

**UNITED STATES DISTRICT COURT  
DISTRICT OF MINNESOTA**

---

IN RE MEDTRONIC, INC.  
IMPLANTABLE DEFIBRILLATORS  
PRODUCTS LIABILITY LITIGATION

MDL NO. 05-1726 (JMR/AJB)

This documents relates to:  
All Cases

---

**ORDER FOR APPROVAL OF  
ALLOCATION AND RESOLUTION PROCESS**

Upon consideration of Plaintiff's Co-Lead Counsel and the PSC's Motion for Approval of Allocation and Resolution Process, and based on the Memorandum supporting such Motion and the exhibits to same, and the record in its entirety, it is hereby ordered that Plaintiffs' Motion for Approval of the Allocation and Resolution Process is GRANTED. UPON CONSIDERATION OF THE ABOVE, IT IS HEREBY ORDERED AS FOLLOWS:

A. The MDL Allocation and Resolution Process (hereinafter the "MDL Program") as set forth in Plaintiffs' Memorandum In Support of the Allocation and Resolution Process and Summary Sheet is adopted, as set forth herein:

1. The purpose of the MDL Program is to establish a system subject to the jurisdiction of this MDL Court whereby the claims of the Participating Claimants will be quickly, consistently, and fairly reviewed and resolved by the MDL Court through Magistrate Judge Boylan (hereinafter "Special Master") and subject to review by Chief Judge Rosenbaum. This Program will be in lieu of any further litigation by the

Participating Claimants with respect to their acquisition or use of a Recalled Device as defined by the Scope Report. Defendant Medtronic will not have any role in structuring or administering this MDL Program. The terms, conditions, and qualifications set forth in the AMSA are incorporated herein and into the MDL Program as if fully set forth therein.

2. The MDL Program shall have three components: (a) Individual Awards; (b) Enhanced Awards; and (c) a Subrogation Process. Only those Participating Claimants who are eligible for an Individual Award are eligible to submit claims to the Enhanced Award Fund. Eligibility for payment in the MDL Program will be based on the Recommendation Form previously submitted to the PSC and completion of a Claim Form (collectively referred to herein as “Claim Materials”), together with submission of medical records and other documentation as set forth herein or as specified by the Special Master. A copy of the proposed Claim Form is attached as Exhibit A.

a. Individual Awards

Participation in, and eligibility for, an award from the Individual Award Fund is based on objective criteria set forth in the Claim Materials and accompanying medical records. Factors considered in determining the eligibility and Individual Award amount include: (1) the implant of one or more Recalled Device(s); (2) the explant of one or more Recalled Device(s); (3) the duration of time between the implant and explant of the Recalled Device(s); and (4) the duration of time between the applicable Recall (i.e., the April 2004 or February 2005 Field Actions as set forth in the Scope Report) and the explant(s). Individual Awards will be grouped into two categories: Category I (non-

explant claims) and Category II (explant claims). An Individual Award Fund will be established to finance the Individual Awards for eligible and Participating Claimants. The proposed Individual Award Fund, as well as the base Individual Award amounts, by Category, is set forth in the Summary Sheet, attached as Exhibit B.

b. Enhanced Awards

Participating Claimants who have suffered documented emotional distress, additional and/or extensive hospitalizations, complications, death, un-reimbursed economic injury, or other catastrophic injuries causally related to the Recall and/or explant of a Recalled Device may seek additional compensation through an Enhanced Award Fund. Participating Claimants may apply, and may be eligible for, additional compensation through the Enhanced Award Fund if: (1) they satisfy the criteria for participation in the Individual Award Fund; and (2) they have a documented catastrophic or enhanced injury related to the Recall or explant of a Recalled Device. Expert reports submitted in lieu of medical records will not be sufficient to establish causation and/or entitlement to Enhanced Awards. Contemporaneous medical records documenting, and a short statement identifying, the specific complication/enhancement alleged must be included in the Claim Materials. Participating Claimants shall not seek an award from the Enhanced Award Fund absent a good faith basis for asserting such a claim. The Special Master shall have the discretion to reduce the Participating Claimant's base award if the Special Master feels that such action is appropriate based on the conduct of the Participating Claimant or his or her counsel in seeking an unwarranted Enhanced

Award. The base amount for the proposed Enhanced Award Fund is set forth in the Summary Sheet, attached as Exhibit B.

c. Subrogation Process - Medicare

The PSC has retained The Garreston Law Firm (“TGLF”) to verify the Participating Claimants who may have potential Medicare obligations related to their Recalled Device and to facilitate reimbursement and resolution of Medicare’s interests in the recoveries of Medicare-entitled Participating Claimants. TGLF will charge a fee for its services with regard to the global resolution of Medicare liens, which will be paid out of the Settlement Fund and deducted from any award received by a Medicare recipient on a pro rata basis. A Medicare Fund will be established within the Settlement Fund to finance the Medicare reimbursement process. The amount set aside for the Medicare Fund is set forth in the Summary Sheet, attached as Exhibit B.

d. Subrogation Process – Medicaid

To streamline the resolution of any individual Medicaid liens for Participating Claimants, TGLF will utilize a Medicaid-specific “Reimbursement Model” to determine the likely course of treatment associated with each compensable injury category. For those Participating Claimants verified as Medicaid beneficiaries, TGLF will secure claims histories from the appropriate agency and audit each claims history against the Reimbursement Model checklist. TGLF will resolve such liens individually and the final lien amount will be deducted from each respective Medicaid-entitled Participating Claimant’s final award. TGLF will coordinate direct reimbursement to each Medicaid agency to ensure the satisfaction of the agencies’ potential lien interest. TGLF’s fee for

its services with regard to the resolution of Medicaid liens will be paid out of the Settlement Fund, and then deducted from awards received by any Medicaid-entitled Participating Claimant on a pro rata basis.

e. Subrogation Process – Private Third Party Payor Liens

Each Participating Claimant and his or her individual counsel shall be required to identify and determine whether or not any non-participating private third party payor subrogation liens exists and, to the extent such subrogation liens exist, whether those issues have been resolved. Prior to the release of Participating Claimants' total award amount, the Participating Claimant and his or her individual counsel must: (1) certify to the Special Master that subrogation liens have been resolved; or (2) certify to the Special Master that TGLF has been engaged to resolve the outstanding subrogation liens; or (3) certify to the Special Master that the Participating Claimant's counsel has reviewed the contents of the Participating Claimant's file, conferred with the Participating Claimant, and confirmed that no Notice of Lien or subrogation liens exist. All Participating Claimants and their individual counsel must also sign an Indemnification Agreement holding the Special Master, Plaintiffs' Co-Lead Counsel and the PSC harmless for any subrogation liens that are made by any non-participating private third-party payors related to liens that are within the scope of MDL 1726, as defined by the Scope Report, and resolved through this MDL Program.

3. A Claim Review Committee, as recommended by Co-Lead Counsel and appointed by the Special Master, shall provide the Special Master with award recommendations for each Participating Claimant. Thereafter, the Special Master shall

have the sole and exclusive authority (subject only to the appropriate review by Chief Judge Rosenbaum) to determine eligibility or non-eligibility for payment under the MDL process and to determine the sum awarded to that Participating Claimant.

4. The determinations made by the Special Master (including any review by the MDL Court) are final and shall not be subject to any further review or appeal, whether by mandamus, writ, declaratory action, or otherwise, whether directly or indirectly to any other court, tribunal, or governmental subdivision by the Participating Claimant or Defendant.

5. Upon enrollment in the Program, the Participating Claimant consents to the terms and conditions of the Program and accepts the jurisdiction of the MDL Court, regardless of whether their claim was filed in, transferred to, or unfilled, until all proceedings under the Program have been concluded. Such Participating Claimants agree that this MDL Court is empowered to enter Orders: (a) appointing a Special Master to oversee and manage the Program; (b) terminating the Participating Claimants' rights to sue Defendant for claims, filed or unfilled, within the scope of this MDL, as defined by the Scope Report; (c) authorizing the Special Master to pay from the Settlement Fund any award made in favor of a Participating Claimant consistent with this Program in return for a Release of all claims against Defendant Medtronic within the scope of this MDL, as defined by the Scope Report, together with the requisite lien certification and Indemnification; and (d) exercising such additional powers as may be called for under the Program or as may be necessary for the proper management of cases and claims which are before the MDL Court pursuant to this Program.

B. The MDL Court, by consent of the PSC, Participating Claimants, and Defendant Medtronic, shall assume jurisdiction over all Participating Claimants, including those who have unfiled cases and claims within the scope of MDL 1726, as defined by the Report and Recommendation Regarding Scope of MDL 1726 of the MDL Court dated March 6, 2007 (hereinafter "Scope Report"), until all proceedings under the MDL Program have been concluded, at which time Participating Claimants' filed and unfiled claims and cases within the scope of MDL 1726, as defined by the Scope Report, shall be deemed filed and dismissed with prejudice.

C. Participating Claimants shall provide completed Claim Forms (attached as Ex. A) and submit all claim materials no later than **February 29, 2008**. Failure to submit the Claim Form and related materials by this deadline, or within the time set forth in any approved extensions thereof, may, at the discretion of the Special Master, result in denial of such claim and dismissal with prejudice.

D. Plaintiffs' Co-Lead Counsel shall make a recommendation regarding the membership of a Claims Review Committee prior to **January 29, 2008**. The Special Master shall appoint a Claims Review Committee on or before **February 1, 2008**. This Claims Review Committee shall be responsible for providing the Special Master with initial allocation recommendations regarding each of the Participating Claimants. The recommendations of the Claims Review Committee shall be advisory and the Special Master retains the authority to adjust such recommendations in accordance with the terms and conditions of the MDL Program and totality of materials submitted in the Claims Process.



## **EXHIBIT A**



Telephone

Fax Number

Email Address

**III. DEVICE INFORMATION**

**A. If you received a Medtronic ICD subject to the April 2004 or February 2005 Field Actions (“Recalled Device”), please state:**

- 1. Serial Number(s) of the Recalled Device: \_\_\_\_\_
- 2. Date(s) Recalled Device was implanted: \_\_\_\_\_
- 3. If you had more than one Recalled Device implanted (i.e., multiple Recalled Devices), please provide the implant dates for each Recalled Device.
- 4. Please provide a copy of your device registration card or other documentation confirming the date of implant and the device model and serial number.
- 5. Was the Recalled Device Explanted? Yes \_\_\_\_\_ No \_\_\_\_\_

**B. If your Recalled Device was explanted, please state:**

- 1. Date(s) Recalled Device was explanted: \_\_\_\_\_
- 2. If you had more than one Recalled Device explanted (i.e., multiple Recalled Devices), please provide the explant dates for each Recalled Device.
- 3. If the Recalled Device was explanted, you must attach medical records documenting the fact and date of the explant (e.g., operative report, discharge summary etc.) for each Recalled Device.
- 4. Did you experience any complications causally related to the explant of the Recalled Device?  
Yes \_\_\_\_\_ No \_\_\_\_\_
- 5. If yes, please describe in Section V.6 and attach the relevant documentation as set forth in Section V.

**C. If Medicare, Medicaid, or private insurance paid any portion of your explant**

procedure, please state:

- 1. Did Medicare or Medicaid pay for any portion of the explant procedure(s) related to your Recalled Device? **If yes, attach any documentation you have regarding the relevant medical bills, Medicare/Medicaid coverage and payments.**

\_\_\_\_\_
\_\_\_\_\_  
 Yes                      No

- 2. Did private insurance or any other third party (other than Medicare/Medicaid) pay for any portion of the explant procedure(s) related to your Recalled Device? **If yes, attach any documentation you have regarding the relevant medical bills, private insurance or other third party coverage and payments.**

\_\_\_\_\_
\_\_\_\_\_  
 Yes                      No

- 3. If yes, please state the name of the insurer and your policy number.

\_\_\_\_\_
\_\_\_\_\_  
 Insurer    Policy Number

**IV. WRONGFUL DEATH CLAIMS**

- 1. Claimant's Date of Death \_\_\_\_\_

- 2. Do you allege that Claimant died from the **failure** of a Recalled Device?

\_\_\_\_\_
\_\_\_\_\_  
 Yes                      No

**If yes, you must attach contemporaneous medical records documenting the failure of the Recalled Device at the time of Claimant's death.**

- 3. Do you allege that Claimant died as a result of the **explant** of a Recalled Device?

\_\_\_\_\_
\_\_\_\_\_  
 Yes                      No

**If yes, you must attach contemporaneous medical records documenting the death as a result of the explant of the Recalled Device.**

**V. ENHANCED INJURY FUND (“EIF”)**

1. Is Claimant seeking additional compensation from the EIF based on the inability to have the Recalled Device explanted?

\_\_\_\_\_ Yes \_\_\_\_\_ No

2. Is Claimant seeking additional compensation from the EIF for complications related to the Explant of a Recalled Device?

\_\_\_\_\_ Yes \_\_\_\_\_ No

3. Is Claimant seeking additional compensation from the EIF based on the implant or explant of multiple Recalled Devices?

\_\_\_\_\_ Yes \_\_\_\_\_ No

4. Is Claimant seeking additional compensation from the EIF based on a wrongful death claim?

\_\_\_\_\_ Yes \_\_\_\_\_ No

5. Did Claimant experience wage loss as a result of documented complications/death from the explant of a Recalled Device or death from the failure of a Recalled Device?

\_\_\_\_\_ Yes \_\_\_\_\_ No

If yes, you must submit medical and wage records documenting lost time/wages as a result of the complication from the either the Explant Procedure or death from the failure of a Recalled Device.

6. If you answer yes to V.A.1-5, please describe AND **attach contemporaneous medical records documenting the complication/wrongful death, as well as any wage or other records documenting catastrophic economic loss (attach additional pages if needed).**

---

---

---

---

---

---

---

**VI. DECLARATION**

I declare under penalty of perjury that all of the information provided in this Claim Form is true and correct to the best of my knowledge, information, and belief.

---

\_\_\_\_\_  
Claimant's Signature

Date

## **EXHIBIT B**

## MDL 1726 ALLOCATION AND RESOLUTION PROGRAM SUMMARY SHEET

### I. FUND CRITERIA

#### A. Individual Award Fund

Individuals seeking to participate in the Individual Award Fund must provide the following documentation:

##### 1. Category I (Non Explant)

- a. Written proof documenting the implant of each Recalled Device (including implant date and device serial number).

##### 2. Category II (Explant)

- a. Written proof documenting the implant of each Recalled Device (including implant date and device serial number).
- b. Medical records documenting each explant (and date of explant) of a Recalled Device.
- c. Absent medical records documenting a claimant's physical inability to undergo the explant procedure at an earlier date, **explants of Recalled Devices that occur after June 4, 2007 shall not qualify for Category II payment unless the claimant provides medical records documenting that the device malfunctioned consistent with the basis of the recall.** Such claimants may apply for Category I payment.
- d. Absent medical records documenting that the explant occurred for reasons related to the April 2004 Field Action Notice, **explants of April 2004 Field Action Devices that occurred prior to April 4, 2004 shall be considered Non-Explants.**
- e. Absent medical records documenting that the explant occurred for reasons related to the February 2005 Field Action Notice, **explants of February 2005 Field Action Devices that occur prior to February 9, 2005 shall be considered Non-Explants.**

## **B. Enhanced Award Fund**

Individuals who have suffered documented emotional distress, additional and/or extensive hospitalizations, complications, death, un-reimbursed economic injury, or other catastrophic injuries causally related to the recall and/or explant of a Recalled Device may seek additional compensation through an Enhanced Award Fund. Claimants can apply, and may be eligible, for additional compensation through the Enhanced Award Fund if (1) they satisfy the criteria for participation in the Individual Award Fund set forth above and (2) they have a documented catastrophic or enhanced injury related to the recall or explant of a Recalled Device, such as documented psychological harm due to the inability to have the Recalled Device explanted; extensive hospitalization related to the explant; severe complications related to the explant; or extensive un-reimbursed economic damages related to a wrongful death or explant claim. Expert reports submitted in lieu of medical records **WILL NOT** be sufficient to establish causation and/or entitlement to an Enhanced Award.

## **II. ESTIMATED AWARD VALUES**

### **A. Category I (Non Explant):**

1. Each qualifying claimant with a Recalled Device that was implanted **prior to** October 1, 2003, shall receive a minimum guaranteed payment of \$5,000 as their base settlement amount.
2. Each qualifying claimant with a Recalled Device that was implanted **between** October 1, 2003 and October 1, 2004 shall receive a minimum guaranteed payment of \$6,000 as their base settlement amount.
3. Each qualifying claimant with a Recalled Device that was implanted **between** October 1, 2004 and February 9, 2005 shall receive a minimum guaranteed payment of \$7,500 as their base settlement amount.

### **B. Category II (Explant):**

1. Each qualifying claimant with a Recalled Device that was implanted **3 or more years prior to** the explant of the Recalled Device shall receive a minimum guaranteed payment of \$30,000 as their base settlement amount.

2. Each qualifying claimant with a Recalled Device that was implanted **less than 3 years but more than 6 months prior to** the explant of the Recalled Device shall receive a minimum guaranteed payment of \$34,000 as their base settlement amount.
3. Each qualifying claimant with a Recalled Device that was implanted **less than 6 months prior to** the explant of the Recalled Device shall receive a minimum guaranteed payment of \$40,000 as their base settlement amount.
4. Each qualifying claimant with a Recalled Device that was implanted between October 1, 2003 and October 1, 2004, and explanted no more than 6 months after the recall date applicable to that device, shall receive an additional \$2000.
5. Each qualifying claimant with a Recalled Device that was implanted after October 1, 2004, and explanted no more than six months after the recall date applicable to that device, shall receive an additional \$4000.

### C. Category III (Enhanced Award Fund)

A certain percentage of the total settlement amount paid by Medtronic shall be reserved for the Enhanced Award Fund to compensate settling claimants with unique situations. Enhanced Awards will be based on the nature, severity and duration of the qualifying complication or malfunction as documented in medical records contemporaneous with the (1) injury and (2) recall or explant.

Claimants shall not seek an award from the Enhanced Fund absent a good faith basis for asserting such a claim. Enhanced award claims must be based on (1) psychological injury (requiring medical treatment) related to the Recall of the Recalled Device or the documented inability to have the Recalled Device explanted; (2) complications directly related to the explant of a Recalled Device; or (3) wrongful death **causally related** to the failure of a Recalled Device or as a **direct consequence** of the explant of a Recalled Device. Complications can range from a stroke, heart attack, or other catastrophic condition to infection requiring limited or extensive hospitalization. The Participating Claimant's age at the time of the qualifying explant may also be considered when the claimant is 30 years old or younger at the time of the explant and he or she is at an increased risk of future injury or harm from the explant.

Expert reports submitted in lieu of medical records **WILL NOT** be sufficient to establish causation and/or entitlement to Enhanced Awards. Contemporaneous medical records documenting, and a short statement identifying, the specific

complication/enhancement alleged **must** be included in the Claim Materials. Claimants shall not seek to an award from the Enhanced Award Fund absent a good faith basis for asserting such a claim. The Special Master shall have the discretion to reduce the claimant's base award if the Special Master feels that such action is appropriate based on the conduct of the claimant or his or her counsel in seeking an unwarranted enhanced award.

**III. CATEGORY FUNDS (based on 2600 claimants; to be adjusted *pro rata*):**

- A. The Category I (Non-Explant) Fund shall be \$7 million dollars and, in the event the Category I payment fund is not depleted, the balance shall be added to Category III (Enhanced Injury Fund).
- B. The Category II (Explant) Fund shall be \$65 million dollars and, in the event the Category II payment fund is not depleted, the balance shall be added to Category III (Enhanced Injury Fund).
- C. The Category III (Enhanced Injury) Fund shall have an initial balance of \$14,000,000, plus any spillover funds from the Categories I, II, IV, and V Funds.
- D. The Category IV (TPP) Fund shall be \$3 million dollars and, in the event the Category IV payment fund is not depleted, the balance shall be added to Category III (Enhanced Injury Fund).
- E. The Category V (Medicare) Fund shall be \$3 million dollars and, in the event the Category V payment fund is not depleted, the balance shall be added to the Category III (Enhanced Injury Fund).

In addition to the allotment and adjustment of the Fund balances provided above, the Special Master shall have the authority to adjust the payments or balances of any Fund up or down.