

**UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA**

In re: MEDTRONIC, INC.,
IMPLANTABLE DEFIBRILLATORS
PRODUCTS LIABILITY LITIGATION.

Multidistrict Litigation No.
05-1726 (JMR/AJB)

AMENDED ORDER FOR THE PRESERVATION OF EVIDENCE

Pursuant to the Court’s duty to supervise pretrial proceedings in this case, including discovery, and pursuant to the court’s inherent power, the court hereby orders, effective immediately, that Medtronic, Inc., their officers, employees and attorneys (collectively, “Medtronic”) and all named plaintiffs and their attorneys (collectively, “the Parties”) comply with the following directives relating to the preservation of evidence in the above captioned matter:

Device Preservation

A. Devices Subject to this Section

The provisions of this Order shall pertain to the following Medtronic implantable cardioverter defibrillators and chronic resynchronization therapy devices subject to the field actions by Medtronic that may be relevant to this MultiDistrict Litigation (the “Devices”). Nothing in the Preservation Order shall be used by either party as a basis to limit any party’s rights to challenge or define the extent of jurisdiction of this MDL No. 1726 and the devices subject to referral to this Court with regard to MDL No. 1726.

1. Medtronic Marquis VR, Model 7230 Single Chamber Implantable Cardioverter Defibrillator (ICD),

2. Medtronic Maximo VR, Model 7232 Single Chamber Implantable Cardioverter Defibrillator (ICD);
3. Medtronic Marquis DR, Model 7274 Dual Chamber Implantable Cardioverter Defibrillator (ICD).
4. Medtronic InSync Marquis, Model 7277 Dual Chamber Implantable Cardioverter Defibrillator (ICD) with Cardiac Resynchronization Therapy.
5. Medtronic Maximo DR, Model 7278 Dual Chamber Implantable Cardioverter Defibrillator (ICD).
6. Medtronic InSync III Marquis, Model 7279 Dual Chamber implantable Cardioverter Defibrillator (ICD) with Cardiac Resynchronization Therapy.
7. Medtronic InSync 111 Protect, Model 7285 Dual Chamber Implantable Cardioverter Defibrillator (ICD) with Cardiac Resynchronization Therapy.
8. Medtronic InSync 11 Marquis, Model 7289 Dual Chamber Implantable Cardioverter Defibrillator (ICD) with Cardiac Resynchronization Therapy.
9. MICRO JEWEL II Model 7223Cx (defibrillators).
10. GEM DR Model 7271 (defibrillators).

B. Testing and Analysis Permitted by Medtronic

The Court will specifically allow the following:

1. Non-Destructive Testing and Analysis. Non-destructive testing and analysis by Medtronic of the Devices is allowed. This testing and analysis may include, but is not limited to: (1) reprogramming the device to turn the ventricular fibrillation detection therapy “off,” if it is programmed “on;” (2) interrogation of the device utilizing

a Medtronic programmer; (3) recording battery voltage; (4) creating a Save-to-Disk file of any data extracted from the device through interrogation; (5) importing the Save-to-Disk file to any associated internal regulatory reporting system; (6) photographing the device; and (7) sterilizing the device. The information obtained using the programmer and downloaded to the disk will be preserved. The device will be retained.

2. Destructive Testing and Analysis. In addition to the testing allowed in Paragraph I, above, Medtronic may perform destructive testing and analysis on all of the above described Devices that have been returned to Medtronic after being explanted from a patient or are the subject of research in the laboratory without having been implanted; provided, that: (i) Medtronic maintains a record, in writing or electronically, of such testing and analysis and, where possible, a Save-to-Disk file for any device that was explanted and returned; and (ii) Medtronic agrees, as part of said testing and analysis, to make the results available to plaintiff's liaison counsel subject to the terms of the protective order entered in this case. Medtronic shall not conduct any destructive testing or analysis of the above described Devices until and unless the patient whose device it was or his/her counsel and Plaintiffs' Liaison Counsel in MDL No. 1726 have been notified of the plans for the destructive testing or analysis and shall provide to said patient and/or his/her counsel or one member of Plaintiffs' Steering Committee ("PSC") in MDL No. 1726 (chosen from a specified and pre-approved list of no more than ten individuals designated by the PSC) an opportunity to observe, in person, the specific, limited destructive testing or analysis of the physical battery of the Device performed by Medtronic Energy and Component Center (MECC) in accordance with Medtronic's

Confidential protocol. Plaintiff shall be allowed to have an expert present at the destructive testing or analysis of the battery; provided, however, said expert and Plaintiff or counsel attending said testing on behalf of Plaintiff are not allowed to direct any questions to the Medtronic representatives conducting such testing or analysis. In addition, no photographs or video tapes will be taken by the lawyer or expert attending said testing on Plaintiff's behalf or by the Plaintiff if he/she chooses to attend on his/her own behalf. Medtronic agrees that it will, in good faith, attempt to accommodate a reasonable request for additional photographs made by Plaintiff's counsel or the expert attending on Plaintiff's behalf. The PSC shall identify Plaintiff's expert and said expert shall execute and the PSC shall provide counsel for Medtronic with a copy of Exhibit A to the Protective Order entered in MDL No. 1726 and a copy of the expert's curriculum vitae five (5) business days prior to the destructive testing or analysis of the battery. In addition, the PSC shall provide Medtronic with a copy of any and all reports prepared by said expert and related to the destructive testing or analysis of the battery observed within ten (10) days after any such report is prepared. Prior to any destructive testing or analysis Medtronic must provide to the patient whose device it was or his/her counsel or the designated member of the PSC who will attend said testing, a proposed protocol for conducting the destructive testing or analysis and provide reasonable notice of the time and place for the destructive testing to be conducted and provide the PSC with copies of all materials created, electronically or otherwise, to conduct and memorialize the results of the destructive testing and analysis performed by Medtronic within thirty (30) days after the completion of said testing and analysis.

C. Testing and Analysis by Plaintiffs or Agents of Plaintiffs

In the event plaintiffs and/or their attorneys or agents retain any explanted Device described herein, plaintiffs and/or their agents and attorneys must notify Medtronic of the Model and Serial number of the explanted device for tracking purposes within thirty (30) days after the entry of this Amended Order for the Preservation of Evidence (this “Amended Order”). Each and every plaintiff joined in MDL No. 1726 after the date of this Amended Order who has retained, personally and/or through his/her attorneys or agents, any explanted Device described herein shall notify Medtronic of the Model and Serial number of the explanted device within thirty (30) days after the action is either filed in or transferred to MDL No. 1726. In addition, any Device described herein that has been retained by plaintiff and/or his/her attorneys or agents shall be subject to the requirements, including production of said Device to Medtronic, set forth in the Amended Order Establishing Protocol for Testing Regarding Devices in Plaintiffs’ Possession, dated January __, 2007 (the “Testing Order”). Each and every plaintiff joined in MDL No. 1726 after the date of this Amended Order who has retained, personally and/or through his/her attorneys or agents, any explanted Device described herein shall comply with the requirements of the Testing Order within thirty (30) days after the action is either filed in or transferred to MDL No. 1726. Failure to timely produce any Device in accordance with this Amended Order and/or the Testing Order shall be grounds for a motion by Medtronic to preclude the use at trial by plaintiff of any evidence regarding the Device’s performance. Plaintiffs shall not conduct any destructive testing or analysis of the Device, until and unless Medtronic and its counsel have been notified of the plans for

the destructive testing or analysis and provided an opportunity to observe, in person, the destructive testing or analysis. Prior to any destructive testing or analysis, plaintiffs must (i) provide Medtronic with a proposed protocol for conducting the destructive testing or analysis, (ii) agree to allow a representative of Medtronic, one of Medtronic's lawyers, and a designated expert for Medtronic to be present at the destructive testing or analysis and provide reasonable notice of the time and place for the destructive testing to be conducted, and (iii) provide Medtronic with copies of all materials created, electronically or otherwise, to conduct or memorialize the results of the destructive testing and analysis performed by plaintiffs or their agents within thirty (30) days after the conclusion of said testing and analysis. Medtronic shall identify its expert and said expert shall execute and Medtronic shall provide the PSC with a copy of Exhibit A to the Protective Order entered in MDL No. 1726 and a copy of the expert's curriculum vitae five (5) business days prior to the destructive testing or analysis. In addition, Medtronic shall provide the PSC with a copy of any and all reports prepared by said expert and related to the destructive testing or analysis within ten (10) days after any such report is prepared. Prior to any such testing or analysis, Plaintiffs shall provide Medtronic with an opportunity to 1) evaluate whether the battery is functioning; and 2) interrogate the device with a Medtronic programmer, record the battery voltage, and download that information to a Save-to-Disk file, which will be preserved by Medtronic.

D. Maintenance of Device Components and Additional Testing

All components, parts or pieces of any Device destructively tested or analyzed pursuant to this Order shall be maintained by the Party conducting said testing in their

post-testing condition in a sealed package and shall not be further tested in any fashion without notice to the other Parties in accordance with the terms of this Order as set forth above.

E. Other Devices

Medtronic may continue its customary device testing and analysis for any device not described herein.

F. Data to be Preserved

The Parties may perform destructive analysis on the above described Devices only as authorized by this Order or by further Order of this Court. Otherwise, the parties shall not destroy, dispose of, alter or destructively test or analyze any of the above described Devices.

Dated: January 31, 2007

s/ Arthur J. Boylan
ARTHUR J. BOYLAN
UNITED STATES MAGISTRATE JUDGE