

**URGENT MEDICAL DEVICE SAFETY INFORMATION
& CORRECTIVE ACTION**

June 17, 2005

Subject: VENTAK PRIZM[®] 2 DR, Model 1861

Dear Doctor:

This letter provides important safety information regarding PRIZM 2 DR, Model 1861 implantable cardioverter defibrillators (ICDs) manufactured on or before April 16, 2002. The FDA has indicated that it will classify this action as a recall. 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. The short 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.

Analysis and Reliability Data

There have been 28 reports of this failure worldwide, in 26,000 devices built prior to the April 2002 change. 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 the devices built after the April 2002 change (including the approximately 11,000 devices built after the April 2002 change and before the November 2002 change). Approximately 13,900 devices built before the April 2002 change remain in service in the United States.

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 physicians with a list of patients implanted with PRIZM 2 DR ICDs made before the November 2002 change and will clearly denote those devices manufactured between the April 2002 and November 2002 changes. 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 the 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 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.

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). Early replacement of pre-April 2002 PRIZM 2 DR devices may not provide the patient with a lower risk, relative to the risks of an invasive procedure. As always, physicians should make the final determination on a case-by-case basis regarding whether device replacement is warranted based upon 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, and provide unreimbursed medical expenses to patients for documented out-of-pocket expenses up to \$2500, provided the device being explanted was manufactured prior to November 13, 2002 and has not reached its ERI.

In addition, Guidant does not recommend routinely using 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.

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 intend to provide you with a letter that you can share with them.

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. If you have additional questions, please contact your Guidant representative or Guidant Technical Services at 1-800-CARDIAC (1-800-227-3422).

Sincerely,

A handwritten signature in cursive script that reads "Allan Gorsett".

Allan Gorsett
Vice President, Reliability and Quality Assurance
Guidant Cardiac Rhythm Management