



FDA Warning about Malfunction of Certain Guidant Implantable Defibrillators

The U.S. Food and Drug Administration draws public attention upon the malfunctioning of certain defibrillators produced by Guidant Corporation. Guidant recalled a number of implantable defibrillators last month, and yesterday, the Food and Drug Administration classified recalled devices; the full list includes 11 models, classified into three categories, with Class I being the most serious.

These implantable devices, that have the size of a mini-cassette, are designed to recognize certain types of abnormal heart rhythms (arrhythmias) and correct them by delivering precisely calibrated and timed electrical shocks, when needed, in order to restore a normal heartbeat. It was found, however, that they can develop an internal short circuit when attempting to deliver the electrical shock, caused by a deterioration of electrical insulation in the device. This prevents them from forcing the heart back into its proper rhythm, and perhaps one of the most worrisome aspects is that there is no way to predict whether or when a device will fail.

Out of the 42,000 recalled devices, 20,600 are still implanted; two deaths associated with these have been so far reported to the FDA. However, it's also important to understand that in most cases these defibrillators work well and save lives, says Daniel Schultz, MD, Director of FDA's Center for Devices and Radiological Health. FDA advises patients to call their doctor for personalized advice before taking any action.

The three models listed as Class I recalls are: PRIZM 2 DR, Model 1861; CONTAK RENEWAL, Model H135; and CONTAK RENEWAL 2, Model H155. For Class I recalls, there is a reasonable probability that the malfunctioning devices will cause serious adverse consequences or even death. However, the designation does not necessarily require removal, and replacement has its own risks as well.

Guidant Corporation was required to provide additional instructions for safe use, and these include consulting your physician for any questions and contacting your doctor or going to the emergency room as soon as you feel a shock or hear the device beep.