April 14, 2016

Canadian Heart Rhythm Society
Device Committee

RE: Advisory: 37 Units of Ellipse™ Implantable Cardioverter Defibrillator (None in Canada)
Models Affected:
CD1411-36Q / CD2411-36C / CD2377-36QC
CD1411-36C / CD1377-36QC / CD2377-36C
CD2411-36Q / CD1377-36C

Nature of the Advisory:

St-Jude medical has issued an advisory for some Ellipse devices. *"The recall is the result of findings from a routine electrical evaluation at final manufacturing test …, in which St. Jude Medical identified that a small number of devices had experienced test errors. An investigation revealed that patient notifier components from a specific component lot were slightly larger in thickness than components used previously. This variation could result in damage to the insulation on the ICD's high voltage capacitor, which could in turn result in a limited number of Ellipse ICD devices being unable to deliver high voltage therapy."*

Scope of the problem:

Thirty seven units were identified. None in Canada.

Response of the CHRS Device Committee:

- No affected units were imported or distributed in Canada. There is no impact for Canadian patients at this time
- The CHRS device committee will follow with St-Jude Medical to monitor this issue
- No other action for the time being

François Philippon, MD, FRCPC, FHRS
Chair
Device Committee, CHRS

CONFIDENTIAL

ST. JUDE MEDICAL

Holding Statement:

St. Jude Medical can confirm a global recall related to it's Ellipse ICD that impacts 37 patients worldwide. All physicians managing those patients have been notified. There have been no serious injuries or patient deaths reported to the company associated with this issue. However, due to the potential for the impacted Ellipse ICD devices being unable to deliver appropriate high voltage therapy, the company has recommended all 37 patients receive a new device. St. Jude Medical will supply a replacement device at no charge and reimburse costs associated with the procedure.

Additional Background:

The recall is the result of findings from a routine electrical evaluation at final manufacturing test of our Ellipse devices, in which St. Jude Medical identified that a small number of devices had experienced test errors.

An investigation revealed that patient notifier components from a specific component lot were slightly larger in thickness than components used previously. This variation could result in damage to the insulation on the ICD's high voltage capacitor, which could in turn result in a limited number of Ellipse ICD devices being unable to deliver high voltage therapy.

In addition, all non-implanted Ellipse ICDs subject to this recall previously distributed have been accounted for and removed from the market.

Messaging:

1. **St. Jude Medical has quickly and proactively communicated with physicians managing 37 patients worldwide who have received an Ellipse ICD subject to a recall.**
    - The recall is limited in scope.
    - The recall is a result of a sizing variation in a limited batch of patient notifier components that could result in damage to the insulation on the ICD's high voltage capacitor. This potential damage could in turn result in the ICD being unable to deliver high voltage therapy.
    - The company has communicated with our regulatory partners in all impacted markets.

2. **There have been no serious injuries or patient deaths reported to the company associated with this issue.**

3. **In consultation with our Medical Advisory Board, the company has recommended each patient receive a new ICD device.**
    - St. Jude Medical will supply a replacement device at no charge and reimburse costs associated with the procedure.

4. **Patient safety is our highest priority. We have worked quickly to inform physicians about this situation so that they can best manage their patients.**
    - In addition, as part of our commitment to maintaining the highest standards of quality, we have carefully assessed our internal processes to help ensure we meet or exceed our customer's' expectations regarding the quality and safety of our products.

ST. JUDE MEDICAL

Important Medical Device Advisory

37 Units of Ellipse™ Implantable Cardioverter Defibrillator

Models Affected:

CD1411-36Q	**CD2411-36C**	**CD2377-36QC**
CD1411-36C	**CD1377-36QC**	**CD2377-36C**
CD2411-36Q	**CD1377-36C**	

See the Below List of Affected Serial Numbers

April 6, 2016

Dear {Doctor-Name},

This letter provides you with important information related to 37 implanted units of our Ellipse ICD device worldwide, which are subject to a global recall due to the potential inability to deliver high voltage therapy. There have been no serious injuries or patient deaths reported to the company associated with this issue. All remaining non-implanted affected devices that were previously distributed have been accounted for and removed from the market.

Our records indicate that you are providing care for {X} of the total 37 implanted patients globally. The table below provides the specific information for the devices impacted:

Model Number	Serial Number

Recommendations:

St. Jude Medical recommends that all patients who have been implanted with devices from this affected population receive a new non-affected device as soon as possible. St. Jude Medical will supply a replacement device at no charge and reimburse costs associated with the procedure.

Summary of Issue:

Through routine electrical evaluation at final manufacturing test of our Ellipse Devices, St. Jude Medical identified that a small number of devices experienced test errors. An investigation was

immediately initiated, and it was discovered that the patient notifier components in a specific component lot were slightly larger in thickness than previously used components. We have determined that during manufacturing assembly Patient Notifiers from this component lot can damage the Parylene coating (insulation) on the High-Voltage Capacitor and that slight shifting of internal components, such as during simulated shipping conditions, could cause narrowing of the distance between these two adjacent components resulting in electrical current leakage or arc between the High-Voltage Capacitor and the Patient Notifier and result in the inability to deliver high voltage therapy.

There have been no serious injuries or patient deaths reported to St. Jude Medical as a result of this issue. As a result of our internal investigation, and in consultation with our medical advisory board, we determined that due to the circumstances described above, all devices from this group should be considered to have the potential to experience an electrical arc or short.

If you have any questions about this advisory, please contact your local Sales Representative or St. Jude Medical Technical Services at [Insert appropriate toll free international number], which is available 24 hours a day, seven days a week.

Patient safety is our highest priority. We have worked quickly to inform physicians about this situation so that they can best manage their patients. In addition, and as part of our commitment to maintaining the highest standards of quality, we have also carefully assessed our internal processes to help ensure we meet or exceed your expectations regarding the quality and safety of our products.

Yours Sincerely,

Jeff Fecho
Vice President, Global Quality