



Health Santé
Canada Canada

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

The Health Products and Food Branch (HPFB) posts on the Health Canada web site safety alerts, public health advisories, press releases and other notices as a service to health professionals, consumers, and other interested parties. These advisories may be prepared with Directorates in the HPFB which includes pre-market and post-market areas as well as market authorization holders and other stakeholders. Although the HPFB grants market authorizations or licenses for therapeutic products, we do not endorse either the product or the company. Any questions regarding product information should be discussed with your health professional.

This is duplicated text of a letter from **Guidant Canada Corporation**
Contact the company for a copy of any references, attachments or enclosures.

**Health Canada Endorsed Important Safety Information on
CONTAK RENEWAL[®] 3 and 4, RENEWAL 3 and 4 AVT[®] and RENEWAL RF**



June 24, 2005

Subject: Important Safety Information on CONTAK RENEWAL[®] 3 and 4, RENEWAL 3 and 4 AVT[®], and RENEWAL RF implantable cardiac defibrillators

Dear Health Care Professional:

This letter is intended to inform you of important safety information regarding all serial numbers of CONTAK RENEWAL 3 and 4, RENEWAL 3 and 4 AVT, and RENEWAL RF. Our records indicate that you have implanted or are monitoring patients that have these devices. This letter is intended to advise physicians and their patients about the problem and to limit adverse events. At this time, we are in the very early stages of a diligent evaluation of the component failure described below. We will continue our evaluation and communicate with you further as more information is learned. As a precautionary measure, physicians should discontinue implants of these devices pending further notice.

Guidant's Cardiac Rhythm Management Quality System has determined that the devices listed above are subject to a component failure that may limit available therapy. Engineering analysis has determined that the magnetic switch in these devices may stick in the closed position. Four occurrences have been confirmed out of approximately 46,000 devices; a fifth occurrence is suspected but cannot be confirmed. In the four occurrences in which the device was implanted, patients and/or physicians were alerted to the condition by audible device tones that signaled the magnetic switch was closed. These four occurrences have resulted in device replacement. One occurrence occurred prior to implant. To date, there have been no patient injuries beyond device replacement.

Clinical Implications

In normal device function, application of a magnet closes the magnetic switch and enables the magnet mode that controls temporary device function. If "Enable Magnet Use" is programmed "ON," as it is in default settings, and the magnetic switch becomes stuck in the closed position, treatment of ventricular or atrial tachyarrhythmias is inhibited, while bradycardia pacing is

unaffected. Under these conditions, device safety features will cause the device to emit tones, and battery depletion will be accelerated. If “Enable Magnet Use” is programmed “OFF” and the magnetic switch becomes stuck in the closed position, the device will continue to provide tachyarrhythmia therapy and bradycardia pacing therapy as programmed; however, the remaining device life will be reduced significantly. Elective replacement indicators (ERI), including audible tones (if activated, as in default settings), remain intact though the time between ERI and end-of-life (EOL) indicators may be shortened.

Recommendations

We provide the following recommendations for you to consider in discussions with your patients:

1. Programming Enable Magnet Use “OFF” will ensure that appropriate therapy to treat ventricular and atrial tachyarrhythmias will be provided in the event that the magnetic switch becomes stuck in the closed position.

NOTE: If Enable Magnet Use is programmed “OFF”:

- A magnet will no longer inhibit therapy.
- The Patient Triggered Monitor feature remains available.
- Temporary suspension of tachyarrhythmia therapy can be performed with a programmer.
- Magnet exposure would offer no therapeutic benefit, and could then be avoided.

2. Patients should contact their physicians or go to the hospital emergency room **immediately** if they hear tones from their device. Physicians should contact their local Guidant representative or Guidant Technical Services at 1-800-CARDIAC (1-800-227-3422) for assistance in device evaluation.

Devices Impacted

All serial numbers of CONTAK RENEWAL 3 and 4, RENEWAL 3 and 4 AVT, and RENEWAL RF.

| Device Family | Model Numbers |
|---------------------------|------------------|
| CONTAK RENEWAL 3** | H170, H173, H175 |
| CONTAK RENEWAL 3 HE** | H177, H179 |
| CONTAK RENEWAL 4 | H190, H195 |
| CONTAK RENEWAL 4 HE | H197, H199 |
| CONTAK RENEWAL 3 AVT** | M150, M155 |
| CONTAK RENEWAL 3 AVT HE** | M157, M159 |
| CONTAK RENEWAL 4 AVT* | M170, M175 |
| CONTAK RENEWAL 4 AVT HE* | M177, M179 |
| RENEWAL RF** | H230, H235 |
| RENEWAL RF HE** | H239 |

* Under clinical investigation in some geographies.

** Not available in Canada

A list with patients implanted with affected devices will be provided to physicians with this communication if applicable. There have been no reported injuries in Canada.

Future Actions By Guidant

We will continue to investigate this issue and we will provide any additional information that may help you care for your patients.

Further Information

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. 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[®] 3 and 4, RENEWAL 3 and 4 AVT[®] or RENEWAL RF defibrillators 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)

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