

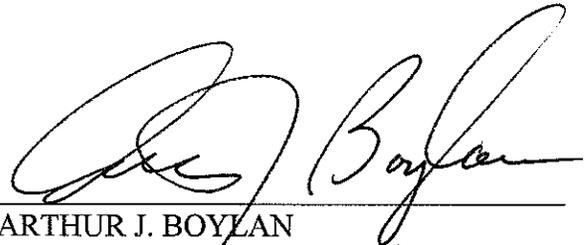
UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA
THIRD DIVISION

IN RE: GUIDANT CORP. IMPLANTABLE
DEFIBRILLATORS PRODUCT LIABILITY
LITIGATION

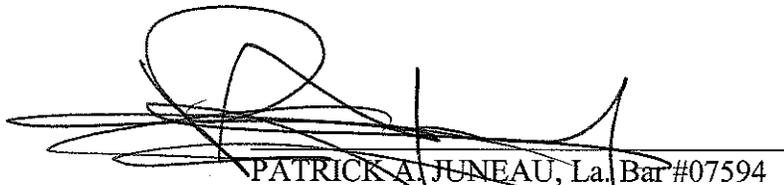
MDL NO. 1708
(DWF/AJB)

IMPLEMENTATION OF SETTLEMENT CONSIDERATION FORM
SUPPLEMENTATION PROTOCOL

Under the provisions of the Master Settlement Agreement, the Special Master and Assistant Special Master adopt and direct implementation of the Settlement Consideration Form Supplementation Protocol attached as Exhibit 1.



ARTHUR J. BOYLAN
United States Magistrate Judge
Special Master
636 U.S. Courthouse
316 North Robert Street, Room 9E
St. Paul, MN 55101
Telephone: (651) 848-1210
Facsimile: (651) 848-1212



PATRICK A. JUNEAU, La. Bar #07594
Assistant Special Master
1018 Harding Street, Suite 202
Lafayette, Louisiana 70503
Telephone: (337) 269-0052
Facsimile: (337) 269-0061

February 14th, 2008.

CERTIFICATE OF SERVICE

I **HEREBY CERTIFY** that copies of the foregoing report were this day served on the plaintiff's class through the Plaintiffs' Management Committee and on the Attorneys for the settling defendants by U.S. Mail.

Lafayette, Louisiana this 14th day of February, 2008.


PATRICK A. JUNEAU
Assistant Special Master

Guidant MDL 1708 Settlement Consideration Form Supplementation Protocol

Plaintiffs' counsel shall submit supplemental documentation described below, in the same procedural manner and required in the Court's Order of July 16, 2007, **no later than March 28, 2008.** Counsel is cautioned that failure to provide the necessary documentation to support a proof of claim in a particular category will result in that claim being considered on its merit as submitted, which may result in a claim being valued at a lower category or without consideration of alleged device malfunctions or failures. **No further opportunity to supplement the claim will be provided.**

The settlement funding process approved by the Special Masters and the PSC requires that counsel submit relevant supplemental documentation which is necessary to support a claim under one or more of the categories identified and described in more detail in the following section, consistent with the requirements of the Settlement Consideration Form (SCF) and the relevant Q&A #3 published by the Plaintiff's Steering Committee.

It is imperative in this process that only true complications, malfunction and death cases be submitted for Category III- Extraordinary Injury Fund consideration. Common pain, scarring, anxiety, and typical hospitalizations will not be considered a complication of the explant procedure. The section provides examples of the severity of injury necessary to seek categorization of a case as a Category III- Extraordinary Injury Fund or EIF claim. The Court shall retain the right to issue any, and all orders, including Orders to Show Cause why sanctions should not be entered, with respect to any frivolous, non-meritorious, or duplicative EIF claims.

What proof is acceptable?

Each claim should be accompanied with a cover sheet (provided as Exhibit 1) with the claimant's name, Social Security Number (SSN) and date of birth. All claim submissions should be classified, on this initial cover sheet, in one of the two base categories for non-explant or explant. If the previous SCF submission did not classify the claim or if after further review a determination is made to change a previous category, it is a requirement to clearly identify such information in your supplemental submission. Further, each claimant shall indicate **in addition to the base category** whether a claim is being brought for Category III -Extraordinary Injury Fund consideration, and if so, 1) the type of EIF claim being asserted, and 2) whether the claim involves a wrongful death. If the Claimant is making an Extraordinary Injury Claim (i.e. malfunction, complications, and/or Death) a second coversheet (provided as Exhibit 2) should be completed indicating which type Category III-Extraordinary Injury Claim the individual is making.

In order to streamline the process, counsel or claimants will be provided with an electronic spreadsheet containing the claimant's last name, first name, SSN, DOB, Device(s) Information and Explant or Non-Explant Status as provided by submitted SCFs. Columns will be provided on the spreadsheet for Counsel to indicate whether the Claimant is stating a Category III claim under the Allocation Plan for the following: 1) Wrongful Death Claim (y/n), 2) Complication Status (y/n) and/or 3) Malfunction Status (y/n).



1. Category I. - Non Explant

Proof of implantation of a recalled device which can be identified as being subject to a Guidant Advisory as indicated on Guidant's website must be established through one of the following:

- a. ICD Card
- b. Medical record of implant procedure;

NOTE: Operative reports must include: name of claimant, date of implant and name and serial number of device being implanted.

2. Category II. - Explant

To support a proof of claim for an explant or replacement of a device (see Q&A #3 and definition below), counsel must submit the following:

- a. Implant Records as required for Category I. - Non-explant cases listed above; AND
- b. Operative report or physician medical record documenting the replacement surgery.

NOTE: Operative reports must include: name of claimant, date of explant and name and serial number of device being explanted.

3. Category III. A. - EIF Benefits due to Complications

To support a Category III EIF claim for complications as a result of the surgery to replace the recalled device, severe psychological or emotional complications, or from the inability to have replacement surgery due to medical or financial circumstances, the following is required:

- a. Implant Records as required for Category I. - Non-explant cases listed above.
- b. A separate statement, as required by the SCF, containing at least a one paragraph summary prepared by Claimant or Plaintiff's counsel which succinctly explains the complication and resulting injury sustained, which should point to specific pages or instances in the attached documentation which supports such claim for complication. Form language statements are discouraged, and Claimant's or Plaintiff's counsel should use their best efforts to accurately describe the complications claim being presented; AND
- c. Medical records documenting complications, such as the following examples:
 - i. Extreme anxiety post notification of the recall which is clearly documented in the records as resulting in physical manifestations such as shingles or hives OR requiring new anxiety medication or increased dosing of a previous prescription OR psychological treatment;
 - ii. Proof of inability to explant due to physical or financial circumstances,
 - iii. Severe infection related to the replacement surgery requiring antibiotic treatment and/or readmission to the hospital;
 - iv. Subsequent surgery to correct ICD pocket, dislodged wire, treat infection, and the like;
 - v. Extensive out of pocket expenses due to lack of or insufficient insurance (medical billing required);
 - vi. Significant Wage Loss; and/or

- vii. Other similar complications directly related to replacement of the recalled device.

4. Category III.B. – EIF Claim for Wrongful Death

To support a claim for death, claimants must submit the following:

- a. Implant Records as required for Category I. - Non-explant cases listed above.
- b. Summary describing how the death is related to device malfunction or failure of the device OR complications related to the surgery to replace the recalled device; which should point to specific pages or instances in the attached documentation which supports such claim for wrongful death. Form language statements are discouraged, and Claimant's or Plaintiff's counsel should use their best efforts to accurately describe the wrongful death claim being presented; AND one or more of the following:
 - i. A death certificate;
 - ii. Medical records supporting a related death;
 - iii. (Optional) Expert Reports will be permitted which are consistent with supporting medical records and cannot be submitted in lieu of medical records.

NOTE: Unrelated deaths will be categorized according to the claimant's injury immediately preceding his or her death. (e.g. non-explant, explant)

5. Category III.C. - EIF Claim for Malfunctions (Please refer to Q&A #3 for additional information)

To support a claim for additional funds for an injury due to a malfunction or failure, claimants must provide at least the following:

- a. Implant Records as required for Category I. - Non-explant cases listed above.
- b. Page 2 of the SCF, which includes a brief summary of the failure or malfunction consistent with the FDA announced failure mode, which should accurately describe the malfunction sustained, the injury that resulted from the malfunction, and should point to the page or instances in the supporting documentation and records which support such malfunction claim; AND
- c. Documentation of inappropriate pacing or loss of therapy consistent with the claimant's particular device defect; AND
- d. Documentation of an injury resulting from the inappropriate pacing or loss of therapy, including supporting medical records. Expert Reports will be permitted which are consistent with supporting medical records and cannot be submitted in lieu of medical records; OR
- e. Device Testing Results (verifiable) indicating a Malfunction. (The last PTO 15 device testing date is January 14, 2008 and claimants who wish to have their device tested should contact Elizabeth Peterson in Lead Counsel's office at eap@zimmreed.com).
- f. If the claim for malfunction arose before the recall date, and the claimant seeks damages for explant arising from the malfunction, the claimant shall submit medical records indicating that the explant was the result of the

malfunction and make such claim to the Category III Extraordinary Injury Fund.

NOTE: Inappropriate pacing or device malfunctions that did not lead to explantation of the device, or death, should be carefully scrutinized before submission. As a reminder, explant of the device after the alleged malfunction or failure does not qualify as an “injury” related to malfunction or failure. (See SCF Page Two and Q&A #3). Inappropriate shocking is typically not related to device malfunction, but instead is a product of the programming of the device, lead wires, or the patient’s condition.

In no event shall documentation supporting a proof of claim, including claims for Category III consideration, exceed 30 pages without PRIOR permission from the Special Masters. Thus, if counsel or a claimant previously submitted voluminous documentation, the claim package attachments should be revised to incorporate only what is necessary and relevant to the factors delineated below. The Special Masters shall have the right to reject the review of claims with more than 30 pages of documentation.

Question related to the supplementation of claims may be directed to Elizabeth Peterson in Lead Counsel’s office at eap@zimmreed.com.

Attachments

**MDL 1708 - IN RE GUIDANT CORP. IMPLANTABLE DEFIBRILLATORS PRODUCTS
LIABILITY LITIGATION
SUPPLEMENT COVERSHEET TO SETTLEMENT CONSIDERATION FORM**

Claimant Name: _____

Claimant Social Security Number: ____-____-____ Claimant Date of Birth: ____/____/____

Claimant Base Category (Please check one):

Category I: Non-Explant (includes deceased claimants without a wrongful death claim)

Category II: Explant

Extraordinary Injury Claim (Please check if you are making claim for Extraordinary Injury Fund Consideration based upon Device Malfunction or Severe Complications, including claims for Wrongful Death):

Category III: Extraordinary Injury Claim (Must complete EIF coversheet)

Wrongful Death (Check if EIF claim involves claim for wrongful death)

**Checklist for EVERY GUIDANT DEVICE for which Claimant is seeking
settlement funds.**

Model Information: (Please List Information Specifically)

1. Model Type (Ventak 2, Contak 3, etc)
2. Model Number (1861, H135, 1298, etc)—Both Model Type and Number must be included
3. Device Serial Number—Must be complete 6 digit number

Implant Information:

1. Implant Date

Proof of Implant attached:

- Guidant Medical Device Card
- Medical Record of implant surgery (must include device name and Serial Number)
- Already Provided

Explant Information (if Applicable):

1. Explant Date

Proof of Explant attached:

- Medical Record of explant surgery (must include device name and Serial Number)
- Already Provided



MDL 1708 - IN RE GUIDANT CORP. IMPLANTABLE DEFIBRILLATORS PRODUCTS
LIABILITY LITIGATION

Extraordinary Injury Claims Coversheet

NOTE: Expert Reports without Medical Records will not be accepted

Claimant Name: _____

Claimant Social Security Number: _____ - _____ - _____ Claimant Date of Birth: ____/____/____

Summary statement of Extraordinary Injury Claim(s) (REQUIRED)-Please attach.

Wrongful Death Claims (Please check appropriate boxes and provide necessary information and required evidence)

Death (Allocation Plan IV(D)(1)(k)) (Check if claim involves death of claimant)

Proof of Death:

Death Certificate

Medical Records

Any causal relationship between device failure and death:

Medical Records

Other: _____

Any causal relationship between explant surgery due to recall and death:

Medical Records

Other: _____

Malfunction Claims (Please check appropriate boxes and provide necessary information and required evidence)

Device Malfunction (Allocation Plan IV(D)(1)(b))

Proof of device malfunction:

Medical records

Guidant testing records

Other: _____

Complications Claims (including complications related to device malfunction) (Please check appropriate boxes and provide necessary information and required evidence)

Extraordinary psychological injury (Allocation Plan IV(D)(1)(a & c))

Proof of contemporaneous extraordinary psychological injury:

Medical records dated after recall date

Pharmaceutical records dated after recall date

Other: _____

Extraordinary physical injury (as defined in Allocation Plan IV(D)(1)(g, h, i & j))

Proof of contemporaneous extraordinary physical injury:

Medical records

Other: _____

Inability to explant (Allocation Plan IV(D)(1)(d & e))

Proof of inability to explant due to health condition:

Medical records

Other: _____

Proof of inability to explant due to financial condition:

Financial records

Other: _____

Extraordinary Economic Losses (Allocation Plan IV(D)(2)(a))

Summary of economic losses (include total dollar loss)

Proof of economic losses:

Financial records (Tax records, credit card records)

Employment records

Funeral expenses

Medical bills (hospital, pharmacy, doctor, ER, psychiatrist, etc)

Travel expenses

Other: _____

Loss of Consortium (Allocation Plan IV(D)(2)(b))

Signed and Dated Personal Statement from Third Party

Other: _____