



Warning of Pacemaker Failures

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Fig. 1. Another brand of Pacemaker, not affected by this warning



Guidant Corporation admits that 28,000 people using implanted heart pacemakers produced by the company may need to have them replaced, because of their recently discovered defects. Pacemaker Information

The HeartZine guide to Pacemakers

The announcement was made on the same day an Institute of Medicine report was issued, concerning the Food and Drug Administration's monitoring of medical device safety. The report criticized the agency's performance in this respect and found the monitoring of post-market studies regarding these products deficient as well.

The safety warning issued yesterday by Guidant concerned pacemakers implanted between 1997 and 2000. Approximately one month before, another warning had been issued that involved 109,000 implanted defibrillators produced by Guidant as well. This time, however, the announcement explicitly warns doctors that the product may need replacement.

The explanation for the failures reported seems to be a gradual degrading of a seal within the struc-

ture of the pacemakers, which subsequently allows a higher degree of moisture to enter. 69 failures in nine models were reported to the company, according to their statement, having as a result loss of consciousness and possible heart failure in several patients. There was one death reported, but since the device was not returned for testing, Guidant representatives say they could not confirm that the pacemaker was responsible for it. Sales were discontinued for these nine models in 2000.

However, the company approximated that 28,000 pacemakers are still in use, 18,000 of which are in the United States. Thousands of people could now face unexpected surgery to replace their devices.

The Institute of Medicine panel that issued the report on FDA's monitoring of medical devices said that large computerized databases from health maintenance organizations and hospitals should give much more comprehensive and immediate information on both drugs and medical devices. However, the system for computer coding of device records remains far behind the one for drugs, IOM adds.

"The FDA is running a pilot program to more aggressively collect information about device failures and adverse events. The Medical Product Surveillance Network (MedSun) collects information from 300 medical facilities, including 20 children's hospitals". (Washington Post, July 19, 2005)