ICD Premature Battery Depletion Advisory Update — October 2018

Since the original October 11, 2016 communication, Abbott (formerly St. Jude Medical) has continued to analyze and review the performance data from the affected device population. The rates reported below summarize performance data through August 31, 2018.

Importantly, the information contained in this notice has not altered our previously communicated patient management recommendations. This information is designed to keep you informed of ongoing analysis of products returned to the company.

Rates

The table below summarizes the updated worldwide experience for the affected devices that were returned for product analysis due to premature battery depletion (PBD). We have included both confirmed and unconfirmed shorts in the table below. The table includes both the updated data through August 31, 2018, and data from the original (October 11, 2016) and periodic (May 31, 2018) communications.

Updated (through August 2018)

Worldwide Patient Impact	Number/Rate Original October 11, 2016	Number/Rate through May 31, 2018	Number/Rate through August 31, 2018
No Harm Reported/Additional Surgery Only*	792/0.20%	2,080/0.52%	3,281/0.82%
Loss of Pacing — Minor (Dizziness)	37/< 0.01%	51/0.01%	53/0.01%
Loss of Pacing — Major (Syncope)	10/< 0.01%	14/< 0.01%	16/< 0.01%
Loss of Defibrillation — Major/Emergency	0/0%	3/< 0.01%	3/< 0.01%
Loss of Defibrillation — Death	2/< 0.01%	2/< 0.01%	2/< 0.01%
Grand Total	**841/0.21%**	**2,150/0.54%**	**3,355/0.84%**

Total Units Sold	398,740

*All impacts in this table were related to a replacement surgery, as the data are from units explanted and returned for analysis. The category "No Harm Reported/Additional Surgery Only" means there was no associated report of patient symptoms in addition to the replacement of the affected unit.

Note: The calculation includes an increased number of investigations primarily associated with Battery Performance Alert notifications. These are reflected in the "No Harm Reported/Additional Surgery Only" category.

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Elective Replacement Interval (ERI) and End of Life (EOL) Analysis Update

Worldwide ERI to EOL Impact Table

The following table represents the analysis results of the time interval between ERI and EOL for devices returned to Abbott for analysis where premature battery depletion was determined, no electronic or other assignable cause was found, battery testing found lithium clusters and the battery voltage was sufficient to allow retrieval of device diagnostic data. Of the 3,355 units returned to Abbott as of the date of analysis, 1,046 units met the above criteria.

ERI to EOL Duration (for Returned Units with Lithium Cluster PBD and Device Retrievable Data)**	Number of Units
ERI detected; patient notifier alert was triggered	1,032/98.66%
≤ 1 day; patient notifier alert was triggered	153
> 1 day and ≤ 10 days; patient notifier alert was triggered	162
> 10 days and ≤ 30 days; patient notifier alert was triggered	96
> 30 days; patient notifier alert was triggered	56
Above EOL, therefore ERI to EOL duration not applicable; patient notifier alert was triggered if ERI was reached	565
ERI not detected; patient notifier alert was not triggered, but was below ERI threshold of 2.59 V	14/1.34%

Total Number of Units	1,046
Total Units Sold	398,740

**Our intent is to provide these data to help explain the statement "battery depletion can occur in these devices within a day to a few weeks, which may result in the inability to deliver therapy" in the original field advisory notification.

These data are provided for information only and should not be used to make specific patient management decisions that would depart from recommendations previously communicated by the company. The patient management recommendations in the original advisory letter remain applicable.

The number of units in each of the groups above is not a predictor of future performance of a specific unit currently implanted.

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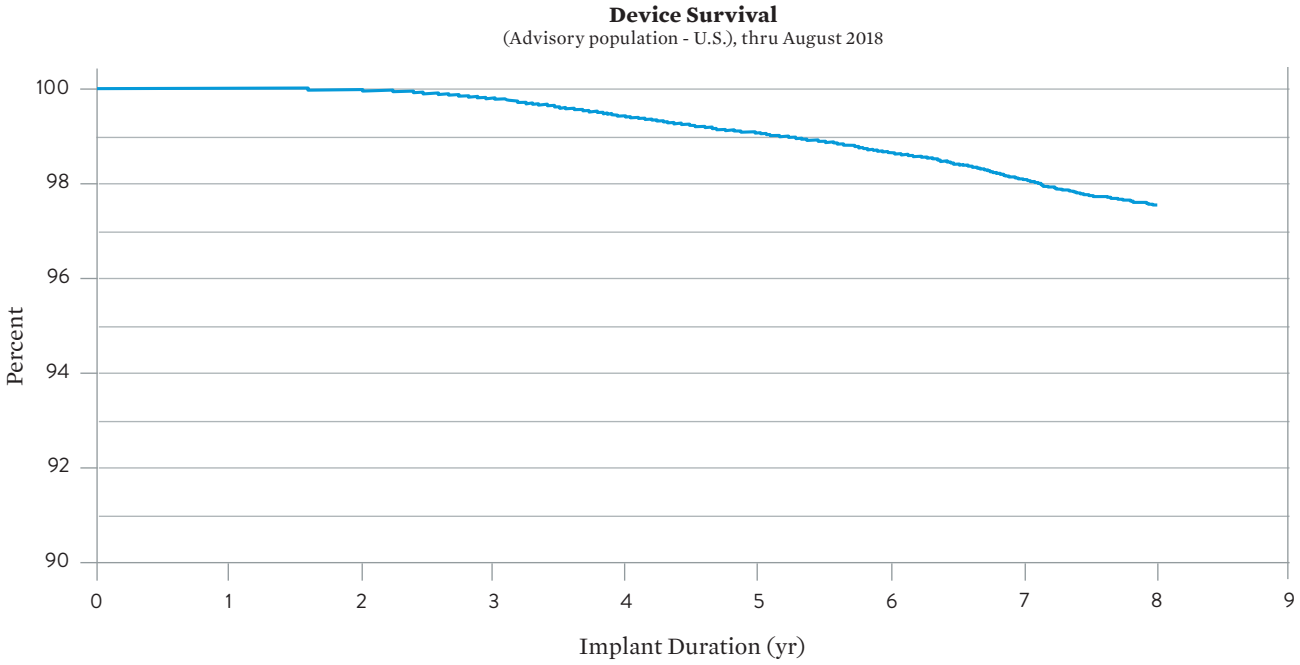
Estimated Performance of Affected Fortify™ Implantable Cardioverter Defibrillator (ICD), Fortify Assura™ ICD, Quadra Assura™ Cardiac Resynchronization Therapy Defibrillator (CRT-D), Unify™ CRT-D, Unify Assura™ CRT-D and Unify Quadra™ CRT-D Devices

Eight-year combined Kaplan-Meier survival curve of freedom from premature battery depletion associated with lithium deposits in affected U.S. Advisory device population



UNIFY™ CRT-D/FORTIFY™ ICD/UNIFY ASSURA™ CRT-D								
Year	1	2	3	4	5	6	7	8
Survival Probability	99.999%	99.977%	99.781%	99.408%	99.061%	98.636%	98.057%	97.532%
Sample Size	224,000	209,000	190,000	144,000	101,000	65,000	30,900	4,900

Survival Calculation General Methods

Internal modeling based on an analysis of field returns related to premature battery depletions associated with lithium clusters; updated with data through August 31, 2018

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St. Jude Medical is now Abbott.

Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

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