HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

# Safety Notice

## Medical Devices

## Implantable Cardioverter Defibrillator:

### St. Jude Medical Fortify™, Fortify Assura™, Quadra Assura™, Quadra Assura MP™, Unify™, Unify Assura™ and Unify Quadra™


## Priority 1 – For Immediate Action

**HPRA Safety Notice: SN201633** **Issue Date: 13 Oct 2016**

| MANUFACTURER / SUPPLIER | HPRA CASE REFERENCE |
|---|---|
| St. Jude Medical | V29552 |

| ISSUE |
|---|
| The HPRA has been advised by St. Jude Medical that there is a risk of premature battery depletion associated with St. Jude Medical Fortify™, Fortify Assura™, Quadra Assura™, Quadra Assura MP™, Unify™, Unify Assura™ and Unify Quadra™ ICD and CRT-D devices manufactured before May 23, 2015.<br><br>St. Jude Medical advised that 398,740 devices have been sold worldwide and that 841 devices that were returned for analysis, due to premature battery depletion, have had evidence of lithium material in the form of "clusters" in the battery. Forty-six (46) exhibited visible clusters bridging the cathode and anode causing shorting. Lithium cluster formation is a known phenomenon with this type of battery. |

## ACTION OR RECOMMENDATIONS

**The HPRA advises that users:**

1. Immediately examine your stock and quarantine affected devices. **Do not implant** unused affected devices.
2. Follow all the actions outlined by the manufacturer in the accompanying field safety notice (FSN).
3. Conduct patient follow-up and patient monitoring as per your local standard practice, taking into account the information provided in relation to the FSN section titled 'Mode and Identification of Premature Battery Failure'.
4. Review the most recent Programmed Parameters printout
5. Advise patients that an ERI indication triggers a vibratory alert.
6. In the event of an ERI indicator in these devices, demonstrating premature battery depletion, immediate device change is recommended.
7. Forward a copy of the manufacturer's FSN to all those who need to be aware of it within your organisation.
8. Forward a copy of the FSN to any other organisations to whom affected devices have been transferred.
9. Forward a copy of this HPRA Safety Notice to all relevant personnel.
10. Report any adverse events / incidents associated with these devices to the manufacturer and the HPRA.

## TARGET GROUPS

| | |
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| Cardiac pacemaker/ICD technicians | Medical Directors |
| Cardiologists in pacing and electrophysiology | Nursing Staff |
| Clinical Engineers / Biomedical Engineers | Private Hospital Staff |
| HSE Hospital Staff | Purchasing / Procurement / Material Managers |
| Hospital Managers | Risk Managers |
| Healthcare professionals who use these devices | Surgeons |
| | Supplies Managers |
| | Theatres |

## BACKGROUND

St. Jude Medical confirmed that there have been 2 deaths that have been associated with the loss of defibrillation therapy as a result of premature battery depletion.

St. Jude Medical have indicated that a precise estimate of the rate of premature battery failure is difficult to obtain due to potential underreporting of battery depletion in general and battery depletion which may be due to this failure mode but not recognized.
841 returned devices (0.21%) of 398,740 devices worldwide have premature depletion in association with lithium clusters inducing short circuits. Forty-six (46) devices worldwide had visible electrical shorting due to lithium clusters. At this time 349,852 affected devices are still in service worldwide and, therefore, potentially at risk.

St. Jude Medical advised that high voltage devices (ICDs and CRT-Ds) that utilize Lithium-based battery chemistries are subject to Lithium cluster formation during high voltage charging. Depending on their location, Lithium clusters may cause a short circuit that can lead to premature battery depletion. St. Jude Medical's investigation indicates that if a short circuit occurs, battery depletion can occur in these devices within a day to a few weeks, which may result in the inability to deliver therapy.

The HPRA is issuing this safety notice to raise awareness of this FSN.

## MANUFACTURER / AUTHORISED REPRESENTATIVE/ DISTRIBUTOR CONTACT INFORMATION

Enquiries to the **manufacturer** should be addressed to:


Vicki Snow
St. Jude Medical (UK) Ltd
Capulet House, Banbury Road
Stratford-upon-Avon
CV37 7GX
Great Britain

Telephone: +44 (0) 1789 207 637
Fax: +44 (0)1789 207601
E-mail: VSnow@sjm.com
Website:


## HPRA CONTACT INFORMATION

All **adverse incidents** relating to a medical device should be reported to:


Health Products Regulatory Authority
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2

Telephone: +353-1-6764971
Fax: +353-1-6344033
E-mail: devicesafety@hpra.ie
Website: www.hpra.ie