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Urgent Field Safety Notice

EnTrust VR/DR/AT ICDs

IMPORTANT MEDICAL DEVICE INFORMATION

Medtronic ref : FA541

March 2012

Dear Doctor,

Medtronic is advising you that a small percentage of EnTrust ICDs may not meet expected longevity or provide at least three months of device operation between the Elective Replacement Indicator (ERI) and End of Life (EOL) due to a more-rapid-than expected drop in battery voltage. An estimated 39,000 EnTrust ICDs are currently implanted worldwide. No patient deaths or serious injuries have been reported as a result of this issue.

The reported events have involved a drop in battery voltage from ~3.0 V to ERI (2.61 V) over a time period ranging from approximately one week to six months. All reported events have occurred at least 30 months after implant. Medtronic has confirmed nine reports of charge circuit time out during automatic capacitor formations and one report of loss of pacing, all occurring between ERI and device explant. Although the potential exists for loss of high voltage therapy between ERI and device explant, this has not been reported to date.

Medtronic has identified the cause of these occurrences to be an internal battery short that develops as the battery capacity is consumed. As of February 20, 2012, reported events for this issue include 44 (0.15%) single chamber (VR) and 16 (0.04%) dual chamber (DR/AT) devices. The current failure rate is low; however, there is uncertainty in projecting future performance. We are committed to providing you with ongoing updates in our Product Performance Report, available at: http://wwwp.medtronic.com/productperformance/.

After consultation with Medtronic's Independent Physician Quality Panel, Medtronic offers the following patient management recommendations:

- Physicians should continue routine follow-up sessions at least every three months in accordance with product labeling.
- Physicians should program the audible patient alerts for "Low Battery Voltage ERI" and "Excessive Charge Time EOL" to ON
- Physicians should replace devices promptly after they reach ERI if the decline in voltage is more rapid than expected.
- Prophylactic replacement of EnTrust ICDs is not recommended.

Attached are the specific model and serial numbers of affected devices that were shipped your facility.

The Medicines and Healthcare products Regulatory Agency (MHRA) has been informed of this action.

We regret any difficulties this may cause you and your patients. If you have any questions, or if we can be of assistance, please contact your local Medtronic Representative on 01923 212 213 or Medtronic Technical Services on 08702 403 304.

Yours sincerely

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