

DEFECTIVE IMPLANTABLE CARIOVERTER DEFIBRILATORS



If you or a loved one has been implanted with a defibrillator for abnormal heart rhythm and suffered an adverse event or death from the following devices contact Eichen Levinson for a free consultation.

Guidant Implantable Cardioverter Defibrillators

Guidant Corporation has recalled the following defibrillators because they can develop an internal short circuit without warning, resulting in failure to deliver a shock to the heart when needed.

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. As of December 30, 2005 , Guidant has reported 67 failures. There have been 7 deaths reported to FDA that were associated with this malfunction. Guidant claims that it discovered the short circuiting defect in 2002 and changed the manufacturing of the devices that year to correct the defect. However, Guidant continued to sell the old defective devices without notifying doctors that improved ones were available.

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.