

Large Capacity LiMnO₂ Batteries Extended CRT-D Longevity in Clinical Use Compared to Smaller Capacity LiSVO Batteries Over 6 Years

An independent poster presented at Heart Rhythm Society's (HRS) 2015 Annual Meeting comparing contemporary CRT-D longevity

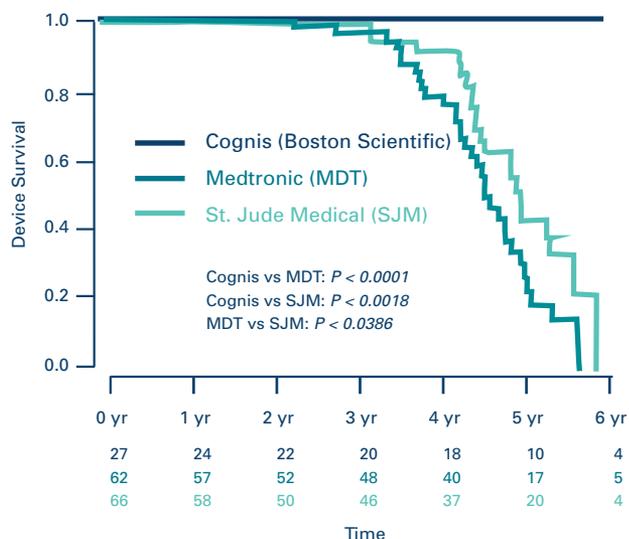
DESCRIPTION

Large Capacity LiMnO₂ Batteries Extended CRT-D Longevity in Clinical Use Compared to Smaller Capacity LiSVO Batteries Over 6 Years was an independent, retrospective observational study comparing battery longevity of contemporary cardiac resynchronization therapy defibrillators (CRT-Ds) of all patients implanted with CRT-ICDs from 2008 through 2009 at Royal Victoria Hospital in Belfast, Northern Ireland.¹

IMPORTANT OUTCOMES

- High-capacity LiMnO₂-powered CRT-Ds outlasted smaller-capacity LiSVO-powered CRT-Ds in clinical use
 - 2 Ah LiMnO₂ battery CRT-Ds showed **100% survival after 6 years** (Boston Scientific, Group 1)
 - 1.4 Ah LiSVO battery CRT-Ds began to reach ERI after 2.5 years
 - **No devices remained in service by 7 years** (Medtronic, Group 2)
 - 1.875 Ah LiSVO battery CRT-Ds began to reach ERI after 2.8 years
 - **None were in service after 6 years** (St. Jude Medical, Group 3)
- Both battery chemistry and capacity appear to effect device longevity
- With the same budget, 64% more patients can be treated using the longest lasting devices studied compared to the shortest
- Selecting longer-lasting devices reduces healthcare resource under-utilization through device decommissioning from patient death

Life of Device Service (Device Survival Function for ERI)



This study agreed with the results of studies from Drs. Saba², Johansen³, Williams⁴, Ellis⁵ and Landolina's⁶ – Boston Scientific CRT-Ds are lasting significantly longer than Medtronic CRT-Ds.

Get the facts and cut the risk.

Boston Scientific ICDs and CRT-Ds with ENDURALIFE™ Battery Technology are designed to be the world's longest lasting — with up to 80% more battery capacity than other available models.⁷ Better defibrillator longevity could mean a reduced risk of exposure to complications and infections for your patients.^{8, 9, 10}

For more information, visit www.devicelongevity.com.

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PATIENT COHORT

All patients implanted (N=155) with a CRT-D at Royal Victorian Hospital in Belfast, Northern Ireland from 2008 through 2009. Medtronic = 62 patients, St. Jude = 66 patients, Boston Scientific = 27 patients.

PRIMARY ENDPOINTS

Device replacement for the battery reaching the elective replacement indicator (ERI).

PRINCIPAL INVESTIGATOR

Ernest Lau, M.D., Consultant Electrophysiologist at Royal Victoria Hospital, Belfast.

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1. Lau E, Wilson C, Ashfield K, McNair W, McEneaney 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. Alam MB, Munir MB, Rattan R, Flanigan S, Adelstein E, Jain S, Saba S. Battery longevity in cardiac resynchronization therapy implantable cardioverter defibrillators. *Europace* (2014) 16, 246-251. Kaplan Meier curves depicting survival of CRT devices free from battery depletion by device manufacturer. Battery Longevity in Cardiac Resynchronization Therapy Implantable Cardioverter Defibrillators is an independent, single-center, retrospective observational study comparing battery longevity of contemporary cardiac resynchronization therapy defibrillators (CRT-Ds) of all patients implanted with CRT-ICDs from January 1, 2008 to December 31, 2010 at University of Pittsburgh Medical Center hospitals. The initial study population included 746 patients: 94 were excluded at the onset because they were lost to follow-up within a month of implant, 6 others were excluded because they had a Biotronik CRT-D and that number of devices precludes meaningful comparison. Medtronic = 416 patients, Boston Scientific = 173 patients, St. Jude = 57 patients. Survival rate calculated using device replacements for battery depletion as indicated by ERI.
3. 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>. Device Longevity in Cardiac Resynchronization Therapy Implantable Cardioverter Defibrillators Differs Between Manufacturers was an independent, retrospective observational study comparing battery longevity of contemporary cardiac resynchronization therapy defibrillators (CRT-Ds) of all patients implanted with CRT-ICDs from January 1, 2007 to October 31, 2013 in Denmark. The initial study population included 2,793 patients: battery depletion or device failure was identified in 43 Medtronic, 4 Biotronik, 1 Boston Scientific and 33 St. Jude devices. Medtronic = 651 patients, Boston Scientific = 136 patients, St. Jude = 1,587 patients, Biotronik = 369. Time to exchange of the device because of battery depletion or device failure recorded in the Danish ICD Registry was the endpoint. Survival rate calculated using device replacements for battery depletion as indicated by ERI.
4. 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](http://www.onlinejcf.com/article/S1071-9164(14)00389-3/fulltext) Contemporary Cardiac Resynchronization Implantable Cardioverter Defibrillator Battery Longevity in a Community Hospital Heart Failure Cohort was an independent, retrospective observational study comparing battery longevity of contemporary cardiac resynchronization therapy defibrillators (CRT-Ds) of all patients implanted with CRT-ICDs from July 1, 2008, to October 31, 2010, at The Good Samaritan Hospital in Lebanon, PA. Medtronic = 28 patients, St. Jude = 10 patients, Boston Scientific = 53 patients.
5. C. Ellis, T. Markus, D. Dickerman, J. Orton, S. Hassan, E. Good, T. Okabe, A. Greenspon. 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](http://www.onlinejcf.com/article/S1071-9164(14)00337-6/fulltext) Ampere Hour (Ah) as a Predictor of CRT ICD Pulse Generator Battery Longevity is a multi-center, retrospective, observational study comparing battery longevity of contemporary cardiac resynchronization therapy defibrillators (CRT-Ds) of all patients implanted with CRT-ICDs from August 1, 2008, to December 31, 2010 at Vanderbilt University, Eastside Cardiovascular Medicine, University of Michigan, Thomas Jefferson University, Robert Wood Johnson University Hospital, Cooper Health System and North Ohio Research. Medtronic = 587 patients, St. Jude = 153 patients, Boston Scientific = 273 patients. Survival rate calculated using device replacements for battery depletion as indicated by ERI.
6. 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.
7. Boston Scientific ICDs and CRT-Ds with EnduraLife Battery Technology have 1.8 Ah. Medtronic ICDs and CRT-Ds both have 1.0 Ah.
8. de Bie, MK. et al. Cardiac Device Infections are Associated with a Significant Mortality Risk. *Heart Rhythm* 2012; 9:494-498.
9. Pfenninger Khan D. The Advisory Board Company, Re-focusing technology investments on cost effectiveness, long-term outcomes, Nov 2011. <http://www.advisory.com/Research/Cardiovascular-Roundtable/Cardiovascular-Rounds/2011/11/Refocusing-technology-investments-on-cost-effectiveness-long-term-outcomes>.
10. Ramachandra. Impact of ICD Battery Longevity on Need for Device Replacements. *PACE* 2010; 33:314-319.

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 \leq 35% and QRS duration \geq 120 ms
- Left bundle branch block (LBBB) with QRS \geq 130 ms, EF \leq 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 atrial tracking 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)*

CRT-D Systems from Boston Scientific – PUNCTUA™, ENERGEN™, and INCEPTA™

Indications and Usage

The PUNCTUA™, ENERGEN™, and INCEPTA™ 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 \leq 35% and QRS duration \geq 120 ms
- Left bundle branch block (LBBB) with QRS \geq 130 ms, EF \leq 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 external 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 atrial-tracking 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. 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.

Precautions

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

ICD Systems from Boston Scientific – PUNCTUA™, ENERGEN™, and INCEPTA™

ICD Indications and Usage

PUNCTUA™, ENERGEN™, and INCEPTA™ ICDs are intended to provide ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias.

Contraindications

Use of these ICD systems are contraindicated in: Patients whose ventricular tachyarrhythmias may have reversible cause, such as 1) digitalis intoxication, 2) electrolyte imbalance, 3) hypoxia, or 4) sepsis, or whose ventricular tachyarrhythmias have a transient cause, such as 1) acute myocardial infarction, 2) electrocution, or 3) drowning. Patients who have a unipolar pacemaker.

Warnings

Read the product labeling thoroughly before implanting the pulse generator to avoid damage to the ICD system. For single patient use only. Do not reuse, reprocess, or resterilize. Program the pulse generator ventricular Tachy Mode to Off during implant, explant or post-mortem procedures. Always have external defibrillator protection available during implant and electrophysiologic testing. Ensure that an external defibrillator and medical personnel skilled in cardiopulmonary resuscitation (CPR) are present during post-implant device testing. 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 to diathermy. Do not use atrial tracking modes in patients with chronic refractory atrial tachyarrhythmias. Do not use this pulse generator with another pulse generator. Do not kink, twist or braid lead with other leads. 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. 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.

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. Advise patients to avoid sources of electromagnetic interference (EMI).

Potential Adverse Events

Potential adverse events from implantation of the ICD 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, psychological intolerance to an ICD system – patients susceptible to frequent shocks despite antiarrhythmic medical management/imagined shocking, and component failure. In rare cases severe complications or device failures can occur.

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

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