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WILL YOUR DEFIBRILLATOR OR PACEMAKER SHORT CIRCUIT?

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DEFIBRILLATORS

On March 14, 2005, a 21 year-old college student died when his implantable cardioverter-defibrillator (ICD) malfunctioned. He suffered from a genetic heart condition that gave him a high risk of sudden death from ventricular fibrillation (Vfib). His ICD had been implanted to detect the onset of Vfib and deliver an electric shock to convert the heart back to a normal rhythm. Analysis of the ICD after his death showed that deterioration of electrical insulation, that had occurred some time since implantation, caused a short-circuit, permanently inactivating the ICD's ability to shock the heart.

His doctors found that the manufacturer, Guidant, had filed 43 similar reports with the Food and Drug Administration (FDA). When confronted, Guidant refused to notify physicians until just hours before the New York Times released a May 23, 2005 article about the student's death and Guidant defibrillators. The Times article forced the issue and Guidant has issued a recall of affected devices.

IDC's manufactured prior to April 2002, when the manufacturer first identified the problem, are at risk. Guidant fixed the problem in subsequent devices, but continued to sell pre-April 2002 ICD's without modification. You are not necessarily safe if you received your Guidant ICD after April 2002. Discuss replacement with your doctor.

Luckily, adverse events have been rare: 'Only' forty three device-related deaths have occurred in 42,000 people with affected IDC's implanted worldwide. This may underestimate the true failure incidence: Heart patients who require ICD's inherently have a high mortality risk and their devices may not have been analyzed after their death.

The recalled devices are: Prizm 2 DR manufactured prior to April 2002, and Contak Renewal Models H135 and H155 manufactured prior to August 26, 2004. Guidant provides replacement devices at no charge.

Other less serious malfunctions have occurred in Guidant's Ventak Prizm AVT, Vitality AVT, Renewal AVT, Contak Renewal 3 and 4, Renewal 3 and 4 AVT, and Renewal RF ICD's. These malfunctions either give a warning tone of component failure (indicating the need for replacement) or cause a software memory problem that can be fixed by reprogramming.

The other two ICD manufacturers, Medtronic and St. Jude Medical, have also recently reported device malfunctions. Some Medtronic devices experience premature battery failure, corrected by replacement. The St. Jude Medical ICD's may have rare anomalies that can be repaired with a software download.

PACEMAKERS

Guidant Corporation also issued an alert involving safety concerns with some of its pacemakers. The company has recalled several models (see table) manufactured betwen November, 1997 and October, 2000.

A sealing component of the affected pacemakers was degrading and leaking, resulting in "unanticipated device behaviors."

These 'behaviors' include loss of battery power, inappropriate stimulation of the heart to beat very fast, failure to induce a paced beat when the heart's natural beat stops and the display of incorrect messages. Such failures most likely would occur late in the pacer's life. Guidant has not identified any test that will predict if a device will exhibit these failure modes in the future.

Guidant Pacemakers Recalled

Device Family	Model Numbers
PULSAR MAX	1170, 1171, 1270
PULSAR	0470, 0870, 0970, 0972, 1172, 1272
DISCOVERY	1174, 1175, 1273, 1274, 1275
MERIDIAN	0476, 0976,1176, 1276
PULSAR MAX II	1180, 1181, 1280
DISCOVERY II	0481, 0981, 1184, 1186, 1187, 1283, 1284, 1285, 1286
CONTAK TR	1241

None of the affected products have been sold or implanted within the last 4 years. No pacemaker has failed before 44 months and only 69 failures in over 30,000 pacemakers have been reported. The actual failure rate may be higher, because past failures may not have been reported.

A decision about whether or not to replace a pacemaker depends on a number of factors: The medical problem that led to the pacer, the ability to withstand the consequences of failure and the remaining service life of the pacemaker all contribute to the decision. People who are 'pacemaker dependent' do not have a heart beat unless the pacer functions properly. If this is you, and you have an affected pacemaker, you should have it replaced. People who merely have a slow heart rate and get short of breath if the pacer malfunctions, might wait to see if there is a malfunction before replacement. Seek immediate attention if you experience a prolonged rapid heart rate, blackouts, lightheadedness, or shortness of breath.

To increase the likelihood of detecting a failure that has already occurred, Guidant recommends that physicians consider increasing the frequency of programmer follow-ups, as well as increasing monitoring frequency over the telephone.

Physicians or patients who have experienced a problem with any implantable cardiac device should report the event to the FDA's MedWatch program, as well as to the manufacturer of the affected device. File FDA MedWatch reports online at http://www.fda.gov/medwatch, by calling 1-800-FDA-1088 (1-800-332-1088), or by mail to 5600 Fishers Lane, Rockville, MD 20852-9787. Guidant Company information is available at: http://guidant.com/patient/communication/..