Medtronic, Inc.
8200 Coral Sea Street NE
Mounds View, MN 55112
www.medtronic.com

URGENT: MEDICAL DEVICE CORRECTION

EnTrust® VR/DR/AT ICDs

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. Medtronic is also communicating this information to the appropriate regulatory agencies.

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) devices 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 you are following according to our device registration records. 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 or Medtronic Technical Services at 800-723-4636.

Sincerely,

Tim Samsel
Vice President, Quality and Regulatory
Medtronic Cardiac Rhythm Disease Management

Medtronic encourages health care professionals and consumers to report any serious adverse effects with the use of any of our products by calling Medtronic Technical Services at 800-723-4636 and FDA's MedWatch Adverse Reporting program online or at 1-800-332-1088.

PHYSICIAN DEVICE ADVISORY NOTICE

Advisory Date: March 2012

Manufacturer	Medtronic Inc.	
Products Implantable Cardioverter Defibrillator (ICD)	***Trade Name*** EnTrust	***Model Number*** **Entrust® Devices:** D153ATG, D153DRG, D153VRC, D154ATG, D154DRG, D154VRC
Market released manufactured on or before (date)	U.S. release: June 2005	
Performance Failure	Specific battery issues: - Reduced longevity - 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.	
Root Cause (if known)	Medtronic has identified the cause of this issue to be an internal battery short that develops as the battery capacity is consumed.	
Date Manufacturer Corrected Product Available (if known)	NA	
Has all affected product been retrieved?	NA	

FDA CLASSIFICATION STATUS

Advisory classification Class: ☒ Decision Pending

CLINICAL ACUITY

	USA	Worldwide
Estimated total number of units currently implanted	Approx. 21,600	Approx. 39,000
Estimated number of potentially affected devices of this model worldwide	Approx. 69,000	
Estimated incidences of this performance failure over the remaining projected life of the device (rapid decline in battery voltage)	The current failure rate is low; however, there is uncertainty in projecting future performance.	
Total # with observed Performance Failure % of Performance Failures		

	Affected Population	Confirmed Reports as of 2/20/2012
EnTrust/VR	29,000	44 (0.15%)
EnTrust DR/AT	40,000	16 (0.04%)

Mean age of product in active implanted population	65 months in the U.S.	
Patient deaths reported	☐ Yes	☒ No
Patient deaths with probable relationship to device failure	☐ Yes	☒ No