ICD Premature Battery Depletion Advisory Update – July 2018

Since the original October 11, 2016 communication Abbott (formerly St. Jude Medical) has continued to analyze and review performance data from the affected device population. The rates reported below summarize performance data through May 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 affected 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. We have included both confirmed and unconfirmed shorts in the table below. The table includes both the updated data through May 31, 2018 and data from the original (October 11, 2016) and periodic (February 28, 2018) communication.

Updated (through May 2018)

Worldwide Patient Impact	Number/Rate Original October 11, 2016	Number/Rate Through February 28, 2018	Number/Rate Through May 31, 2018
No Impact Reported/Additional Surgery Only*	792/0.20%	1461/0.37%	2,080/0.52%
Loss of Pacing – Minor (Dizziness)	37/< 0.01%	50/0.01%	51/0.01%
Loss of Pacing – Major (Syncope)	10/< 0.01%	13/< 0.01%	14/< 0.01%
Loss of Defibrillation – 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%	1529 / 0.38%	2,150/0.54%

Total Units Sold	398,740

*All impacts in this table were related to a replacement surgery, as the data is from units explanted and returned for analysis. The category "No Impact 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 (BPA) notifications. These are reflected within the '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 diagnostics data. Of the 2,150 units returned to Abbott as of the date of analysis, 947 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 alert delivered	933/98.52%
< = 1 day; patient notifier alert was triggered	142
> 1 and < = 10 days patient notifier alert was triggered	158
> 10 and < = 30 days patient notifier alert was triggered	94
> 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	483
ERI not detected, patient alert was not delivered, but below ERI threshold of 2.59V	14/1.48%

Total Number of Units	947
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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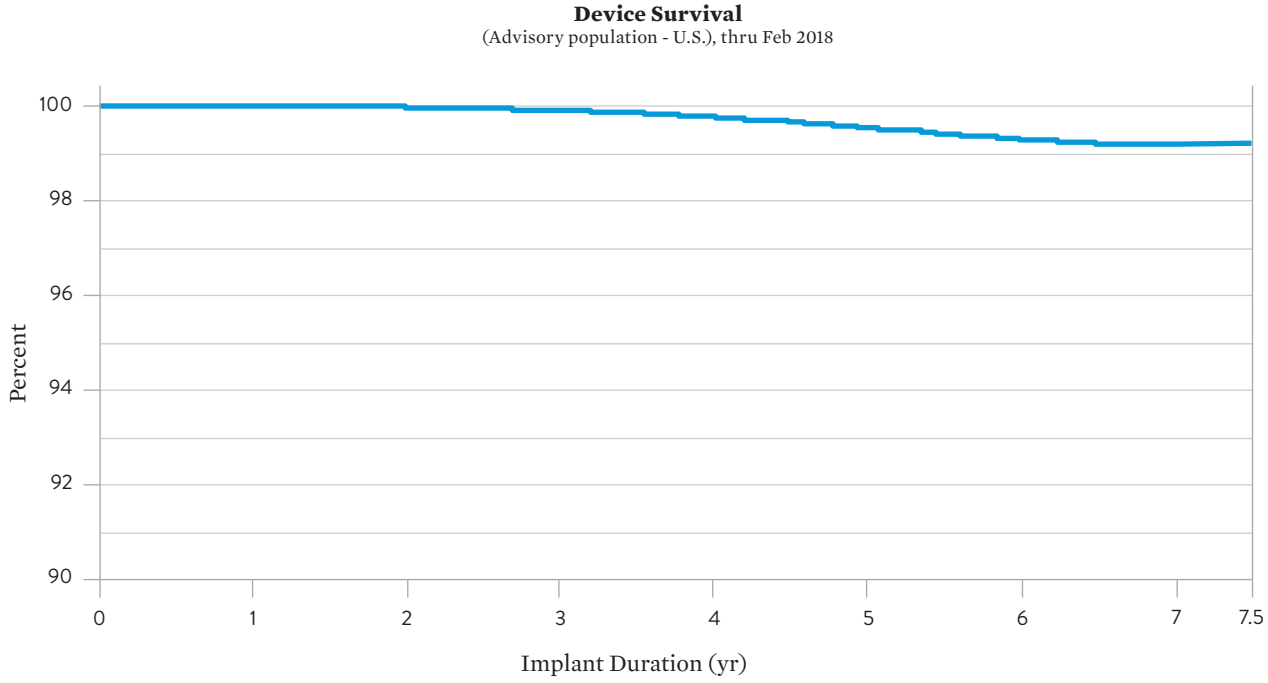
Estimated Performance of Affected Fortify™, Fortify Assura™, Quadra Assura™, Unify™, Unify Assura™ and Unify Quadra™ Devices

Seven-year combined Kaplan-Meier (KM) survival curve of freedom from premature battery depletion associated with Li deposits in affected device population.



UNIFY/FORTIFY/ASSURA								
Year	1	2	3	4	5	6	7	7.5
Survival Probability	99.999%	99.977%	99.872%	99.702%	99.509%	99.240%	99.016%	98.969%
Sample Size	~224,000	~208,000	~173,000	~126,000	~85,000	~49,000	~15,000	~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 February 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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