

## Important Medical Device Advisory

**Dear St. Jude Medical Patient:**

### **What you need to know:**

St. Jude Medical recently announced a global medical device advisory for a subset of our company's Fortify™, Fortify Assura™, Quadra Assura™, Unify™, Unify Assura™ and Unify Quadra™ implantable cardiac defibrillator (ICD) and cardiac resynchronization therapy defibrillator (CRT-D) devices. This advisory was implemented after an analysis found that some devices manufactured prior to May 2015 contain batteries which may run out of energy earlier than expected. This is termed: "**Premature Battery Depletion**".

### **Hospital records indicate that you have a device made prior to May 2015.**

The likelihood that this will impact your health is low, as the vast majority of devices have not experienced Premature Battery Depletion.

Currently, 841 devices returned to SJM out of 398,740 (0.21%) devices sold worldwide that are subject to this advisory have demonstrated batteries that have run out of energy earlier than expected. Note that, in general, complaints made to SJM are sometimes underreported and that this rate may change.

The cause for Premature Battery Depletion is attributed to the formation of lithium clusters within the battery causing a short circuit. There is a possibility that affected devices may lose battery power within days. Thus far, there have been two (2) deaths and ten (10) serious events (fainting) that may have been associated with premature battery depletion.

### **What we have done:**

In order to ensure your safety and help you determine next steps with your doctor, we are providing you with this notice. In addition, we have informed your doctor who manages your St. Jude Medical device. A dedicated website has been set up to provide you with current information on this advisory:

**[www.sjm.com/batteryadvisory](http://www.sjm.com/batteryadvisory)**

If you have any questions, please contact the hospital in-clinic follow up center to which you are assigned.

## What you need to do:

You play an important part in knowing if your device has been affected by Premature Battery Depletion.

- 1. At-Home Monitoring** - You may know that St. Jude Medical devices are capable of remote monitoring. This is a proven method of proactively monitoring devices without the need for an in-person office visit. If you do not already utilize remote monitoring for your device, **your physician may soon discuss using Merlin@Home** with you if they feel it is appropriate. Patients can also visit <https://www.sjm.com/en/patients/arrhythmias/our-solutions/remote-monitoring>.
- 2. Vibratory Alert** - Your device is designed to deliver a vibratory alert to you when the battery is nearing its end of life. The device also delivers a notification to your physician with Merlin@Home or during a doctor visit. Your physician may have helped you experience a test alert to ensure you know what this alert feels like. **If you experience a vibratory alert, we recommend that you contact your doctor promptly.**
- 3. It is important for you to understand that if your device is not experiencing Premature Battery Depletion**, replacing your device is **NOT** recommended by St. Jude Medical or our medical advisory board. We are advising physicians on the recommended follow-up of devices subject to this advisory. Your doctor will determine the best course of action with you.

We sincerely apologize for any difficulties this current issue causes you or your caregivers. We take this matter very seriously. Please know that we are available to assist you if you are having problems with your device.

Sincerely,



Jeff Fecho  
VP, Global Quality