

UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA
THIRD DIVISION

In re: Guidant Corp. Implantable Defibrillators
Products Liability Litigation

MDL No. 1708 (DWF/AKB)

This Document Relates to All Actions

PLAINTIFF'S FACT SHEET

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Each Plaintiff who was implanted with a Guidant defibrillator or a pacemaker or combination defibrillator/pacemaker must complete this Fact Sheet. In completing this Fact Sheet, you are under oath and must provide information that is true and correct to the best of your knowledge, information and belief. If you cannot recall all the details requested, please provide as much information as you can if the response to any question is that the person completing this Fact Sheet does not know or does not recall the information requested, that response should be entered in the appropriate location(s). You may and should consult with your attorney, if you have any questions regarding the completion of this form.

If you are completing this form for someone who has died or who cannot complete the Fact Sheet for him or herself, please answer as completely as you can for that person. You may attach as many sheets of paper as are necessary to answer these questions fully.

If you do not know an answer or a question does not apply to you, or you cannot remember an answer, then fill in the blank with "N/A" or "I don't know" or "I don't remember". Its important to FILL IN EVERY LINE.

I. CASE INFORMATION

A. Please state the following for the civil action which you filed:

1. Case Caption: _____

2. Please state name, street address, telephone number, fax number and E-mail address of primary attorney representing you.

Name

Firm

Street Address

City, State and Zip Code

Telephone number

Fax number

E-mail address

B. If you are completing this questionnaire in a representative capacity (e.g., on behalf of the estate of a deceased person or a minor), please complete the following about you, the representative:

1. _____
The Representative's Name:

2. _____
The Representative's Street Address:

3. _____
City, State and Zip Code

4. In what capacity are you representing the deceased or a minor (for example, beneficiary under the will, representative of the estate, executor of the estate, or guardian):

5. If you were appointed by a court in a representative capacity, identify the:

Court

Date of Appointment

6. Your relationship to deceased or represented person:

7. If you represent a decedent's estate, state the date of death and cause of death of the decedent.

[If you are completing this questionnaire in a representative capacity, please respond to the remaining questions in this Fact Sheet with respect to the person who received a Guidant Implantable Defibrillator and/or Pacemaker. Those questions using the term "You" refer to the person who received an implantable defibrillator and/or pacemaker. If the individual is deceased, please respond as of the time immediately prior to his or her death unless a different time period is specified.]

C. Alleged Injuries:

1. Do you claim that you have suffered a physical injury as the result of the use of a Guidant implantable defibrillator and/or pacemaker?

Yes _____ No _____

2. If the answer to the foregoing question is "Yes," state the nature of the injury or injuries which you claim.

3. If you do not claim you have suffered a physical injury as the result of the use of a Guidant implantable defibrillator and/or pacemaker, state how you have been injured or describe the losses you are claiming.

II. PERSONAL INFORMATION

A. Last Name: _____

First Name: _____

Middle Name: _____

B. Maiden or other names used or by which you have been known, including alias/nicknames:

C. Present Street Address:

Street

City, State and Zip Code

D. Current or last occupation:

E. Social Security Number:

F. Place of Birth:

G. Date of Birth:

H. Sex: Male: _____ Female _____

IF YOU ARE MAKING A CLAIM FOR PHYSICAL INJURIES:

Answer questions I-K.

IF YOU ARE NOT MAKING A CLAIM FOR PHYSICAL INJURIES, skip to SECTION III.

I. Have you filed a worker's compensation claim in the last ten (10) years?

Yes _____ No _____

If yes, please state

1. Year claim was filed: _____
2. Where was the claim filed: _____
3. Claim/docket number, if applicable: _____
4. Nature of disability: _____
5. Period of disability: _____
6. Street address of claims office: _____

7. Whether the claim was settled and amount of any settlement:

[Attach additional sheets if necessary to describe more than one claim]

J. Have you ever filed a social security disability claim within the last ten years?

Yes _____ No _____

1. If yes, please state

a. Year claim was filed: _____

b. Where claim was filed: _____

c. Nature of disability: _____

d. Period of disability: _____

e. Street address of claims office: _____

f. Monthly amount of any disability payments: _____

g. Amount of any lump sum settlement: _____

h. [Attach additional sheets if necessary to describe more than one claim]

K. Have you ever filed a lawsuit or made a claim, other than the present lawsuit, relating to any physical injury?

Yes _____ No _____

If yes, state:

1. The courts in which your other lawsuits were filed:

2. The civil action or docket number assigned to each such lawsuit

3. State whether you have ever testified under oath (e.g., in a courtroom or in a deposition) in any of these lawsuits.

III. MARITAL STATUS

A. Are you currently married?

Yes _____ No _____

B. Has your spouse filed a loss of consortium claim?

Yes _____ No _____

C. Spouse's name: _____

D. Spouse's date of birth: _____

E. Spouse's occupation: _____

F. If not currently married, do you have any former spouses who have filed loss of consortium claims?

Yes _____ No _____

G. If any former spouses have filed loss of consortium claims, please provide:

1. Name of former spouse: _____

2. Date of birth of former spouse: _____

3. Date of marriage to former spouse: _____

4. Date of dissolution of marriage from former spouse: _____

IV. IMPLANT/EXPLANT INFORMATION

If you received a Guidant implantable defibrillator and/or pacemaker, for which you are making a claim of injury, then for each device, please answer the following questions:

A. Implantation Data:

1. The date of implantation: _____

2. The name and street address of your doctor who told you that you need to have the implantable defibrillator and/or pacemaker implanted: _____

3. The name and street address of the implanting surgeon: _____

4. The specific make, model, lot number and serial number of the Guidant implantable defibrillator and/or pacemaker you received:

5. Name of medical facility where implant was conducted: _____

B. After your Guidant defibrillator and/or pacemaker was implanted, did you participate in regular follow up with your doctor(s) about it.

Yes _____ No _____ I don't know _____

If yes:

1. Please estimate how frequently you follow(ed) up with your doctor(s) about your Guidant defibrillator and/or pacemaker

2. During this follow up, was your Guidant defibrillator and/or pacemaker ever tested by a doctor or a Guidant representative

Yes _____ No _____ I don't know _____

If yes, please provide:

- a. Dates of testing: _____
- b. Facility where testing took place (name & street address): _____
- c. Technician or medical provider performing tests (name & street address): _____
- d. Results of testing: _____

C. Were you given any written instructions, warnings or other information regarding the implantation of the Guidant defibrillator and/or pacemaker?

Yes _____ No _____ I don't know _____

- 1. If "yes," when did you receive the information: _____
- 2. Who gave you the information? _____
- 3. Do you have any of the written information in your possession? If so, please produce a copy of it together with your answers to the Plaintiff's Fact Sheet.

Yes _____ No _____

4. If you no longer have some of the written information in your possession, please describe the information that you received to the best of your ability.

D. Were you ever given any oral instructions, warnings or other information regarding your Guidant Implantable pacemaker and/or defibrillator?

Yes _____ No _____ I don't know _____

- 1. If "yes," when did you receive those instructions? _____
- 2. Who gave those instructions to you? _____

3. Please describe the oral instructions you received to the best of your ability:

E. If you had your Guidant implantable defibrillator and/or pacemaker explanted, please state:

1. The date of explant: _____

2. The reason for the explant: _____

3. The name and street address of the explanting surgeon: _____

4. Name and street address of hospital where explant was conducted: _____

5. The present location of the explanted defibrillator and/or pacemaker: _____

6. If your explanted Guidant defibrillator and/or pacemaker has not been returned to Guidant, has it been tested?

Yes _____ No _____ I don't know _____

a. If "yes," when was it tested? _____

b. Dates of testing: _____

c. Facility where testing took place (name & street address): _____

d. Technician or medical provider performing tests (name & street address): _____

e. Results of testing: _____

7. During your explant surgery, was a replacement defibrillator and/or pacemaker implanted?

Yes _____ No _____

8. If yes, state the manufacturer, make, model, lot number and serial number of the replacement defibrillator and/or pacemaker:

9. Did you pay for any portion of the explant surgery and the replacement defibrillator and/or pacemaker?

Yes _____ No _____

10. If not, identify all entities who paid for any part of the explant surgery and the replacement defibrillator and/or Pacemaker:

F. If you have not had your Guidant implantable defibrillator and/or Pacemaker explanted, do you presently plan to have the device explanted?

Yes _____ No _____

If yes, please provide:

1. The date scheduled for explant surgery: _____

2. The name of the explanting surgeon: _____

3. The name and street address of the hospital where the explant surgery will be performed:

4. The reason for the explant surgery: _____

Regardless of whether your device has been explanted or not, please respond to the following questions:

5. Has any doctor ever told you that you need to have your Guidant Implantable defibrillator and/or pacemaker explanted?

Yes _____ No _____

If yes, provide name and street address of each such doctor:

For each doctor listed, provide the date that the doctor told you that you need to have your Guidant implantable defibrillator and/or pacemaker explanted:

6. Has any doctor told you that your medical condition prevents you from having your Guidant Implantable defibrillator and/or pacemaker explanted?

Yes _____ No _____

If yes, provide the name and street address of each such doctor:

If yes, identify the medical condition: _____

G. If you presently have an implanted defibrillator and/or pacemaker, please state the manufacturer, make, model, lot number and serial number of that device:

V. YOUR MEDICAL HISTORY

A. Age: _____

B. Height: _____

C. Current weight: _____

D. Condition for which the Guidant defibrillator and/or pacemaker was indicated:

E. Current status of condition for which the Guidant defibrillator and/or pacemaker was implanted (e.g., improved, worsened, stable, same):

F. Have you had any of the following tests or procedures in the past 10 years?

Electrophysiology study: Yes _____ No _____ I don't know _____

Cardiac Catheterization: Yes _____ No _____ I don't know _____

If "yes," please complete the following. If you cannot remember all the details, please list as much information as you can.

- a. Type of test: _____
- b. Date administered: _____
- c. Reason for test: _____
- d. Facility name & street address: _____
- e. Ordering doctor: _____
- f. Results/diagnosis: _____

(Attach additional pages, as necessary.)

VI. OTHER MEDICAL INFORMATION

A. To the best of your knowledge, have you ever been told by a doctor or any other health care provider, that you have, may have or had any of the following:

- | | | | | |
|--|-----|------|----|------|
| 1. Hypertension or high blood pressure | Yes | ____ | No | ____ |
| 2. Heart valve problems | Yes | ____ | No | ____ |
| 3. Heart attack | Yes | ____ | No | ____ |
| 4. Stroke | Yes | ____ | No | ____ |
| 5. Any kind of blood clot | Yes | ____ | No | ____ |
| 6. Pulmonary embolism | Yes | ____ | No | ____ |
| 7. Congenital abnormality of heart | Yes | ____ | No | ____ |
| 8. Rheumatic fever | Yes | ____ | No | ____ |
| 9. Cirrhosis, hepatitis or other liver disease | Yes | ____ | No | ____ |
| 10. Alcoholism | Yes | ____ | No | ____ |
| 11. Cancer(s)
If yes, specify type: _____ | Yes | ____ | No | ____ |
| 12. Pulmonary hypertension | Yes | ____ | No | ____ |

- 13. Cardiac arrhythmias Yes ___ No ___
- 14. Endocarditis Yes ___ No ___
- 15. Any cholesterol problem Yes ___ No ___
- 16. Diabetes mellitus or other form of diabetes Yes ___ No ___
If yes, specify type: _____
- 17. Coronary artery disease Yes ___ No ___
- 18. Other heart or lung disease Yes ___ No ___
If yes, specify the type: _____
- 19. Gum disease, tooth infection or abscess Yes ___ No ___
- 20. Transient ischemic attack (TIA) Yes ___ No ___
- 21. Hypotension (low blood pressure) Yes ___ No ___
- 22. Carotid artery disease Yes ___ No ___
- 23. Aortic aneurysm Yes ___ No ___
- 24. Syncope, light-headedness, or dizziness Yes ___ No ___
- 25. Bradycardia Yes ___ No ___
- 26. Sudden cardiac death Yes ___ No ___
- 27. Cardiomyopathy (hypertensive, ischemic) Yes ___ No ___
- 28. Tachycardia Yes ___ No ___

B. If you responded yes to any of the above, please identify the condition, the date of onset and state the name of the physician or other individual and, if not provided elsewhere in this Fact Sheet, the street address of the physician or other individual who made the diagnosis or informed you of the condition. (Use extra pages if necessary.)

- 1. Condition: _____
Onset: _____
Name and street address of diagnosing physician or other person:

- 2. Condition: _____
Onset: _____
Name and street address of diagnosing physician or other person:

- 3. Condition: _____
Onset: _____
Name and street address of diagnosing physician or other person:

- 4. Condition: _____
Onset: _____
Name and street address of diagnosing physician or other person:

- 5. Condition: _____
Onset: _____
Name and street address of diagnosing physician or other person:

- C. State the name and street address of your current family/primary care physician:

- D. State the name and street address of each of your family/primary care physicians going back 10 years.

- E. State the name and street address of each cardiologist, cardiac electrophysiologist, cardiac surgeon and/or thoracic surgeon that has ever seen or treated you.

- F. State the name and street address of each hospital or surgery center where you have ever received treatment in the last 10 years.

- G. State the name and street address of each other physician or healthcare provider from whom you ever received treatment in the last 10 years.

- H. State the name and street address of each pharmacy, drugstore or any other facility where you ever received any prescription medication in the last ten years.

VII. ALLEGED INJURIES, ILLNESS AND DAMAGES

A. If you are making a claim for physical injuries or illness as a result of your Guidant defibrillator and/or pacemaker, please describe the following:

1. Nature of physical injuries or illness: _____

2. The date you first became aware of the physical injuries or illness:

3. How you first became aware of the physical injuries or illness:

4. Are those injuries or illness continuing? _____

5. Did you see a doctor, clinic or other healthcare provider for the physical injuries or illness listed above?

Yes _____ No _____ I don't know _____

B. Psychological injuries

1. Are you making a claim for psychological or emotional injuries as a consequence of having a Guidant implantable defibrillator and/or Pacemaker?

Yes _____ No _____

IF YOU ARE NOT MAKING A CLAIM FOR PSYCHOLOGICAL OR EMOTIONAL INJURIES, SKIP TO SECTION VIII

2. State whether you have been treated for any psychological, psychiatric or emotional problem at any time during the last ten years.

If yes, state:

1. Name and street address of each person who treated you

a. _____
Name

Street address (if not otherwise provided)

b. _____
Name

Street address (if not otherwise provided)

c. _____
Name

Street address (if not otherwise provided)

2. Condition for which treated

3. When treated

VIII. LOSS OF INCOME OR DIMINISHED EARNING CAPACITY

A. Are you making a claim for lost income or impairment of earning capacity as a result of any condition which you believe was caused by your Guidant implantable defibrillator and/or pacemaker?

Yes _____ No _____

IF YOU ARE NOT MAKING A CLAIM FOR LOSS OF INCOME, SKIP TO SECTION IX.

B. If you are making a claim for lost income, state current or last employer:

Name:

Street address:

Dates of Employment:

C. If you are making a claim for lost income or lost earning capacity, please provide the following information with respect to your employment for the past five (5) years.

Employers for Past Five Years	Street Address	Position	Dates of Employment

1. State the total amount of time which you have lost from work as a result of any condition which you claim or believe was caused by your Guidant implantable defibrillator and/or pacemaker:

2. State the total amount of income which you have lost from work as a result of any condition which you claim or believe was caused by your Guidant implantable defibrillator and/or pacemaker:

3. State your earned income for each of the last five years.

Year	Income
_____	\$ _____
_____	\$ _____
_____	\$ _____
_____	\$ _____
_____	\$ _____

IX. MEDICAL AND OUT-OF-POCKET EXPENSES

A. State the amount of medical expenses you have paid or incurred, including amounts billed or paid by insurers and other third party payors, which are related to any condition which you claim or believe was caused by your use of a Guidant implantable defibrillator and/or pacemaker for which you seek recovery in this action. \$ _____

B. If you are making claims from out-of-pocket expenses as a result of the affected product, please complete the following:

1. What are the expenses for? _____

2. Amount of fees or expenses: _____

DOCUMENT REQUEST

Attach the following documents to this declaration, to the extent that such documents are currently in your possession or your lawyers.

Please go through each Request and state whether you do or do not have anything that is responsive to the Request by checking either “Attached,” “Not Applicable,” or “Don’t Have.”

1. All press releases or other public statements made by you relating to this litigation or to your illness, injury, or medical condition that forms the basis of your Complaint.

Attached ___ Not Applicable ___ Don’t Have ___

2. All reports of any testing, including drafts and raw data, conducted on the Guidant implantable defibrillator and/or pacemaker that is the subject of your claim in this litigation.

Attached ___ Not Applicable ___ Don’t Have ___

3. All x-ray images depicting the location of the Guidant implantable defibrillator and/or pacemaker.

Attached ___ Not Applicable ___ Don’t Have ___

4. All documents referring or relating to your claimed damages.

Attached ___ Not Applicable ___ Don’t Have ___

5. Each informed consent form signed by you in connection with treatment by a health care professional and/or institution relating to any Guidant implantable defibrillator and/or pacemaker whether manufactured by Guidant or any other company.

Attached ___ Not Applicable ___ Don’t Have ___

6. All documents, including but not limited to, literature and/or warnings, received by you relating to any Guidant implantable defibrillator and/or pacemaker from any source.

Attached ___ Not Applicable ___ Don’t Have ___

7. All documents referring to or relating to your medical history over the past ten years, including, but not limited to, medical records.

Attached ___ Not Applicable ___ Don’t Have ___

8. All documents relating to your insurance coverage that are applicable to the illness, injury or medical condition which forms the basis of your Complaint, including any application to any insurer for coverage whether insurance was obtained or not.

Attached ___ Not Applicable ___ Don’t Have ___

9. All written, recorded or transcribed statements concerning this action made by any parties or witnesses, or their respective agents, servants or employees.

Attached ____ Not Applicable ____ Don't Have ____

10. If you claim that you have suffered a physical injury as the result of the use of a Guidant implantable defibrillator and/or pacemaker, all documents submitted to or received from the Social Security Administration, any workers' compensation agency, or any disability insurer concerning any disability claim you have made during the past ten years.

Attached ____ Not Applicable ____ Don't Have ____

11. If you are making a claim for loss of earnings or loss of earnings impairment, your state and federal tax returns for the last five years and your employment records for the last five years.

Attached ____ Not Applicable ____ Don't Have ____

12. Authorizations for the release of release of medical, employment, insurance and disability records for those entities identified in this Fact Sheet.

13. If you represent a decedent's estate, provide a copy of the decedent's death certificate and autopsy report (if conducted) as well as a copy of all documents, letters, or orders appointing you as representative of the estate or otherwise reflecting your authority to act in a representative capacity.

Attached ____ Not Applicable ____ Don't Have ____

DECLARATION

I declare under penalty of perjury under the laws of the United States of America that all of the information provided in this Fact Sheet is true and correct to the best of my knowledge. I further declare that I have supplied all the documents requested in the Document Request portion of this Fact Sheet, to the extent that such documents are in my possession or in the possession of my lawyers, and that I have supplied authorizations for the release of medical, employment, insurance and disability records for those entities identified in these responses.

Signature

Date

AUTHORIZATION AND RELEASE FOR MEDICAL RECORDS

TO: **RE: Patient Name:**
Alias/Maiden:
DOB:
SSN:

I authorize the disclosure of all protected medical information in any form to the law firms of **SHOOK, HARDY & BACON L.L.P.** located at 2555 Grand Ave., Kansas City, Mo., 64108-2613 or any members, associates or designees of the firms. I further authorize the disclosure of all protected medical information to be redisclosed to any of consultants, experts, agents, and/or other counsel hired by Shook, Hardy & Bacon. I expressly request that all covered entities under HIPPA identified above disclose full and complete protected medical information, spanning from ten years ago to the present, including but not limited to, the following:

- All medical records, hospital records, inpatient, outpatient and emergency room treatment, all clinical charts, questionnaires/histories, reports, correspondence, test results, discharge summaries, anesthesia records, surgical consultations, social service records, questionnaires/histories, intake sheets, office notes and/or any healthcare provider's handwritten notes; and any records received from other physicians or health care providers;
- All autopsy, laboratory, histology, cystology, pathology, radiology, CT Scan, MRI, echocardiogram, electrocardiograms, pulmonary function tests, stress tests, angiograms, cardiac catheterization tapes, and cardiac catheterizations reports;
- All radiology films, x-rays, mammograms, myelograms, photographs of any type, bone scans, and any and all videos/CDs/films/reels regarding any treatment or tests performed;
- All medical bills, printouts, statements and/or insurance records;
- All pharmacy prescription records, including drug information handouts/ monographs;
- All documents related to amendment of any record request.
- All mental health records, including but not limited to, medical, psychological or other treatment, examination or counseling for any medical condition or psychological or emotional distress or upset. This Medical Authorization specifically authorizes the production and copying of records for alcohol or drug abuse, as provided by 42 CFR § 2.1, et. seq.

I acknowledge the right to revoke this authorization by writing to a representative of Shook, Hardy & Bacon. However, I understand that any actions already taken in reliance on this authorization cannot be reversed, and my revocation will not affect those actions. I acknowledge the potential for information disclosed pursuant to this authorization to be subject to redisclosure by the recipient and no longer be protected under 45 CFR 164.508. I understand that the covered entity to whom this authorization is directed may not condition treatment, payment, enrollment or eligibility benefits on whether or not I sign the authorization. **Any facsimile, copy or photocopy of the authorization shall authorize you to release the records herein.** This authorization expires one year from the date below.

Signature of **Patient** if 18 years of age or older: _____ **Date:** _____

Signature of **Parent or Legal Representative:** _____ **Date:** _____

Relationship to Patient, if not signed by Patient: _____