Advice for Patients with VENTAK PRIZM® 2 DR and CONTAK RENEWAL® Implantable Cardioverter Defibrillators

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Guidant Corporation has recalled the above defibrillators because they can develop an internal short circuit without warning, resulting in failure to deliver a shock to the heart when needed. FDA is providing the following information for patients and their families, so that they will be better able to discuss treatment options with their doctors. We will update this advice if necessary as more information becomes available.

Patients should understand that an FDA recall does not necessarily mean that the device will be removed from the market or that the device needs to be removed from the patient. Recall actions can also include correcting or modifying the device.

The devices affected by this recall are:

- PRIZM® 2 DR, Model 1861, manufactured before April 16, 2002
- CONTAK RENEWAL®, Model H135, manufactured before August 26, 2004
- CONTAK RENEWAL® 2, Model H155, manufactured before August 26, 2004

These devices, called implantable cardioverter defibrillators (ICD)s, are surgically implanted in people who have various forms of heart disease that create the risk of a life-threatening heart arrhythmia (abnormal rhythm). The devices deliver an electrical shock to the heart to restore normal heart rhythm. The device malfunction results in the devices failing to deliver an electrical shock during episodes of arrhythmia—which could lead to a serious, life-threatening event for a patient. There have been two deaths reported to FDA that were associated with this malfunction.

The exact percentage of these defibrillators that might experience a malfunction isn't known at this time. But the number of malfunctions reported so far is very small compared with the number of devices in use, so it's unlikely that a patient will experience one of these events. Still, it's important for each patient to contact his or her doctor to discuss the best course of action, including whether or not to replace the device. This decision will depend on many factors, including the patient's condition and medical history. Replacing the device may be advisable in some cases, but in other cases the risks associated with replacing the device, including the chance of infection or injury during replacement surgery, may be higher than the risk that the device will malfunction.

Advice for Patients

- If you're not sure which model ICD you have, ask your doctor for this information.
- If you have one of the affected models, contact your doctor promptly to discuss the best course of action.

- Be aware that there is no way that you can test your device at home and there may be no signal that your ICD has malfunctioned, so it is important that you keep your regular doctor appointments.
- If you feel an electrical shock from your device, contact your doctor as soon as possible.
- If you or others hear a "beeping" from your device, this may signal a malfunction. Immediately contact your doctor or go to the nearest emergency room.

Your physician has been notified of the problems associated with these model ICDs and has received specific information about how to monitor your device. FDA has been evaluating reported problems with the Guidant's PRIZM® 2 and CONTAK RENEWAL® devices for several weeks and will continue to monitor reports.

FDA and Guidant are working together to see that all physicians are notified of the reported problems and receive accurate, up-to-date information. We are also working with the clinical community through the Heart Rhythm Society and patient advocacy groups to hear their specific concerns about this recall and about recalls in general. Additional information about device recalls, questions to ask your doctor about device recalls, and patient information about ICDs is available at the Heart Rhythm Society's website at http://www.hrspatients.org/patients/device_recalls/default.asp

Information FDA is providing to physicians about the ICD recalls is available at http://www.fda.gov/cdrh/safety.html

Press Release: FDA Updates Consumers on Guidant Corporation's Implantable Defibrillators

Press Release: FDA Issues Nationwide Notification of Recall of Certain Guidant Implantable Defibrillators and Cardiac Resynchronization Therapy Defibrillators

FDA Preliminary Public Health Notification:: Guidant VENTAK PRIZM® 2 DR and CONTAK RENEWAL® Implantable Cardioverter Defibrillators

October 13, 2005 Update to FDA Preliminary Public Health Notification: Guidant VENTAK PRIZM® 2 DR and CONTAK RENEWAL® Implantable Cardioverter Defibrillators

December 28, 2005 Update to FDA Preliminary Public Health Notification: Guidant VENTAK PRIZM® 2 DR and CONTAK RENEWAL® Implantable Cardioverter Defibrillators

Updated January 28, 2006
