



URGENT MEDICAL DEVICE SAFETY INFORMATION & CORRECTIVE ACTION

June 23, 2005

Re: CONTAK RENEWAL[®] 3 and 4, RENEWAL 3 and 4 AVT[®], RENEWAL RF

Dear Doctor:

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. FDA may consider this action as a recall. 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 the United States

Device lists specific to your clinic accompany this communication.

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 or Guidant Technical Services at 1-800-CARDIAC (1-800-227-3422).

Sincerely,



Allan Gorsett
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Guidant Cardiac Rhythm Management