



Medtronic, Inc.
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IMPORTANT MEDICAL DEVICE INFORMATION

Concerto® CRT-D Virtuoso® ICD

September, 2009

Dear Doctor:

Medtronic is advising you about a subset of an estimated 6,300 active implanted Concerto® CRT-D and Virtuoso® ICD devices worldwide that may not meet expected device longevity due to gradually increasing current drain caused by low voltage capacitor degradation. This issue may present in the affected devices as reaching the Recommended Replacement Time (RRT) earlier than projected. This issue does not compromise device functionality or affect therapy delivery. Medtronic has received no reports of death or injury attributed to this issue.

Based on information from returned devices, Medtronic expects that affected devices will continue to provide at least three months of normal device function between RRT and End of Service (EOS) as described in device labeling. As a part of ongoing returned product analysis, Medtronic has confirmed 230 units have exhibited this capacitor degradation.

Concerto and Virtuoso devices in the affected subset were manufactured primarily in 2006 and can be traced to a specific subset of low voltage capacitors. To date, there have been no related confirmed failures in Concerto and Virtuoso devices outside of this subset, including devices that were manufactured during the same time.

After consultation with Medtronic's Independent Physician Quality Panel, Medtronic offers the following recommendations for patients with devices in the affected subset:

- Physicians should continue routine follow-up sessions at least every three months in accordance with product labeling.
- Physicians should verify that the Low Battery Voltage RRT alert is programmed to "On-High." This provides an audible, alternating tone when the device reaches RRT. These devices are shipped with this alert programmed nominally to "On-High."
- Physicians may consider monitoring patients through CareLink. The CareLink home monitor can be used to automatically notify the clinician when the device reaches RRT.

Consistent with the HRS recommendations on device advisory communications, we will be informing patients with registered devices in the affected subset via letter dated September 28, 2009, advising them to contact you for more information. Medtronic's Patient Services group at 800-551-5544 ext. 41835 is available to assist patients. Medtronic is also communicating this information to the appropriate regulatory agencies.

Attached are the specific model and serial numbers of affected devices you have implanted or are following according to our device registration records. You may also look up specific serial numbers online to determine if they are affected at <http://CVSNList.medtronic.com>.

We will continue to monitor and provide regular updates on the actual performance of this subset and all Concerto and Virtuoso devices in our Product Performance Report, available at www.medtronic.com/crm/performance.

Concerto CRT-Ds are covered under Medtronic's 4-year warranty and Virtuoso ICDs are covered under Medtronic's 5-year warranty. These warranties also include coverage of reasonable uninsured medical expenses for patients. See warranty cards or your Medtronic representative for terms and conditions.

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,

A handwritten signature in black ink, appearing to read 'Tim Samsel', with a stylized flourish at the end.

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