

Dear Colleague,

I wanted to write to provide an update regarding the ICD premature battery depletion global medical device advisory we implemented on October 11, 2016.

As you know, our company has worked to continue to better understand the issue as new information has become available and has continued to analyze returned product to provide our customers the most accurate information available.

### **Updated Product Performance Data**

Since our initial communication to our customers and patients in October 2016, we have worked to provide consistent updates to our global customers around ongoing analysis of performance data from the affected device population.

Recently Abbott and our Medical Advisory Board analyzed data from affected devices that were returned for product analysis due to premature battery depletion.

Importantly, rates of patient impact remain low and to date, adverse event rates have shown no indication of acceleration.

The updated information is as follows:

#### **Updated (through May 31, 2017)**

Worldwide Patient Impact	Number/Rate Original October 11, 2016	Number/Rate Through May 31, 2017
No Impact Reported/Additional Surgery Only*	792/0.20%	1098/0.28%
Loss of Pacing – Minor (Dizziness)	37/< 0.01%	45/0.01%
Loss of Pacing – Major (Syncope)	10/< 0.01%	11/< 0.01%
Loss of Defibrillation – Emergency	0/0%	2/< 0.01%
Loss of Defibrillation – Death	2 /< 0.01%	2/< 0.01%
Grand Total	841/0.21%	1158/0.29%

Total Units Sold	398,740
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\*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 unit with a depleted battery.

### **A Review of Patient Management Recommendations**

In addition, we wish to remind physicians caring for patients with affected devices of the recommendations developed in consultation with our Medical Advisory Board and outlined in our communication on October 11, 2016.

These recommendations have not changed and are as follows:

- **Do not implant unused affected devices.**
- **Conduct patient follow-up per standard practice.**
- **Prophylactic device replacement is NOT recommended** because complications following replacement have been reported to occur at a greater rate than the rate of harm associated with premature battery depletion due to lithium cluster induced shorts (see appendix for selected references).
- **In the event of an ERI indicator in these devices, immediate device change is recommended.** At this time there is no factor, method or test to identify devices with this form of premature battery depletion approaching ERI or to accurately predict remaining battery life once ERI appears.
- Physicians should reaffirm the availability of home monitoring to avoid or minimize time without device therapy for bradycardia and tachycardia events.
- **Enroll patients in Merlin.net utilizing the “Direct Alerts” feature** to provide you with an immediate alert notification in the event ERI is reached. For patients currently enrolled in Merlin.net, remind them of the importance of using remote monitoring.
- **Review the most recent Programmed Parameters printout** (see attached for an example).
  - Ensure that under the “Trigger Alerts When” section, that the “Device at ERI” parameter is ON (it is normally ON) for both “Show on FastPath” and “Notify Patient” selections.
  - If the “Device at ERI” alert is OFF, we recommend that the patient be seen promptly to program this parameter ON.
- **Advise patients that an ERI indication triggers a vibratory alert.** At the next scheduled office visit:
  - Interrogate the patient’s device to determine if an ERI alert has been triggered. Premature battery depletion can be identified by physicians through home monitoring showing ERI or more advanced battery depletion.
  - Perform a patient notifier test to confirm that the patient feels and recognizes the vibratory alert.
  - Patients who cannot feel the vibratory alert may experience loss of battery and/or loss of device function without their awareness.
  - Advise the patient to contact your office promptly should they feel a vibratory alert.
    - In-office evaluation should be performed to determine the reason for the alert as other non-critical events can also trigger a vibratory alert.

We understand the impact this advisory has on our customers and their patients, and we are committed to providing timely battery performance data updates in order that you can make good decisions for your patients.

As you may know our Development team has been evaluating patterns in battery voltage measurements that indicate abnormal battery performance that could lead to premature battery depletion.

We hope to use the information to provide earlier notification of devices that may experience premature battery depletion. We will provide an update as more information becomes available.

For the latest information on this advisory and updated performance data, please visit:  
<https://www.sjm.com/en/professionals/resources-and-reimbursement/technical-resources/product-advisories-archive>

Sincerely,

**Mark Carlson, M.D.**  
Chief Medical Officer and Division Vice President