Health Canada Santé Canada

Health Products and Food Branch
Direction générale des produits de santé et des aliments

Health Canada Endorsed Important Safety Information on certain Guidant implantable cardioverter defibrillators

GUIDANT

June 17, 2005

Subject: Important Safety information on VENTAK PRIZM 2 DR, Model 1861 Implantable cardioverter defibrillators

Dear Health Care Professional,

This letter provides important safety information regarding PRIZM 2 DR, Model 1861 implantable cardioverter defibrillators (ICDs) manufactured before April 16, 2002. Our records indicate that you have implanted or are monitoring patients that have these devices. The purpose of this letter is to update information that we sent to you in a letter dated May 23rd on the PRIZM 2 DR, Model 1861.

Issue Description
In February 2002, Guidant's Cardiac Rhythm Management Quality System identified a problem in PRIZM 2 DR ICDs. Subsequent laboratory analysis of returned products revealed that deterioration in a wire insulator within the lead connector block, in conjunction with other factors, resulted in an electrical short circuit. The short circuit caused diversion of shock therapy energy away from the heart and into device circuitry. Resultant circuit damage caused permanent loss of shock therapy and pacing. Manufacturing changes intended to prevent this failure were made on April 16th 2002 and on November 13th 2002. The PRIZM 2 VR Model 1860 has a different lead connector block design, and is not subject to this problem.

Recommendations
Guidant recommends that physicians continue normal monitoring for all patients with PRIZM 2 DR ICDs. **In addition to normal follow-up at three-month intervals, patients with identified PRIZM 2 DR ICDs should consult with their follow-up clinic after receiving a defibrillation shock**.

Guidant does not recommend replacement of these devices prior to the appearance of normal elective replacement indicators (ERI). As always, physicians should make the final determination on a case-by-case basis regarding whether device replacement is warranted based on the individual patient's medical history. However, if you decide to explant a device, Guidant will provide a replacement device at no charge pursuant to Guidant's supplemental replacement policy, provided the device being explanted was manufactured before November 13, 2002 and has not reached its elective replacement indicators.

In addition, Guidant does not recommend routine use of a commanded shock to detect the shorting problem since we have insufficient data to indicate that such testing will be worthwhile for PRIZM 2 DR devices. If a patient has not recently received a high-voltage therapy, you may choose to perform a commanded shock to confirm integrity of the high voltage delivery circuit. While detailed statistical modeling and bench testing indicates that this cannot exclude the low likelihood of subsequent failure, a commanded shock may provide further confidence that high voltage circuitry is working properly at the time of testing.

Analysis and Reliability Data

There have been 28 reports of this failure worldwide, out of 26,000 devices built prior to the April 2002 change (0.1%). This includes an event reported in March of 2005 in which a device was returned after a patient death. The device was found to have experienced this failure in conjunction with attempted delivery of at least one high-voltage therapy. To date, no such failures have been observed in devices built after April 2002 (including the approximately 11,000 devices built after the April 2002 change and before the November 2002 change). The projected rate of future occurrence is 14 events out of the remaining population of 17,000 devices (0.08%).

Our records indicate that there is a maximum of 496 active devices in Canada that have been manufactured prior to November 2002. Of the total 496 devices, 154 of these units were manufactured in the April to November 2002 timeframe. To date, there have been no reported failures in Canada.

After making the manufacturing changes, Guidant sold product manufactured before the April 2002 change. At that time, data did not show an unusual failure rate and Guidant believed the device to be reliable.

Guidant is providing a list of affected PRIZM 2 DR ICD serial numbers for all active devices in Canada made before the November 2002 changes. We are also providing physicians with a list of their own patients implanted with PRIZM 2 DR ICDs made before the November 2002 changes and will clearly identify those devices manufactured between April and November 2002. Guidant expects only a limited number of additional reports of failures. However, Guidant also recognizes that the actual rate of failures may be greater than the reported rate. Deaths associated with device failures may be under-reported, since ICDs are not routinely evaluated postmortem. All reports of known failures have been communicated to the appropriate regulatory bodies. Guidant continues to monitor the performance of these devices and will promptly notify physicians if there is important new information.

Indications of Device Failure
Guidant concluded, based on bench testing, that there is no means of predicting whether any particular device will in fact fail. However, in the event that a failure has occurred, one or more of following indicators will be present:

- Loss of telemetry/programming/interrogation
- Loss of tachyarrhythmia detection and therapy delivery
- Loss of pacing therapy
- Programmer display of a red warning screen upon attempted device interrogation
- Programmer display of yellow warning screen indicating out of range shocking lead impedance

These indicators may result from a variety of causes and as always should be investigated thoroughly. Guidant Technical Services can assist in this effort. For troubleshooting a yellow warning screen, please refer to Guidant's Product Update dated February 14, 2005.

Patient Information
You should be aware that there may be further discussion of this issue in the public media. Such publicity may alarm your patients and we want to be sure that you were aware of this possibility. We intend to provide you with a letter that, at your discretion, can be shared with patients.

Additional Information
If you have additional questions, please contact:

- Your Guidant Canada representative;
- Guidant Technical Services USA at 1-800-CARDIAC (1-800-227-3422); or
- Scott Kadwell (Guidant Canada CRM Country Manager) at 1-800-268-4487, extension 75828.

The identification, characterization, and management of medical device-related adverse incidents are dependent on the active participation of health care professionals in adverse incident reporting programmes. Any occurrences of specific adverse incident or other serious and/or unexpected adverse incidents in patients with VENTAK PRIZM 2 DR, Model 1861 should be reported to Guidant Canada Corporation or Health Canada at the following addresses:

Guidant Canada Corporation
505 Apple Creek Boulevard, Unit #4
Markham, Ontario
L3R 5B1
(800) 268-4487
(905) 947-5800

Any suspected adverse incident can also be reported to:
Health Products and Food Branch Inspectorate
HEALTH CANADA
Address Locator: 3002C
Ottawa, Ontario K1A 0K9
Tel: The Inspectorate Hotline 1-800-267-9675

For other inquiries, please refer to contact information:

Marketed Health Products Directorate (MHPD)
E-Mail: mhpd_dpsc@hc-sc.gc.ca
Telephone: (613) 954-6522
Fax: (613) 952-7738

The Medical Devices Problem Report Form and Guidelines can be found on the Health Canada web site.

http://www.hc-sc.gc.ca/hpfb/inspectorate/md_pro_rep_form_tc_e.html
http://www.hc-sc.gc.ca/hpfb/inspectorate/man_vol_pro_rep_md_entire_e.html

We recognize the impact of this communication on both you and your patients, and want to reassure you that patient safety remains Guidant's primary concern.

Sincerely,

original signed by

Scott Kadwell
Country Manager, Cardiac Rhythm Management
Guidant Canada Corporation