

# GUIDANT & MEDTRONIC IMPLANTED CARDIAC DEVICE MDL LITIGATION

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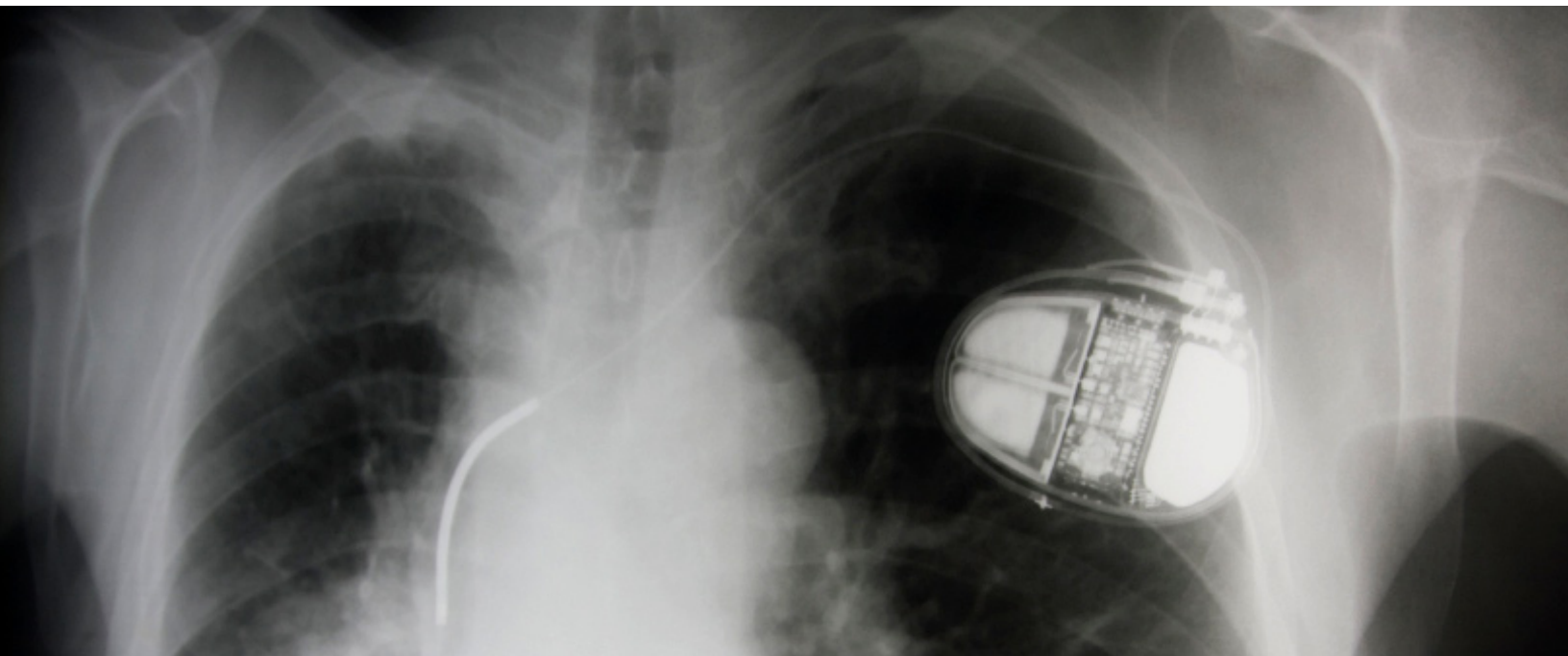
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TYPES OF DEVICES INCLUDED IN CURRENT LITIGATION:

Acronym	Full Nomenclature	Intended Function	Used to Treat
ICD	implanted cardioverter defibrillator	Detection and reversal of ventricular and/or atrial arrhythmias by delivering electrical shock to the heart	Cardiac arrhythmias
CRT-D	Cardiac resynchronization therapy defibrillator	Biventricular pacing with internal defibrillator capacity	Heart failure
CRT- P	Cardiac resynchronization therapy pacemaker	Biventricular pacing without internal defibrillator capacity	Heart failure
Pacemaker	Pacemaker	Correct bradycardia	Slow heartbeat



## DEFENDANTS

### GUIDANT

#### BOSTON SCIENTIFIC CORPORATION

- Headquarters in Massachusetts
- Bought Guidant in 2006

#### GUIDANT CORPORATION

- Headquarters in Indiana when devices were made

#### GUIDANT SALES CORPORATION

- Former subsidiary of Guidant Corporation
- Seller of the devices
- Headquarters in Indiana when devices were made

#### CARDIAC PACEMAKERS, INC.

- Former subsidiary of Guidant Corporation
- Manufacturer of the devices
- Headquarters and manufacturing facility in Minnesota when devices were made

### MEDTRONIC

#### MEDTRONIC CORPORATION

- Headquarters and manufacturing facilities in Minnesota now and when devices were made



## FEDERAL MULTI-DISTRICT LITIGATION

	<b>Guidant MDL</b>	<b>Medtronic MDL</b>
<b>Federal MDL Case Number</b>	MDL 1706	MDL 1726
<b>MDL Court</b>	U.S.D.C., D. Minn. Minneapolis MN	U.S.D.C., D. Minn. Minneapolis MN
<b>MDL Judge</b>	Donovan Frank	James Rosenbaum
<b>MDL Magistrate</b>	Arthur Boylan	Arthur Boylan
<b>MDL Plaintiffs' Lead Counsel</b>	Richard Arsenault Neblett, Beard & Arsenault Alexandria LA	Daniel Gustafson Gustafson Gluek Minneapolis, MN
	Charles Zimmerman Zimmerman Reed, Minneapolis, MN	Charles Zimmerman Zimmerman Reed Minneapolis, MN
	Elizabeth Cabraser Lief, Cabraser, Heinmann & Bernstein San Francisco CA	
	Seth Lesser Locks Law Firm New York NY	
<b>MDL Plaintiffs' Liaison Counsel</b>	Charles Zimmerman Zimmerman Reed Minneapolis, MN	Richard Lockridge Lockridge Grindal Nauen Minneapolis, MN
<b>Service of complaint on de- fense counsel in lieu of formal service of process?</b>	Yes	Yes
<b>Order requiring plaintiff's fact sheet?</b>	Yes	Yes

### PLAINTIFF'S FACT SHEET

- Court-approved form
- Due within 30 days after case is filed, if filed in Minnesota federal court.
- Due within 30 days of acceptance of transfer by MDL court if filed in state other than Minnesota
- Failure to submit completed form on time can result in monetary sanction or dismissal

## FEDERAL MULTI-DISTRICT LITIGATION

	<b>Guidant MDL</b>	<b>Medtronic MDL</b>
MDL order requiring devices produced for interrogation?	Yes	Yes
MDL monthly status conferences for lead counsel for the parties?	Yes	Yes
MDL Court website for consolidated heart device litigation	<a href="http://www.mnd.uscourts.gov/guidant">www.mnd.uscourts.gov/guidant</a>	<a href="http://www.mnd.uscourts.gov/medtronic">www.mnd.uscourts.gov/medtronic</a>
Bundling of plaintiffs in single complaint allowed?	Yes	Yes
Any trials to-date?	No	No
Representative trials scheduled?	Yes (June 2007)	Yes (January 2008)
Motion to dismiss all cases based on federal preemption?	Yes	Yes (Important Ruling 11/28/2006: claims are not preempted)
Motion to dismiss emotional distress damage claims in absence of physical injury?	Yes	No
Number of cases settled	2	0
Can suit in all cases be filed in U.S.D.C., D. Minn?	Yes	Yes
Motion to intervene?	No	Yes (Filed by Bloomberg News & Minneapolis Star Tribune)

## THE LOOK OF A CONSOLIDATED, MULTI-PLAINTIFF COMPLAINT

United States District Court  
District of Minnesota

IN RE: MEDTRONIC, INC. IMPLANTABLE DEFIBRILLATORS PRODUCT LIABILITY LITIGATION

### Group A Plaintiffs

- |                       |                             |
|-----------------------|-----------------------------|
| 1. Laurie Amabide     | 17a. Ronald Karas           |
| 2a. Irvin Ansel       | 17b. Joanne C. Karas        |
| 2b. Corinne Ansel     | 18a. Dorene A. Keefer       |
| 3a. George Berman     | 18b. James Keefer           |
| 3b. Evelyn Berman     | 19a. Peter Keene            |
| 4a. Kathy Blessing    | 19b. Joyce H. Keene         |
| 4b. Charles Blessing  | 20a. Joseph Klingman        |
| 5a. Thomas Bottoms    | 20b. Marietta Klingman      |
| 5b. Mary B. Bottoms   | 21a. Joseph C. Marco, Jr.   |
| 6a. Gerry E. Bram     | 21b. Marilyn Marco          |
| 6b. Michelle S. Bram  | 22a. Joseph P. Morba        |
| 7. Gustino Carlone    | 22b. Ellen Morba            |
| 8a. Nicole Carns      | 23a. John Richardson        |
| 8b. Franklin Carns    | 23b. Margaret M. Richardson |
| 9a. Victor Chirillo   | 24a. R. Michael Skane       |
| 9b. Irma Chirillo     | 24b. Helen B. Skane         |
| 10a. Ray Feather      | 25a. Carl Songer            |
| 10b. Fern Feather     | 25b. Joan Songer            |
| 11. John Fisher       | 26a. Richard Suto           |
| 12. John Gates        | 26b. MaryAnne Suto          |
| 13a. Debra A. Gornall | 27a. Fred Voitko            |
| 13b. Joseph F. Felice | 27b. Olga G. Voitko         |
| 14a. Stanley Gross    | 28a. Edward Weber           |
| 14b. Joan Gross       | 28b. Helena K. Weber        |
| 15a. Richard L. Hill  | 29. Jeff Whitman            |
| 15b. Linda L. Hill    | 30a. Donald Wilhelm         |
| 16. Jerry Holmes      | 30b. Helen Wilhelm          |

MDL No. 05-1726 (JMR/  
AJB)

Consolidated complaint by  
partial adoption for Penn-  
sylvania Citizens

A jury trial is demanded

THE LOOK OF A CONSOLIDATED, MULTI-PLAINTIFF COMPLAINT (CONT.)

United States District Court  
District of Minnesota

IN RE: MEDTRONIC, INC. IMPLANTABLE DEFIBRILLATORS PRODUCT LIABILITY LITIGATION

**Group B Plaintiffs**

- 31a. Bruce Daugherty
- 31b. Roberta Daugherty
- 32a. James Doby
- 32b. Judieh A. Brust
- 33a. Athanasia Haydon
- 33b. Gus M. Haydon
- 34a. Tom McAleer
- 34b. June McAleer
- 35. Danielle Raffaele, a minor, by her mother and guardian, Eileen Raffaele, and Eileen Raffaele, individually
- 36a. Christopher Vogel
- 36b. Janice Vogel



MDL No. 05-1726 (JMR/AJB)

Consolidated complaint by partial adoption for Pennsylvania Citizens

**Plaintiffs vs. .Medtronic, Inc. Defendant**

## COMPLAINT SECTION HEADINGS

- A. Allegations common to all plaintiffs
- B. Allegations common to all Group A injury plaintiffs
- C. Allegations common to all Group B injury plaintiffs
- D. Allegations unique to the Raffaele plaintiffs
- E. Allegations unique to the Vogel plaintiffs
- F. Allegations common to all consortium loss plaintiffs
- G. Group A injury plaintiffs' individual claim allegations
- H. Group B injury plaintiffs' individual claim allegations



The following chart summarizes pertinent facts of individual Group B injury plaintiffs' injury claims.

No.	Name	Model No(s).	Serial No(s).	Implant Date(s)	Explant Date(s)	Complication/ Injury
31	Daugherty, Bruce	7278	PRM601872S	7/13/2004	11/2/2005	Failure to capture and failure to fire
32	Doby, James	7277	PLT605725S	5/27/2003	3/1/2005	Complications of explant reimplant procedure
33	Haydon, Athanasia	7277	PLT608574S	7/3/2003	7/1/2005	Inappropriate shocks
34	McAleer, Tom	7230	PKD104086H	4/7/2003	7/23/2003	Complications of explant reimplant procedure
		7274	PKC120949H	7/23/2003	3/9/2005	Complications of explant reimplant procedure
35	Raffaele, Danielle	7230	PKD107414H	7/1/2003	4/1/2005	Complications of explant reimplant procedure

## TYPES OF CASES

Harm class	Type of harm	Comment
1	The claimant's device was recalled, but it has not malfunctioned causing harm, and it has not been explanted and replaced as a result of its recall and/or a malfunction.	Guidant has a motion to dismiss all of these claims, which it calls "anguish only" cases, pending in the Guidant MDL. The motion addresses anguish as an element of damages in a product liability case based on strict liability, negligence, and/or breach of warranty. It does not reach a cause of action based on intentional conduct resulting in emotional distress.
2	The claimant's device was recalled, and it was explanted and replaced either (a) because it malfunctioned (without causing harm) and/or (b) fear it would malfunction, based on recall information as to failure risk. The explant and reimplant procedure was uncomplicated.	These are simple cases in which case values, exclusive of economic loss, should be similar, regardless of age and other circumstances.
3	The claimant's device was recalled, and it was explanted and replaced either (a) because it malfunctioned (without causing harm) and/or (b) fear it would malfunction, based on recall information as to failure risk. There was a complication of the explant and reimplant procedure.	Classes 2 and 3 are distinguished by whether there was a complication of the explant and reimplant procedure. The most common complication is infection at the device site.
4	The device failed, producing unnecessary shocks to the heart or other harm, irrespective of whether it has been explanted and replaced.	Some cases are combination Class 2 and 4 or Class 3 and 4.
5	The device contributed to causing death, either by malfunction at the time of death, or where death is related to a complication of explant of a recalled device.	Proof of individual causation in a case where device failure at the time of death is alleged can be difficult, and without device interrogation, close to impossible.

## CASE SELECTION

1. Accepting cases with non-recalled devices presents a high degree of risk in terms of effort and expense relative to the reasonable range of outcomes, which makes these cases generally unattractive in the absence of unusual circumstances.
2. Accepting cases from outside the United States is probably a waste of time.
3. One should be circumspect in accepting Class 1 cases, as defined previously, because they might turn out to have no value, and they present a statute of limitations conundrum.
4. Cases against manufacturers of implanted cardiac devices other than Guidant and Medtronic do not get transferred into either MDL and therefore must be judged on their own merit as stand-alone cases.
5. Where there has been an explant of a recalled device, pay attention to why it was explanted. If explanted because of infection, physician decision to switch to a different type of device, end of predicted useful life of the device, or other reason unrelated to recall or malfunction, the case is a Class 1, not a Class 2.
6. In the absence of unusual circumstances, device failure cannot be shown to have contributed to causing death unless the device is or has been interrogated. Therefore if the person is dead and gone with the device, there is no case unless the device was interrogated first or is exhumed.

## Case Selection restated

1. Don't take a case if the device has not been recalled.
2. Don't take a foreign country case.
3. Class 1 cases may not have value.
4. No MDL for devices made by manufacturers other than Guidant and Medtronic.
5. Take a close look at the reason for explant.
6. Generally can't prove a death case without device interrogation, unless death is caused by a complication of recalled device explant procedure.

**How to determine if a device is recalled, subject to a safety bulletin, or subject to a physician communication**

- a. Guidant and Medtronic maintain “look-up” features on their websites for this purpose.
- b. The company websites are reliable for inclusion purposes, but not necessarily for exclusion purposes. There is no other public place to go where this information is readily available, so call on people who have been involved with these cases to help if you are unsure about the recall status.

Exemplar of 130 device guide pages  
hyperlinked to table of contents

**Model:** H135 and H155

**Name:** CONTAC RENEWAL (H135) and CONTAC RENEWAL 2 (H155)

**Type:** CRT-D

<b>Problem</b>	<b>Potential consequences</b>	<b>History</b>	<b>Indications the problem exists</b>	<b>Information source</b>
Shock delivered to the device itself, instead of to the heart, as a result of a short caused by deterioration of a wire insulator in the lead connector block. Once this short occurs, the damage to device function is permanent. Electrical energy intended for the heart is shorted “to the active titanium case during shock delivery.” “Bench testing shows that only about 20% of the intended shock energy will be delivered to the heart” Device replacement is required if this short circuit occurs.	Device will deliver little or no shock to the heart, and thus the device is unlikely to reverse arrhythmic event, which can be fatal.  Also pacing function is lost.	The short circuit potential exists in all units made on or before August 26, 2004.	<ol style="list-style-type: none"> <li>1. Loss of telemetry, programming, or interrogation. Lack of tachyarrhythmia detection and shock delivery.</li> <li>2. Loss of pacing output.</li> <li>3. Red warning screen on interrogation.</li> <li>4. Yellow warning screen on interrogation indicating out of range shocking impedance.</li> </ol>	6/17/05 Guidant Dear Doctor Letter “Urgent Medical Device Safety Information & Corrective Action”

(Continued in original)

[Hyperlinked to source document](#)

Example of original source Guidant correspondence hyperlinked from Device Guide



**URGENT MEDICAL DEVICE SAFETY INFORMATION  
& CORRECTIVE ACTION**

May 12, 2006

Subject: VITALITY<sup>®</sup> HE implantable cardioverter defibrillators (ICDs) and CONTAK RENEWAL<sup>®</sup> 3 and 4 cardiac resynchronization therapy defibrillators (CRT-Ds) implanted beneath the pectoral muscle in an uncommon orientation.

Dear Doctor,

This letter provides important safety information regarding VITALITY HE ICDs, and CONTAK RENEWAL 3 and 4 CRT-Ds (model numbers listed in Table 1 below). Guidant has received two (2) reports of device malfunction associated with subpectoral implantation in an uncommon orientation (serial number facing ribs). While implant orientation is not reported to Guidant, our records indicate that your health care facility may have implanted or is currently monitoring devices that may be at risk. This advisory is limited to those implanted **subpectorally with the serial number facing the ribs** (see Figure 2 below). You are encouraged to review the implant positioning for each patient to determine if any of your patients are affected. The vast majority of devices are implanted subcutaneously and are not subject to this failure mechanism. The United States Food and Drug Administration (FDA) may classify this communication as a recall.

**Description of Issue**

Two reports of malfunction were associated with subpectoral implantation of devices in certain families of ICDs and CRT-Ds (see Table 1). Accelerated life testing has shown that repetitive mechanical stress applied to a specific area of the titanium case can induce component damage and device malfunction. This can occur **only if the device is implanted subpectorally with the serial number facing the ribs**. As shown in Figure 2, an anterior/posterior (AP) radiograph can be used to determine device orientation.

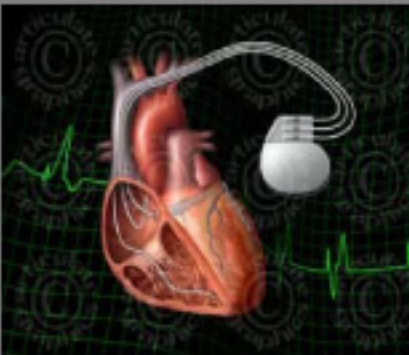


Anterior view



**Figure 1.** Optimal orientation for subpectoral implants. Leads exit in a counter clockwise direction. Serial number is visible at implant

**Figure 2.** Avoid this orientation for subpectoral implants. Leads exit in a clockwise direction. Serial number is facing the ribs



## Implanted Cardiac Device Newsletter

*For Guidant and Medtronic clients*

Anapol, Schwartz, Weiss, Cohan,  
Feldman & Smalley, P.C.

Hill, Peterson, Carper, Bee & Deitzler PLLC

Hill Williams PLLC

Clark, Perdue, Arnold & Scott, LPA

Fall 2006

### **Second Guidant case settled**

*A Guidant heart device case was settled a few days before a trial was to have started in September 2006 in Corpus Christi, Texas.*

*The amount of the settlement is confidential. One previous Guidant case was settled.*

*No Medtronic cases have been settled.*

## Ruling pending on motion to dismiss

*Medtronic argues that federal law defeats all implanted heart device cases*

On October 16, 2006, lead counsel for the plaintiffs in the consolidated federal Medtronic litigation in Minnesota submitted what should be the last of a series of legal documents filed with the court in connection with a motion to dismiss made by Medtronic in March 2006.

Medtronic argues that the federal Medical Device Act of 1976 preempts all claims for injuries against the manufacturer of a medical device that was cleared for sale by the FDA under what is known as the Pre-Market Approval (PMA) process.

Medtronic says that the only remedy against the manufacturer of a device approved by the FDA under the PMA process is whatever, if any, regulatory action the FDA might choose to take against the manufacturer, such as a fine.



Medtronic's World Headquarters in Minneapolis

## WELCOME TO THE ALLIANCE GUIDANT & MEDTRONIC CLIENT DATABASES

Use the buttons below to select the Guidant or Medtronic Client Database, or to log out.

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**Anapol, Schwartz, Weiss, Cohan, Feldman, & Smalley, P.C.**, 1900 Delancey Place  
Philadelphia, PA 19103, (866) 735-2792

**Clark, Perdue, Arnold & Scott**, LPA, 471 East Broad Street, Suite 1400, Columbus OH,  
43215 (800) 647-7003

**Hill, Peterson, Carper, Bee & Deitzler PLLC**, 500 Tracy Way, Charleston WV 25311,  
(800) 822-5667

**Hill Williams PLLC**, 89 12th Street, Wheeling WV 26003, (866)706-1477

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orzolek@hwlaw.us, 866-706-1477.

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The latest Medtronic news from Google continuously updated below