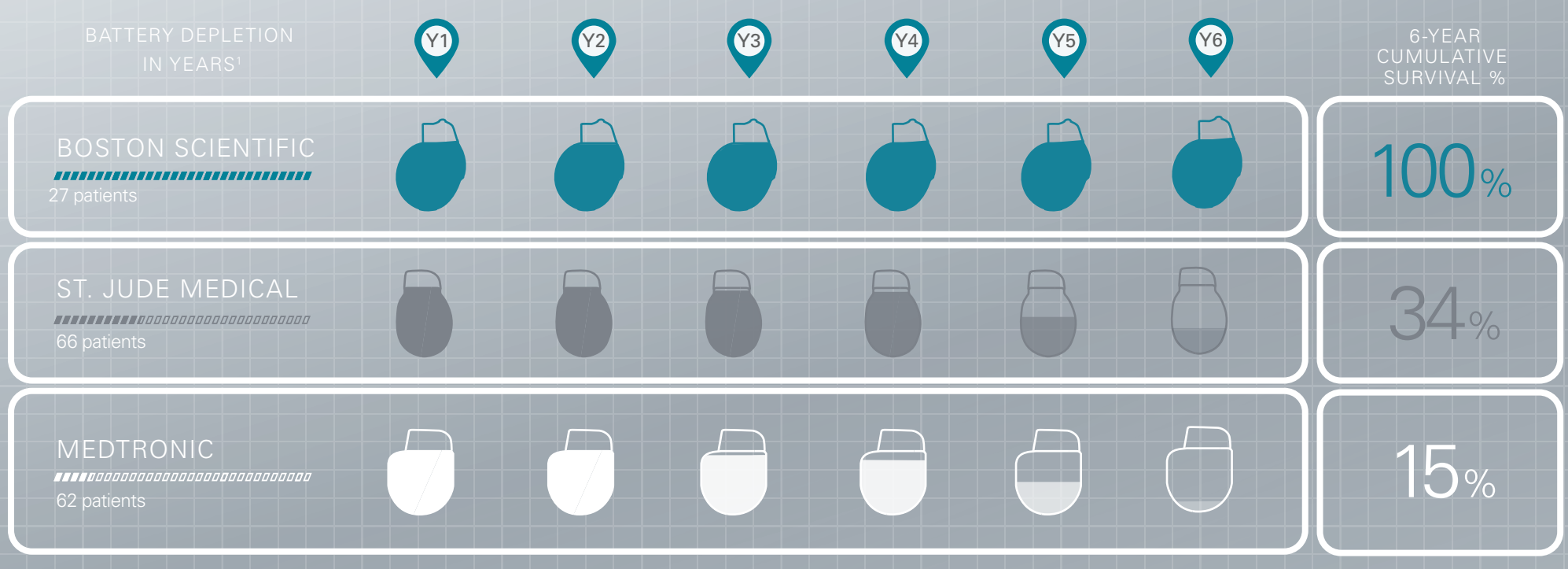
Boston Scientific
Advancing science for life™

ENDURALIFE™ Battery Technology Offers a Clinically Meaningful Difference in CRT-D Longevity

7 RECENT STUDIES AGREE:

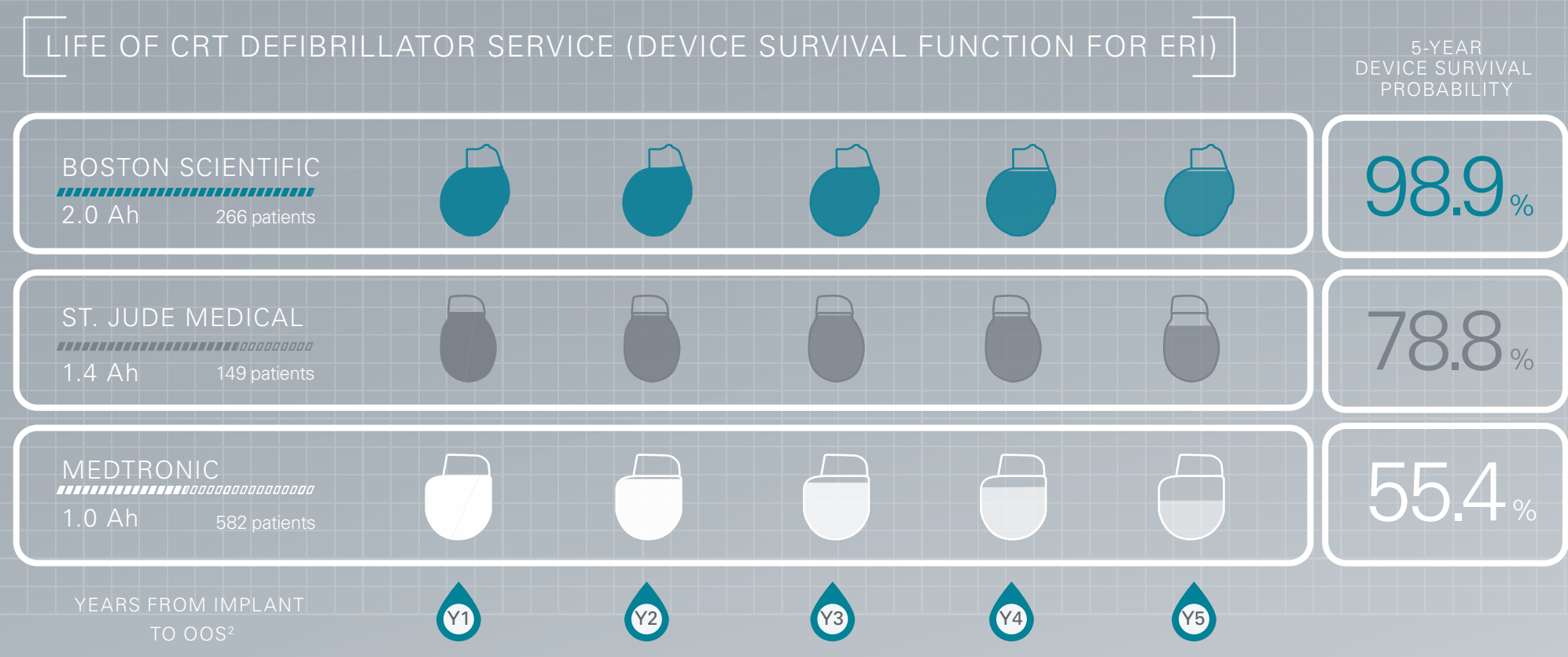
BATTERY DEPLETION IN CRT DEFIBRILLATORS BY VENDOR

LAU STUDY[1]

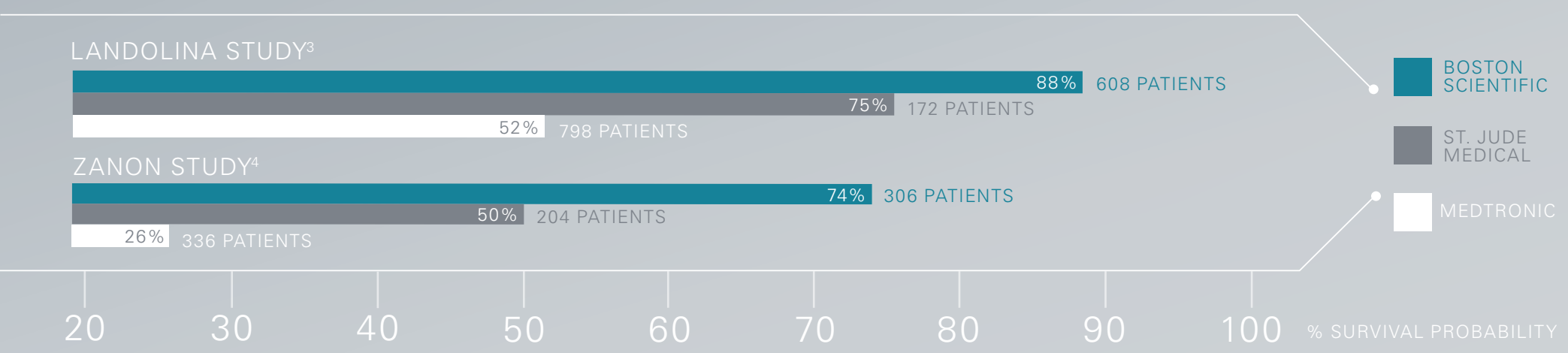


LIFE OF CRT DEFIBRILLATOR SERVICE (DEVICE SURVIVAL FUNCTION FOR ERI)

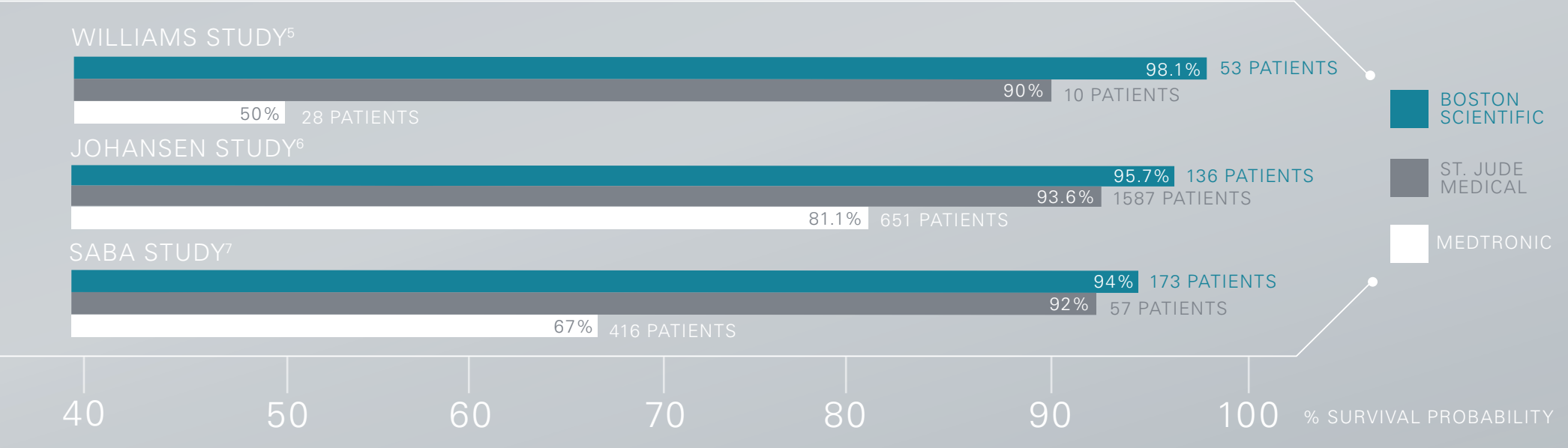
ELLIS STUDY[2]



5-YEAR SURVIVAL RATE OF DEVICE BATTERIES



4-YEAR SURVIVAL RATE OF DEVICE BATTERIES



BOSTON SCIENTIFIC CRT-Ds ARE **LASTING LONGER** THAN MEDTRONIC CRT-Ds.

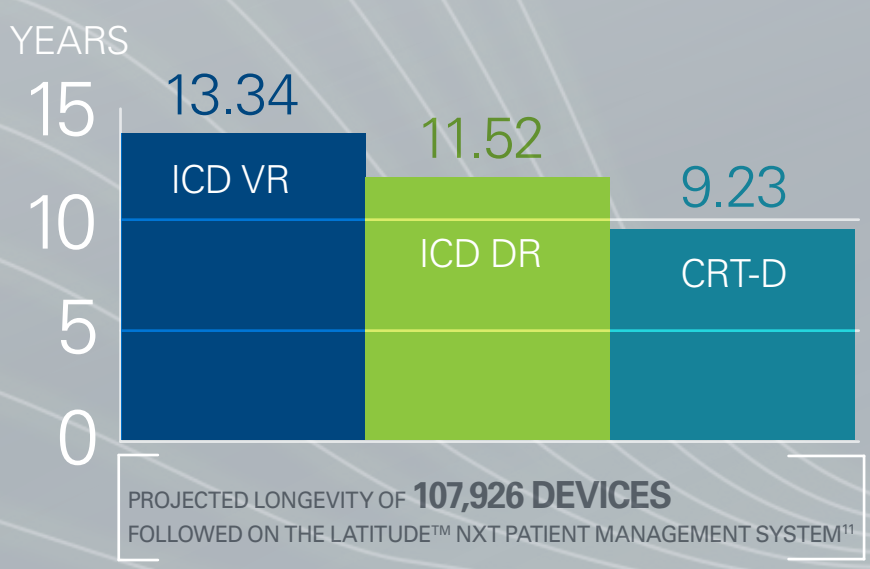
AFTER 6 YEAR PPR

94.1% OF BOSTON SCIENTIFIC CRT-Ds ARE **STILL** IN SERVICE[8]

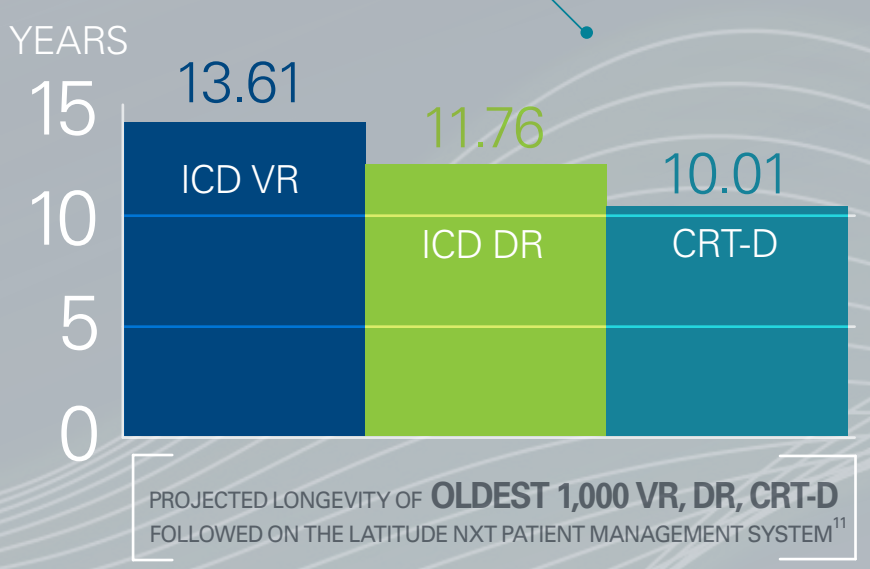
ONLY **68%** OF ST. JUDE MEDICAL CRT-Ds ARE STILL IN SERVICE[9]

ONLY **23%** OF MEDTRONIC CRT-Ds ARE STILL IN SERVICE[10]

AND THE TREND IS **PROJECTED TO CONTINUE:**



PROJECTED LONGEVITY OF **107,926 DEVICES** FOLLOWED ON THE LATITUDE™ NXT PATIENT MANAGEMENT SYSTEM[11]



PROJECTED LONGEVITY OF **OLDEST 1,000 VR, DR, CRT-D** FOLLOWED ON THE LATITUDE NXT PATIENT MANAGEMENT SYSTEM[11]

BOSTON SCIENTIFIC'S EL ICDs AND X4 CRT-Ds USE PROVEN TECHNOLOGY THAT **CONTINUES TO OUTLAST THE COMPETITION.**[1-10]

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

Get the Facts. Cut the Risk.

Sources

[1] Provided by Dr. Ernest Lau on 04/29/15 in support of Lau E, Wilson C, Ashfield K, McNair W, McEneany D, Roberts M, Large Capacity LiMnO2 Batteries Extended CRTD Longevity in Clinical Use Compared to Smaller Capacity LiSVO Batteries Over 6 Years. Presented at HRS 2015. Medtronic = 62 patients, Boston Scientific = 27 patients, St. Jude = 66 patients. Five-year survival rate calculated using device replacements for battery depletion as indicated by ERI.

[2] 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 Cardiovascular 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.

[3] 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.

[4] Provided by Dr. Francesco Zanon on 05/02/15 in support of Biffi M, Zanon F. Device Longevity in a Contemporary Cohort of ICD/CRT-D Patients Undergoing Device Replacement. Presented at HRS 2015. Medtronic = 336 patients, Boston Scientific = 306 patients, St. Jude = 204 patients. Five-year survival rate calculated using device replacements for battery depletion as indicated by ERI.

[5] J. Williams, R. Stevenson. Contemporary cardiac resynchronization implantable cardioverter defibrillator battery longevity in a community hospital heart failure cohort. Presented at HFSA 2014. http://www.onlinejcf.com/article/S1071-9164(14)00389-3/fulltext. Boston Scientific = 53 patients, Medtronic = 28 patients, St. Jude Medical = 10 patients. Four-year survival rate calculated using device replacements for battery depletion as indicated by ERI.

[6] Haarbo J, Hjortshoj S, Johansen J, Jorgensen O, Nielsen J, Petersen H. Device Longevity in Cardiac Resynchronization Therapy Implantable Cardioverter Defibrillators Differs Between Manufacturers: Data from the Danish ICD Registry. Presented at HRS 2014. http://ondemand.hrsonline.org/common/presentation-detail.aspx/15/35/1241/9000. Boston Scientific = 136 patients, Medtronic = 651 patients, St. Jude Medical = 1,587 patients, Bitronik = 369 patients. Time to exchange of the device because of battery depletion or device failure recorded in the Danish ICD Registry was the endpoint. The four-year survival rate for devices in the Danish Registry study was 81.1% for Medtronic and 95.7% for Boston Scientific (P<0.01).

[7] Alam M, Munir B, Rattan R, Flanigan S, Adelstein E, Jan S, Saba S. Battery Longevity in Cardiac Resynchronization Therapy Defibrillators. 2013; Europace (2013) doi: 10.1093/europace/eut301. First published online: October 6, 2013. Kaplan Meier curves depicting survival of CRT devices free from battery depletion by device manufacturer. Battery Longevity in Cardiac Medtronic = 416 patients, Boston Scientific = 173 patients, St. Jude Medical = 57 patients. Four-year survival rate calculated using device replacements for battery depletion as indicated by ERI.

[8] Boston Scientific CRM Product Performance Report, September 2014. Data on file.

[9] St. Jude Medical Product Performance Report, Model 3207-36 Promote™ RF CRT-D, Implantable Electronic Systems Division Product Performance Report 2014 Second Edition, 60066824 Rev_A, p. 41, data collected as of June 30, 2014.

[10] Medtronic CRM Product Performance Report, C154DWK Concerto CRT-D DR, 2014 CDRM Product Performance eSource, data August 3, 2014.

[11] Not intended to replace longevity estimates found in labeling. Analysis of LATITUDE™ Patient Management System data (data on file):
- From oldest 1000 VR, DR and 999 CRT-Ds as of July 2014. This distribution may be different than later groups. Data on file.
- Individual symptoms, situations, circumstances and results vary. This information is not intended to be used for medical diagnosis or treatment or as a substitute for medical advice.
- Device programming was determined by physicians. Accordingly, the aggregate average represents a mean value that is based upon real-world programming. The data reflect projected longevities based upon parameter settings, rather than observed performance.
- This information is a defined data set and could change in the future.
- The low variability may be the result of the devices still being quite young. As the devices continue to age, patient differences in pacing and other factors may cause greater variability in the Approximate Time to Explant.
- The LATITUDE data are assumed to be representative of the general patient population.
- The distribution is non-normal; therefore the standard deviation must be interpreted with care. It may not necessarily be true that ~ 95% of the data lie within standard deviations of the mean, ~99.7% within three, etc.

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

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

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

WARNINGS Read this manual thoroughly before implantation to avoid damage to the pulse generator and/or lead. For single patient use only. Do not reuse, reprocess, or resterilize. Program the pulse generator Tachy Mode(s) to Off during implant, explant, or postmortem procedures to avoid inadvertent high voltage shocks. Always have external defibrillation equipment available during implant and electrophysiologic testing. Ensure that an external defibrillator and medical personnel skilled in CPR are present during post-implant device testing should the patient require external rescue. Patients should seek medical guidance before entering environments that could adversely affect the operation of the active implantable medical device, including areas protected by a warning notice that prevents entry by patients who have a pulse generator. Do not expose a patient to MRI scanning. Do not subject a patient with an implanted pulse generator and/or lead to diathermy. If desired, ensure that Patient Triggered Monitor is enabled prior to sending the patient home. Once the Patient Triggered Monitor feature has been triggered by the magnet and an EGM has been stored, or after 60 days have elapsed from the day that Store EGM was enabled, the patient should not apply the magnet. For leads that require the use of a Connector Tool, use caution handling the lead terminal when the Connector Tool is not present on the lead. Do not directly contact the lead terminal with any surgical instruments or electrical connections such as PSA (alligator) clips, ECG connections, forceps, hemostats, and clamps. Do not contact any other portion of the DF4–LLHH or DF4–LLHO lead terminal, other than the terminal pin, even when the lead cap is in place. Do not use this pulse generator with another pulse generator. This combination could cause pulse generator interaction, resulting in patient injury or a lack of therapy delivery. Do not kink, twist, or braid the lead with other leads as doing so could cause lead insulation abrasion damage or conductor damage. Do not use atrial tracking modes in patients with chronic refractory atrial tachyarrhythmias. Tracking of atrial arrhythmias could result in ventricular tachyarrhythmias.)

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

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

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

CRT-D Systems from Boston Scientific –DYNAGEN/INOGEN/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. 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: 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 System from Boston Scientific – COGNIS™

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 the product labeling thoroughly before implanting the pulse generator to avoid damage to the system. For single patient use only. Do not reuse, reprocess, or resterilize. Program the pulse generator Tachy Mode to Off during implant, explant or postmortem procedures. Always have sterile external and internal defibrillator protection available during implant and electrophysiologic testing. Ensure that an external defibrillator and medical personnel skilled in CPR are present during post-implant device testing. Advise patients to seek medical guidance before entering environments that could adversely affect the operation of the active implantable medical device, including areas protected by a warning notice that prevents entry by patients who have a pulse generator. Do not expose a patient to MRI scanning. Do not subject a patient with an implanted pulse generator to diathermy. Do not use atrialtracking modes in patients with chronic refractory atrial tachyarrhythmias. Do not use atrial-only modes in patients with heart failure. LV lead dislodgment to a position near the atria can result in atrial oversensing and LV pacing inhibition. Physicians should use medical discretion when implanting this device in patients who present with slow VT. Do not kink, twist or braid the lead with other leads. Do not use defibrillation patch leads with the CRT-D system. Do not use this pulse generator with another pulse generator. For Patient Triggered Monitor (PTM) feature, make sure the feature is enabled prior to sending the patient home with a magnet. Once the PTM feature has been triggered and the magnet response programming is set to inhibit therapy, the patient should not reapply the magnet.

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

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

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

Boston Scientific
Advancing science for life™

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