

Heart Device Joint Prosecution Alliance

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100,000 Guidant implanted defibrillators recalled in the U.S.



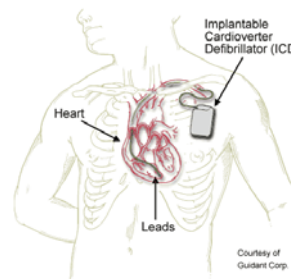
On June 17, 2005, Guidant Corporation recalled approximately 40,000 cardiac defibrillators implanted in U.S. patients. The units have defective lead wire insulation that can short circuit, leading to device failure that can be fatal.

Then on June 24, 2005, Guidant recalled about 60,000 additional units with flaws that can cause the defibrillator to fail. Guidant was incorporated in 1994 as a spin-off from Merck & Co., and it is in the process of being acquired by Johnson & Johnson. Guidant's headquarters are in Indianapolis, and it had revenue of \$3.8 billion in 2004.

Litigation prospects

Preliminary analysis of responses to our newspaper advertising indicates there are far more death and injury claims for people with both Guidant and Medtronic devices than has been reported by the companies or in the media. Our assessment is that more advertising is warranted and is likely to lead to a significant number of additional death and injury claims.

There are two basic categories of claimants: (1) those who have had an event and (2) those who have not. Those who have not had an event can be subdivided into two groups: (a) those who have or will have their units replaced, and (b) those who will not have them replaced, as long as the unit is working, because the risk outweighs the benefit. Those in subclass b will benefit from a monitoring program consisting mainly of having the unit checked frequently to determine if it is working.



The FDA approved the first implantable defibrillators more than 10 years ago. Today's device typically consists of a generator slightly smaller than the size of a wallet attached to electrode catheters. The generator is surgically placed under or over chest or abdominal muscles. The catheters are threaded through veins to their permanent positions in the heart.

Complications of implanting defibrillators are rare, but serious, and include bleeding, infections, and perforation of the heart.

Medtronic recalls 65,000 heart pacing devices



Minneapolis based Medtronic, whose slogan is, "Where life depends on medical technology," announced the recall of approximately 65,000 implanted defibrillators in the U.S. in February of this year. The units have defective batteries, which creates a risk of sudden failure. Medtronic's annual revenue grew to over \$10 billion in its most recent fiscal year.

How an implanted defibrillator works

An implantable defibrillator is an electronic device placed in the body and intended to prevent cardiac arrest from severe ventricular tachycardia. An electrode is connected between the heart and a tiny computer in the defibrillator. The computer monitors the heartbeat, and if it detects an arrhythmia, it activates a built-in pacemaker to restabilize the heart's rhythm. If this fails, the unit delivers a small defibrillating electrical jolt to the heart. In extreme cases, a far stronger jolt is delivered to reset the heart rate.

Death and injury cases

We have about 75 sudden cardiac death and injury cases we intend to file as lawsuits this month. About half are death cases. Both Medtronic and Guidant devices are involved.

Only the manufacturer is being sued, so we expect these cases will be removed to federal court, and for planning purposes we are assuming they will ultimately be transferred to a federal MDL.

Class actions

This month we will file separate class actions against Guidant and Medtronic in New Jersey, Ohio, Pennsylvania, and West Virginia.

The class can be loosely described as including those who have a recalled unit, but who have not had an adverse event.

Damages include the cost of replacing the defective unit for those who have it replaced, and the cost of monitoring for unit failure in those who do not elect to have the unit replaced until it fails. Noneconomic damages are also being sought.

Guidant and Medtronic have made statements about covering some of the cost of replacement, but neither has said it will pay *all* the economic costs, and neither has suggested that it will pay anything for noneconomic damages associated with replacement.



Federal MDL

Guidant has filed for an MDL.

Medtronic is expected to do the same soon.

LexisNexis heart device teleconference

Teresa Toriseva of Hill Toriseva & Williams and Wendy Fleishman of Lief Cabraser Heimann & Bernstein will co-host a Mealey's Heart Device Litigation Conference on July 19, 2005, starting at 2:00 EDT. More information is available on Mealey's website: www.mealeys.com.

Guidant and Medtronic knew of the problems with their defibrillators long before announcing them, and each made a business decision not to inform patients or doctors.

Defective model numbers

Medtronic

Implantable cardioverter-defibrillators:

- Marquis VR 7230 ▪ Marquis VR 7274
- Maximo VR 7232 ▪ Maximo DR 7278

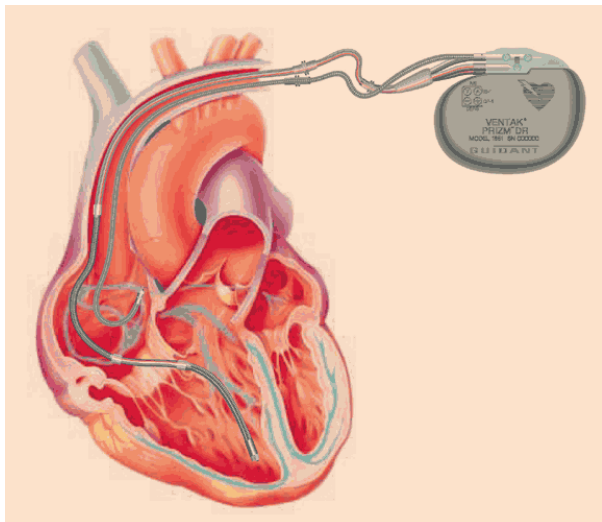
Cardiac resynchronization therapy defibrillators:

- InSync I Marquis ▪ InSync II Marquis
- InSync III Marquis ▪ InSync III Protect 7277
- InSync III Protect 7289

Guidant

- Contak Renewal Model H135 (made before 8/27/04)
- Contak Renewal Model H155 CRT-D (made before 8/27/04)
- Contak Renewal 3 ▪ Contak Renewal 4
- Contak Renewal AVT
- Ventak Prism 2 DR (made before 4/17/02)
- Ventak Prism AVT ▪ Vitality AVT ▪ Renewal 3 AVT
- Renewal 4 AVT ▪ Renewal RF

Replacement is not simple



An interventional cardiologist must open the chest, remove the lead wires from the heart, put new leads in, and close the patient. Risks of infection and other complications are always present.

Contact us

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If you attend the ATLA Convention in Toronto this month...

An ATLA Heart Device Litigation Group has been proposed. If approved, the Group will meet on Tuesday, July 25 from 2:00 to 3:00 pm in the Cosmopolitan Suite on the 4th Floor of the Sheraton. Call Barry Hill (cell 304.280.8103) or Teresa Toriseva (cell 304.312.0986) any time after noon on Saturday, July 23, to confirm that the new group will meet as planned.

Advertising and referrals

If you decide to advertise for heart device cases, we can provide you with a newspaper ad format, an intake sheet, a fact sheet, accept or reject criteria, a timeline, and fee agreements for the different types of cases that come under



the heart devices umbrella. Requesting and/or using these materials creates no obligation on your part.

We welcome referrals irrespective of whether the person had a cardiac event. As long as the person has, or had, a device covered by the recalls, we are interested in the case. Contact anyone listed in the box to the left to discuss referral arrangements.

One client's story

Before Medtronic announced its recall, a 57-year-old New Jersey man's Medtronic defibrillator failed, shocking him violently four times. The fourth shock was delivered as he walked into a hospital emergency department, looking for help. This one took him to his knees. His doctors, who did not know about problems with the units, because Medtronic was keeping the information to itself at that point, deactivated the unit. Then they opened his chest and added a third lead wire, thinking this might fix the problem.

The procedure led to a staph infection, which in turn required removal of the entire unit, including laser removal of the lead wires. Implanting a new defibrillator is on hold, until the infection clears. Medical expenses are over \$100,000 and will be higher after the new defibrillator is put in.

The typical cost for replacing a defibrillator ranges from \$35,000 to \$50,000.