



U.S. Food and Drug Administration



[FDA Home Page](#) | [Search FDA Site](#) | [FDA A-Z Index](#) | [Contact FDA](#)

Safety Advice -- Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

Guidant Initiates Worldwide Physician Communications Regarding Important Safety Information and Corrective Action about Implantable Cardiac Defibrillators

Contact:

Guidant Corporation
1-866-GUIDANT (1-866-484-3268)

FOR IMMEDIATE RELEASE -- Indianapolis, Ind. -- June 24, 2005 -- Guidant Corporation (NYSE: GDT) said today it is voluntarily advising physicians about important safety information regarding certain devices. Guidant apprised FDA of this action, and FDA may classify this action as a recall. At this time, Guidant is in the very early stages of a diligent evaluation of the component failure described below. Guidant will continue its evaluation and communicate further as more information is learned. As a precautionary measure, physicians should discontinue implants of these devices pending further notice. This communication advises physicians and their patients of safety information and is intended to limit adverse events. Physicians should use this information to decide how best to treat their patients.

The devices impacted are:

CONTAK RENEWAL 3 and 4, RENEWAL 3 and 4 AVT, and RENEWAL RF

Guidant has determined that the devices listed above are subject to a component failure that may limit available therapy. We have determined that a magnetic switch in these devices may become stuck in the closed position, which in some cases inhibits the device's ability to treat ventricular or atrial tachyarrhythmias and can accelerate battery depletion. 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.

It is Guidant's recommendation to physicians that they consider programming "Enable Magnet Use" to "OFF" to 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. In addition, patients should contact their physicians or go to the hospital emergency room immediately if they hear tones from their device.

Guidant continues to investigate this issue and will provide any additional information that may help physicians and patients.

Guidant recently announced its intention to establish an independent panel of experts to recommend guidelines for when to disseminate information to physicians and patients about life-sustaining implantable devices. Guidant plans to cooperate with and enlist the support of other interested parties, including the Food and Drug Administration, patient advocates, and physician societies.

Additional information about this potential issue is available for physicians and patients at 1-866-GUIDANT (1-866-484-3268) (24/7) and

http://www.guidant.com/physician_communications/RENEWAL3_RENEWAL4.pdf.

####

[FDA Press Release](#) (*June 17, 2005*)

[RSS Feed for FDA Recalls Information](#) [\[what's this?\]](#)

Get [free e-mail alerts](#) about Class I recalls

[Media Contacts](#) | [Recalls Home Page](#)

[FDA Home Page](#) | [Search FDA Site](#) | [FDA A-Z Index](#) | [Contact FDA](#) | [Privacy](#) | [Accessibility](#)

[FDA Website Management Staff](#)