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

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Contact the company for a copy of any references, attachments or enclosures.

**Health Canada Endorsed Important Safety Information on
CONTAK RENEWAL[®] (Model H135) and CONTAK RENEWAL[®] 2 (Model
H155)**



June 20, 2005

**Subject: Important Safety information on CONTAK RENEWAL[®] (Model H135) and
CONTAK RENEWAL[®] 2 (Model H155) implantable cardiac defibrillators**

Dear Health Care Professional,

Guidant is providing important safety information regarding the CONTAK RENEWAL (Model H135) and CONTAK RENEWAL 2 (Model H155) cardiac resynchronization therapy defibrillators (CRT-Ds) manufactured on or before August 26, 2004. Our records indicate that you have implanted or are monitoring patients that have these devices. This letter is intended to fully advise physicians and their patients about the problem and to limit adverse events.

Laboratory analysis revealed that a deterioration in a wire insulator within the lead connector block, in conjunction with other factors, could cause a short circuit and loss of device function due to diversion of therapy energy away from the heart and into device circuitry. Fifteen (15) reports of this failure mode have been confirmed from approximately 16,000 devices implanted worldwide. This includes an event in which a device was returned after a patient death on May 30, 2005. The device is still being tested but it appears to have experienced this failure in conjunction with attempted delivery of at least one high-voltage therapy.

Issue Description

Laboratory analysis has determined that deterioration in a wire insulator surrounding a high voltage wire within the lead connector block can, in conjunction with other factors, allow shorting of energy to the active titanium case during shock delivery. Diversion of energy away from the heart typically triggers a programmer screen message upon the next interrogation, warning clinicians that full energy was not delivered to the heart during the last shock delivered. Bench testing shows that only about 20% of the intended shock energy will be delivered to the heart when this type of short occurs. If sufficient shock energy is diverted to internal circuitry, it may render the device inoperative, preventing telemetry and delivery of additional shock therapy or pacing therapy. In addition, bench testing has shown that the number of shocks delivered does

not greatly affect the likelihood of device failure. In all cases, device replacement is required if this short circuit occurs.

Recommendations

Guidant recommends the following:

- Continue with normal follow-up patient visits at three-month intervals.
- Advise patients to visit their follow-up clinic or doctor for device evaluation as soon as possible after a shock.
- 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.
- During every patient visit, verify normal device function using routine clinical follow-up procedures.
- In addition, if a shock has been delivered since the last follow-up:
 - 1) Examine the Last Delivered Shock impedance stored in device memory (displayed on the Battery Status screen) for evidence of out-of-range values.
 - 2) If a yellow warning screen is observed, please refer to Guidant's Product Update.

Important Note: If patients hear a post-shock "beeping" they should go to their follow-up clinic or hospital emergency room *immediately*.

Important Note: The low energy shock lead impedance test was designed to verify lead integrity. It cannot be used to diagnose this condition. Again, please see Guidant's Product Update.

Devices Impacted

CONTAK RENEWAL[®] (Model H135) and CONTAK RENEWAL 2 (Model H155) cardiac resynchronization therapy defibrillators (CRT-Ds) manufactured prior to August 26, 2004. Note that CONTAK RENEWAL 3 and RENEWAL 4 CRT-Ds have a different lead connector block design, and are therefore not susceptible to this particular issue.

A list with patients implanted with devices manufactured prior to August 26, 2004 will be provided to physicians with this communication if applicable.

Indications of Device Failure

Guidant concluded, based on bench testing, that there is no means of predicting whether any particular device will 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 output
- 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.

A yellow programmer warning screen describing a low shock lead impedance or a shorted shocking lead condition was observed in 14 of the 15 devices upon programmer interrogation post-shock. In each case, clinical evaluation of the lead system did not identify a lead issue,

although in a few cases the leads were disconnected and capped. Each CRT-D device was explanted and returned to Guidant for analysis. In one case, the yellow screen did not appear, as circuitry damage prevented programmer telemetry. Yellow shock lead warning screens can occur for reasons other than this condition. For more information on troubleshooting a yellow shock lead warning screen, see Guidant's Product Update dated February 14, 2005.

In three of the 15 cases, the problem was identified during in-clinic cardioversion for atrial fibrillation. In 11 cases, patients were away from the clinic, but a warning screen or loss of telemetry was observed when the patient returned to the clinic immediately following shock delivery or for a scheduled office visit. In one case, the device was returned after a patient death.

Rate of Occurrence

Fifteen (15) reports of occurrences of this issue have been confirmed out of approximately 16,000 devices implanted, which equates to a current report rate of 0.094%. Guidant's modeling based on field experience and statistical life-table analysis indicates that the rate of reported failures may increase to between 0.20% and 0.59% over the device family lifetime. A greater increase in failure rate is possible, however, as Guidant also recognizes that the actual event rate may be greater than the rate of reported failures. Deaths associated with the device failures may be under-reported, since CRT-Ds are not routinely evaluated postmortem. It is estimated that 11,900 devices from this population remain in service worldwide.

Our records indicate that there are a maximum of 290 active devices in Canada that have been manufactured prior to August 26, 2004. To date, there have been no reported failures in Canada. Guidant is continuing to closely follow the device performance, and will promptly inform physicians if there is important new information.

Corrective Actions

Guidant has implemented design and manufacturing corrective actions to address internal shorting within the device header. No devices manufactured after August 26, 2004 have exhibited this failure.

Replacement Considerations

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 a decision is made to explant a CONTAK RENEWAL (Model H135) or CONTAK RENEWAL 2 (Model H155) due to this issue, Guidant will provide a replacement device at no charge, provided the device being explanted was manufactured on or before August 26, 2004 and has not reached its normal elective replacement indicator.

Further Information

We intend to provide a letter that you may, at your discretion, share with your patients to inform them of this product issue. As always, if you have any questions regarding this communication, please contact:

- Your local Guidant 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 a specific adverse incident or other serious and/or unexpected adverse incidents in patients implanted with CONTAK RENEWAL (Model H135) or CONTAK RENEWAL 2 (Model H155) should be reported to Guidant 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

Vancouver office
13353 Commerce Parkway, Unit #2103
Richmond, B.C. V6V 3A1
(800) 461-3668
(604) 270-6868

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 Medical Devices Hotline 1-800-267-9675

For other inquiries, please refer to contact information:

Marketed Health Products Directorate (MHPD)

MHPD_DPSC@hc-sc.gc.ca

Tel: (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

Sincerely,

original signed by

Scott Kadwell
Country Manager, Cardiac Rhythm Management
Guidant Canada Corporation