Battery Longevity in Cardiac Resynchronization Therapy Implantable Cardioverter Defibrillators

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CRM-192506-AA-Oct2013

Introduction

- Cardiac resynchronization therapy (CRT) implantable cardioverter defibrillators (ICDs) are indicated for the management of heart failure patients with severe left ventricular (LV) systolic dysfunction and a wide QRS complex
- The benefit of CRT-ICDs depends upon achieving a high burden of ventricular pacing in both the right and left ventricles, with greater benefit seen at or near 100% biventricular pacing
- The need for nearly 100% biventricular pacing comprises of a significant battery drain and is usually the major determinant of battery longevity and thus of the time from device implant to the elective replacement indicator (ERI)

Introduction

- Cardiac resynchronization therapy-ICD pulse generator replacement is an invasive procedure with the potential risks of infection, bleeding, and damage to the implanted leads
- It is an expensive procedure, which along with the cost of a new device, contributes to rising healthcare costs
- Minimizing the frequency of CRT-ICD replacement for battery depletion is therefore desirable for both patients and the healthcare system as a whole
- Independent head-to-head comparisons for battery longevity for CRT-ICDs from various manufacturers are lacking

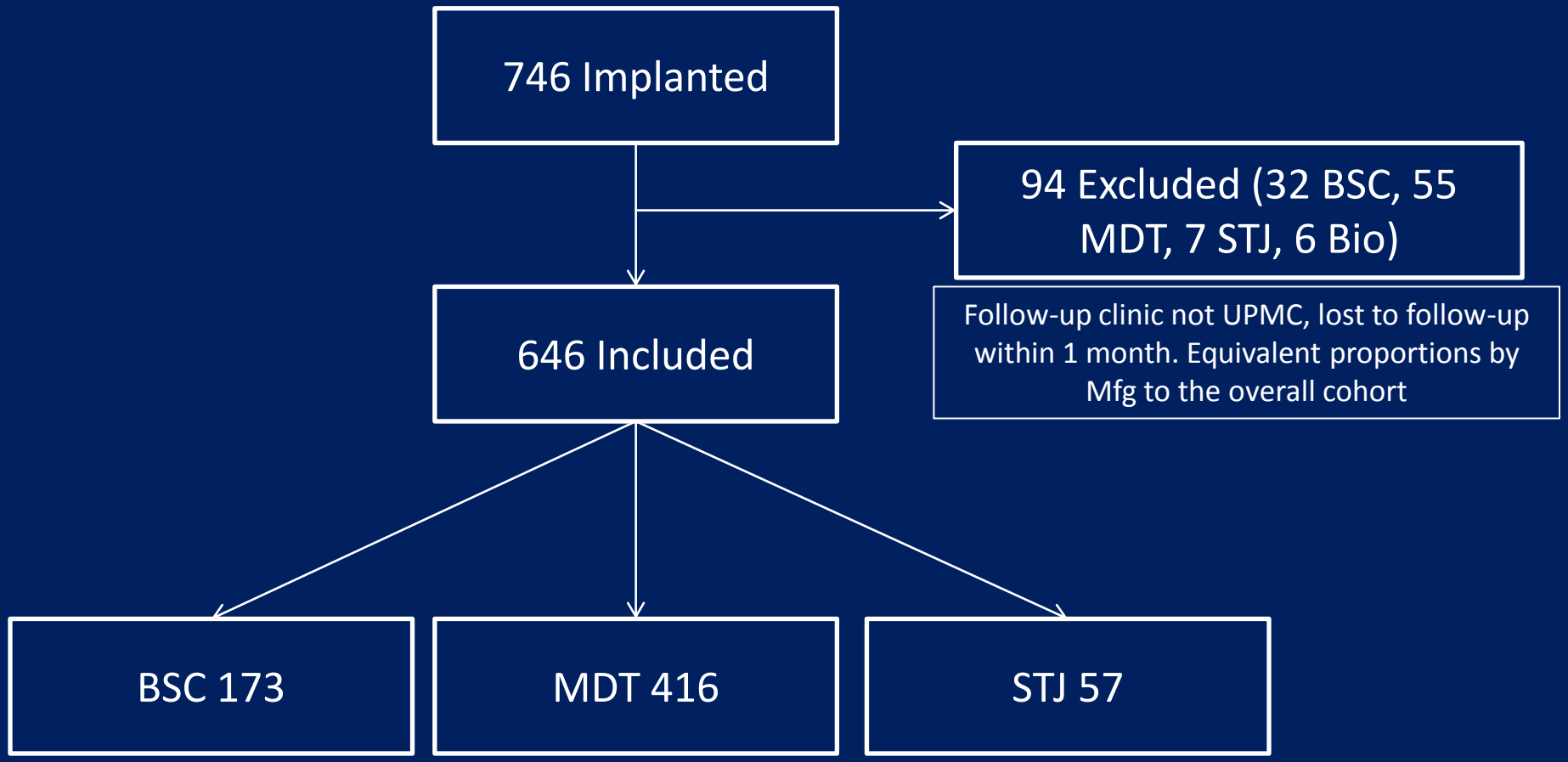
Rationale

We investigated the real-life battery longevity on CRT-D across different manufacturers, in a contemporary cohort of patients

Method

- All patients implanted with CRT-ICDs from January 1, 2008 to December 31, 2010 at the hospitals of the University of Pittsburgh Medical Center were included in this analysis.
- The primary endpoints of this analysis were the rate of battery depletion (reaching ERI) as well as the time from device implantation to battery depletion by device manufacturer.

Methods


746 Implanted
94 Excluded (32 BSC, 55 MDT, 7 STJ, 6 Bio)
Follow-up clinic not UPMC, lost to follow-up within 1 month. Equivalent proportions by Mfg to the overall cohort
646 Included
BSC 173
MDT 416
STJ 57

Baseline Characteristics

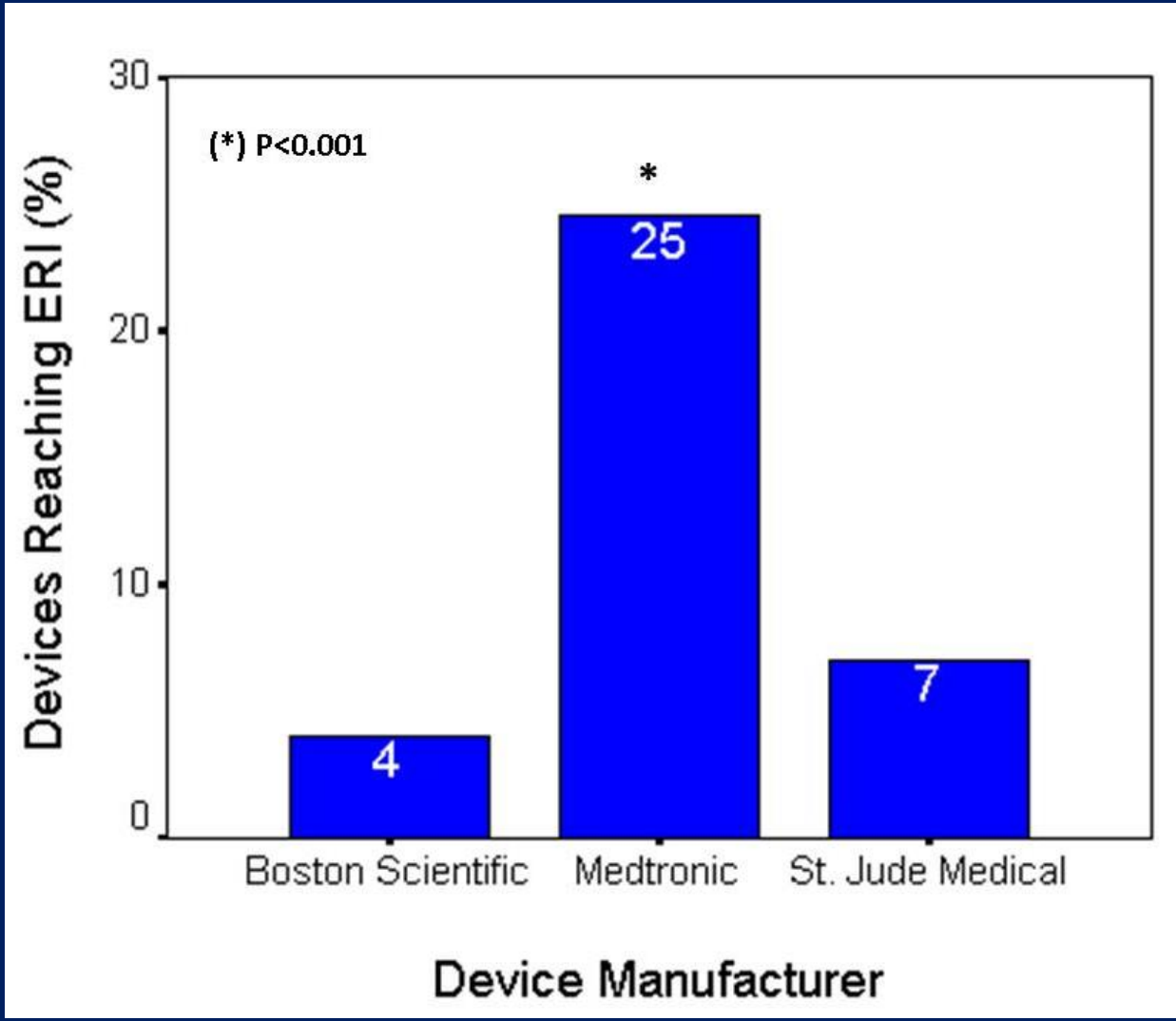
Variable	Overall Cohort	Boston Scientific	Medtronic	St. Jude Medical
N	646	173	416	57
Age (years)	69±13	70±12	69±13	70±13
Gender (female)	26%	20%	29%	21%
Coronary Artery Disease *	64%	70%	62%	61%
Diabetes Mellitus	34%	38%	33%	33%
Hypertension *	66%	69%	65%	70%
Left Ventricular Ejection Fraction (%)	29±12	28±12	30±13	29±10
Serum Creatinine (mg/dL) *	1.4±2.0	1.7±3.9	1.3±0.5	1.3±0.4
Heart Rate (beats per minute)	74±15	73±16	74±15	75±17
Paced QRS width (ms)	155±29	157±30	154±28	156±30
Follow-up time (years) • Mean • Median (IQR)	 2.7±1.6 3.1 (1.3 - 3.9)	 2.5±1.6 3.0 (0.9 - 3.9)	 2.7±1.5 3.1 (1.5 – 4.0)	 2.8±1.5 3.2 (1.6 – 4.1)

*P<0.05

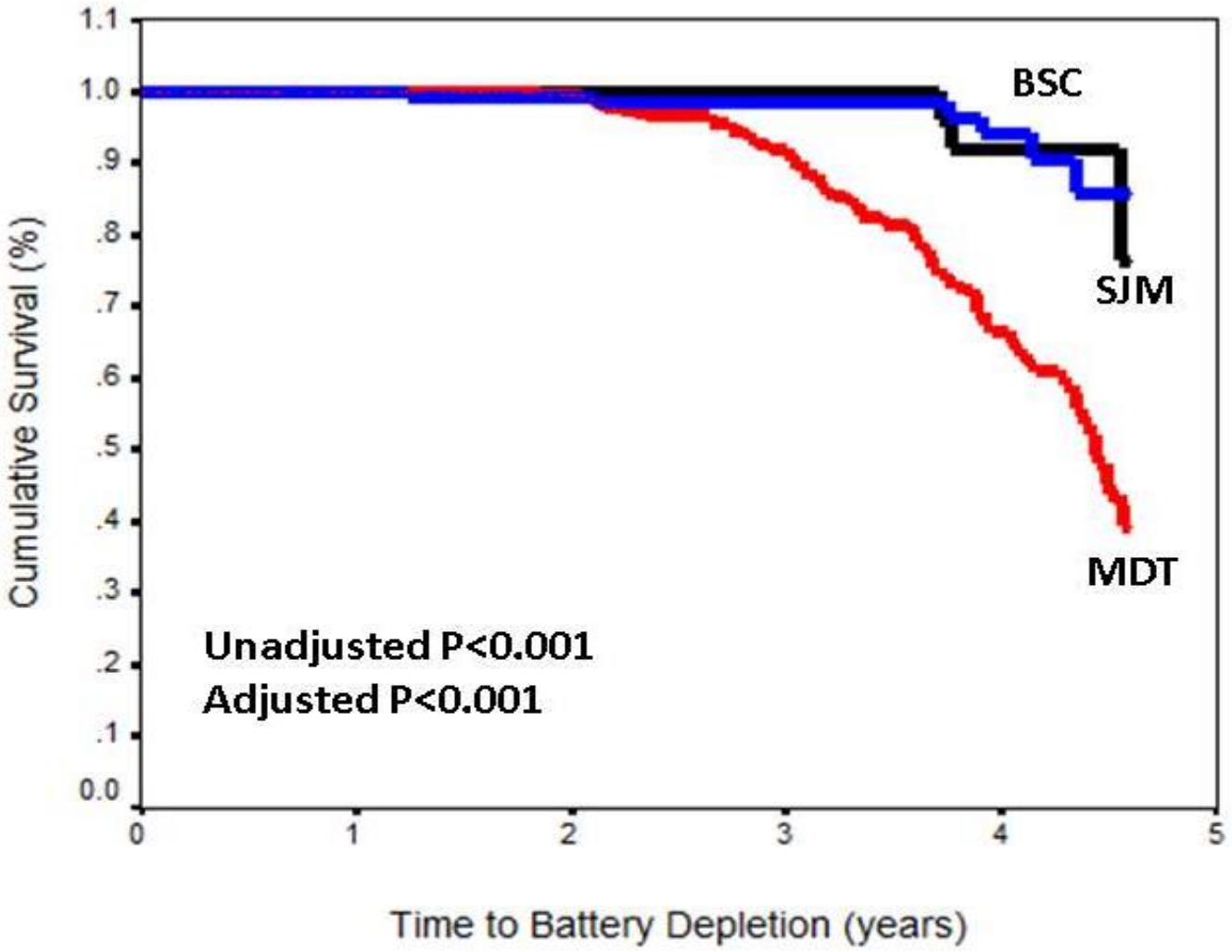
Devices reaching ERI

Manufacturer (N)	Device model (N)	Devices reaching ERI (N)	ERI N (%)	Follow-up time (years)
Boston Scientific (173)	H220 LIVIAN (16)		7 (4%)	2.5±1.6
	H225 LIVIAN (2)	H225 LIVIAN (1)		
	H227 LIVIAN HE (18)	H227 LIVIAN HE (4)		
	N118 COGNIS 100-D (22)			
	N119 COGNIS 100-D (100)	N119 COGNIS 100-D (2)		
	H210 Contak Renewal 3 RF (10)			
	H217 Contak Renewal 3 RF HE (3)			
	H219 Contak Renewal 3 RF HE (1)			
Medtronic (416)	8042 InSync III (6)		102 (25%)	2.8±1.5
	C154DWK Concerto (178)	C154DWK Concerto (41)		
	C154VWC Concerto (1)			
	D224TRK Consulta (227)	D224TRK Consulta (60)		
	D274TRK Concerto II (1)			
	D284TRK Maximo II CRT-D (3)	D284TRK Maximo II (1)		
St Jude Medical (57)	3207-30 (3)		4 (7%)	2.7±1.5
	3207-36 (37)	3207-30 (1)		
	CD3211-36 (14)	3207-36 (3)		
	CD3215-36Q (1)			
	3211-36 (1)			
	3211-36Q (1)			

Rate of Devices Reaching ERI by Manufacturer



Battery Depletion in CRT Defibrillators by Vendor



Boston Scientific	172	128	113	87	34
Medtronic	415	333	287	216	100
St. Jude Medical	56	45	39	31	15

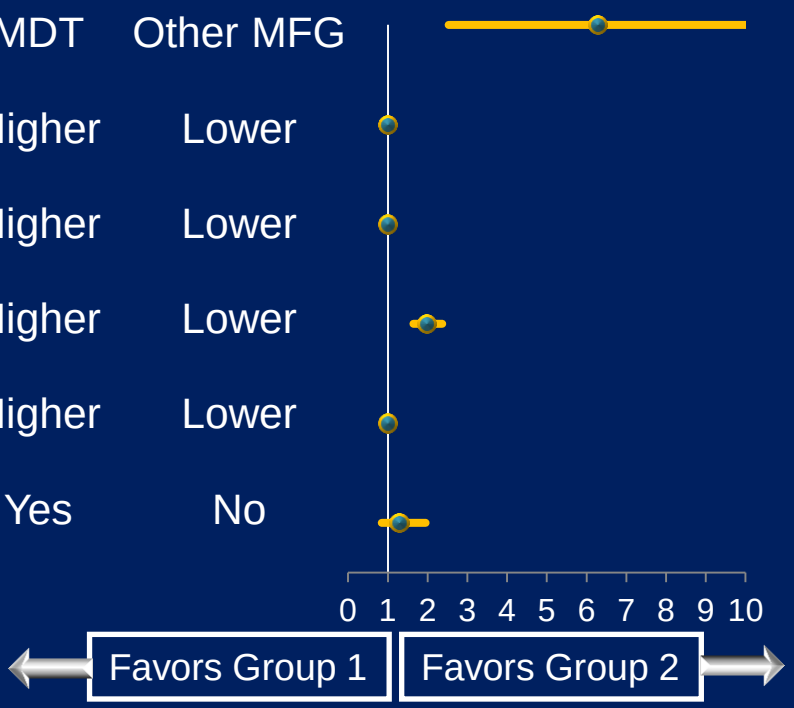
Device Usage Data

Variable	Boston Scientific	Medtronic	St. Jude
RA output (V)	2.6±0.7	2.6±0.9	2.6±0.6
RA Pulse width (ms)	0.49±0.04	0.49±0.11	0.50±0.14
RA Impedance (Ω) *	493±195	604±596	396±67
RA pacing burden (%)	21±33	25±34	20±29
RV output (V)	2.8±0.7	2.6±0.8	2.8±0.7
RV Pulse width (ms)	0.50±0.04	0.52±0.21	0.53±0.12
RV Impedance (Ω) *	511±116	503±181	446±93
RV pacing burden (%)	91±17	92±20	94±16
LV output (V) *	2.9±0.9	2.7±1.0	2.7±0.8
LV Pulse width (ms)	0.69±0.34	0.65±0.31	0.75±0.38
LV Impedance (Ω) *	663±243	587±287	565±190
LV pacing burden (%)	94±12	92±20	94±14
Pct of patients receiving any shocks including DFT testing (%) *	55	39	5.3
Proportion of patients receiving anti-tachycardia pacing (%) *	30	16	11

*P<0.05 for ANOVA comparison of the three manufacturers

Independent Predictors of Battery Longevity

Variable	Group 1	Group 2	Odds Ratio ± 95% CI	OR	95% CI	*P* value
Manufacturer	MDT	Other MFG		**6.27**	**2.53-15.52**	**<0.001**
RA impedance	Higher	Lower		1.00	1.00-1.00	0.762
RV impedance	Higher	Lower		1.00	0.99-1.00	0.786
LV Output	Higher	Lower		**1.97**	**1.64-2.37**	**<0.001**
LV Impedance	Higher	Lower		**1.00**	**0.99-1.00**	**0.036**
Shock	Yes	No		1.29	0.85-1.95	0.22



Discussion

- First head-to-head comparison of CRT-D battery performance using the hard endpoint of device replacement
- In contrast to earlier publications, includes only contemporary CRT-ICD models available in the USA and the rest of the world
- Battery longevity has direct implications on patient care and outcomes
- Shorter battery life requires more frequent device replacement, which increases healthcare costs
- Complications from device replacements for battery depletion are significant

Conclusions

- Our data demonstrate a large discrepancy in CRT-ICD battery longevity by device manufacturer in a contemporary cohort of patients with device models that are currently implanted in the USA and all over the world
- These findings have important implications for patient care. Other large, independent, cohorts of patients at other institutions may be needed to confirm these findings

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

• Left bundle branch block (LBBB) with QRS ≥ 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)