

IMPORTANT MEDICAL INFORMATIONSt. Jude Medical
Ellipse™ Implantable Cardioverter Defibrillators (ICDs)

Dear St. Jude Medical Patient:

St. Jude Medical is committed to keeping you and your doctor informed of all important product information. As such, St. Jude Medical recently provided doctors with important information about our Ellipse family of ICDs, model numbers CD1309, CD1311, CD1409, CD1411, CD2277, CD2309, CD2311, CD2409, and CD2411 (all -36, -36Q, -36C and -36QC suffixes).

As you know, your ICD is a medical device that can provide defibrillation therapy should you need it. We have informed doctors who manage patients with these Ellipse families of ICDs that an anomaly with a component (capacitor) has been identified in a small percentage of patients' devices. This information applies only to these specific models of Ellipse ICDs identified above. No other St. Jude Medical products are affected by this issue.

If this anomaly were to occur, by design, the ICD's internal patient notifier would vibrate giving you an indication that you should contact your physician. In addition, upon interrogation with a programmer in your physician's office or clinic, or with a transmission from the Merlin@home™ remote monitoring system, your physician would be notified with an alert message. We encourage you to speak with your doctor's office about any specific questions or concerns you may have at your next scheduled office or clinic visit if you have not already heard from them regarding this matter. The information we have provided to doctors is more detailed since they are in the best position to know how to manage your individual care.

We sincerely apologize for any concern that this may cause you or your family. We are dedicated to providing the most reliable medical products for doctors and patients and deeply regret when an issue such as this happens. We are committed to helping doctors manage this issue by continuing to provide them with all the latest information and necessary support.

Sincerely,



Mark Carlson, MD
Vice President, Global Clinical Affairs
and Chief Medical Officer



Jeff Fecho
Vice President, Global Quality