

UNITED STATES DISTRICT COURT  
DISTRICT OF MINNESOTA

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IN RE:

Multidistrict Litigation  
No. 08-1905 (RHK/JSM)

MEDTRONIC, INC. SPRINT FIDELIS  
LEADS PRODUCTS LIABILITY  
LITIGATION

ORDER NO. 6

THIS DOCUMENT RELATES TO:  
ALL ACTIONS

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PRESERVATION ORDER

Upon the submissions of the parties and for good cause shown,  
IT IS HEREBY ORDERED ADJUDGED AND DECREED that:

- (1) Order No. 2 is VACATED; and
- (2) 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., Medtronic USA, Inc., Medtronic Puerto Rico, Inc. (n/k/a Medtronic International Technology, Inc.), and Medtronic Puerto Rico Operations Co. (collectively "Medtronic" or "Defendants") and all named Plaintiffs in all cases that have been and will be transferred into MDL 08-1905 (hereinafter "Plaintiffs")(collectively, "the Parties") shall comply with the following directives relating to the preservation of evidence in the above-captioned matter:

**A. Definitions**

**"Sprint Fidelis Leads"** means those leads marketed by Medtronic under the following model numbers:

1. the 6949 LFJ extendable/retractable screw fixation (S) model;

2. the 6948 LFH tined fixation (T) model;

3. the 6931 LFT S fixation model; and

4. the 6930 LFK T fixation model.

**B. Leads and Devices Subject to This Order**

The provisions of this Order shall pertain to the following:

**1. Explanted Sprint Fidelis Leads**

The provisions of this Order shall pertain to Medtronic Sprint Fidelis leads that have been returned to Medtronic after being explanted from a patient (“Explanted Sprint Fidelis Leads”).

**2. Health Care Provider-Opened Sprint Fidelis Leads**

The provisions of this Order shall also pertain to Medtronic Sprint Fidelis leads sold, distributed, or delivered to a customer that are returned to Medtronic after the lead’s packaging was opened by a health care provider or his/her designee for purposes of implantation but where the leads were not implanted in a patient (collectively, “HCP-Opened Sprint Fidelis Leads”).

**3. Other Sprint Fidelis Leads**

The provisions of this Order shall also pertain to Medtronic Sprint Fidelis leads that have been, are, or will be the subject of research without having been implanted in patients, excluding any HCP-Opened Sprint Fidelis Leads (collectively, “Other Sprint Fidelis Leads”).

4. **Returned Implanted Products**

The provisions of this Order shall also pertain to any other Medtronic products that have been returned to Medtronic that, through reasonable efforts, can be identified as having been implanted together with Sprint Fidelis Leads, including other lead models, implantable cardioverter defibrillators (“ICDs”), and implantable pulse generators (“IPGs”) (collectively, “Returned Implanted Products”).

C. **Physical Evidence**

The parties shall take good faith reasonable steps, including due diligence, to preserve any physical evidence within their possession, custody or control containing information that is relevant to the claims, defenses, or subject matter of this litigation. In this regard, the following is permitted:

1. **Non-Destructive Testing and Analysis**

Non-destructive testing and analysis by Medtronic of Explanted Sprint Fidelis Leads, HCP-Opened Sprint Fidelis Leads, Other Sprint Fidelis Leads, and Returned Implanted Products is allowed. Where appropriate, this testing and analysis of such products may, pursuant to Medtronic’s usual business practices, include, but is not limited to: (1) reprogramming to turn the ventricular fibrillation detection therapy “off,” if it is programmed “on”; (2) interrogation utilizing a Medtronic programmer; (3) recording continuity and electrical testing; (4) creating a Save-to-Disk file of data extracted from such products; (5) importing the Save-to-Disk file to any associated data system, including but not limited to Medtronic internal regulatory reporting systems;

(6) photographing (including x-rays); and (7) decontaminating and sterilizing. Information obtained using the Medtronic programmer and the Save-to-Disk process shall be preserved. Except as otherwise permitted by this Order, all Explanted Sprint Fidelis Leads, HCP-Opened Sprint Fidelis Leads, Other Sprint Fidelis Leads, and Returned Implanted Products shall be retained unless otherwise agreed to by the parties.

2. **Destructive Testing and Analysis for HCP-Opened Sprint Fidelis Leads.**

In addition to the actions allowed in Section C.1 above, in the event Medtronic, pursuant to its usual business practices, performs destructive testing and analysis of HCP-Opened Sprint Fidelis Leads, it will maintain and preserve a record, in writing or electronically, of such testing and analysis.

3. **Destructive Testing and Analysis for Returned Implanted Products and Other Sprint Fidelis Leads.**

a. In addition to the actions allowed in Section C.1, above, Medtronic may, pursuant to Medtronic's usual business practices, perform destructive testing and analysis of Returned Implanted Products, provided that Medtronic maintains a record, in writing or electronically, of such testing and analysis and, where possible, a Save-to-Disk file of data extracted from Returned Implanted Products

b. In addition to the actions allowed in Paragraph 1, above, Medtronic may, pursuant to Medtronic's usual business practices, perform destructive testing and analysis of Other Sprint Fidelis Leads.

**4. Destructive Testing of Explanted Sprint Fidelis Leads**

a. Medtronic shall not conduct any destructive testing or analysis of Explanted Sprint Fidelis Leads until Plaintiffs' Lead Counsel (or a mutually agreeable number of counsel, experts, or other representatives designated by Lead Counsel) has had the opportunity to observe demonstrations of how Medtronic conducts destructive testing and analysis of Explanted Sprint Fidelis Leads ("Observation Period"). Unless otherwise agreed upon by the Parties, this Observation Period shall consist of no more than nine (9) separate (and non-consecutive) days of demonstrations ("Demonstration Days"), the first such Demonstration Day to occur within thirty (30) calendar days of the date of entry of this Order.

b. At least ten (10) days prior to the first Demonstration Day, Plaintiff's Lead Counsel (and his designees) shall be provided with a protocol for conducting the destructive testing or analysis. At least fifteen (15) days in advance of each Demonstration Day, Plaintiff's Lead Counsel (and his designees) shall be provided with the date, time, location of the Demonstration Day, and (to the extent that Sprint Fidelis Leads explanted from named Plaintiffs are to be tested) the communication shall also include the corresponding names of such named Plaintiffs. The Parties will work to accommodate reasonable scheduling issues regarding each Demonstration Day.

c. Medtronic shall maintain a record of the results, in writing or electronically, of all such destructive testing and analysis conducted during the Observation Period

d. Within fifteen (15) days following the end of the Observation Period Medtronic may, pursuant to Medtronic's usual business practices, perform destructive testing and analysis of Explanted Sprint Fidelis Leads, maintaining a record of the results, in writing or electronically, of such testing and analysis, unless Plaintiffs file an objection to a resumption of such testing. If Plaintiffs file an objection, the parties will continue the Observation Period protocol until the objection is ruled upon by the Court.

e. Each Plaintiff that has an Explanted Sprint Fidelis Lead tested under this Order has a right to perform an in-person inspection of his or her Explanted Sprint Fidelis Lead following any testing done by or on behalf of Medtronic and a right to conduct his or her own analysis and testing of any such leads. If such a request is made by a Plaintiff, the Parties will meet and confer regarding the applicable protocol for such additional testing subject to the provisions of Sections C.1 and C.4 of this Order.

**5. Surgically Removed Sprint Fidelis Leads in Plaintiffs' Possession**

a. In the event any Plaintiffs retain any surgically removed Sprint Fidelis Leads, Plaintiffs must notify Medtronic of the Model and Serial number of the surgically removed Sprint Fidelis Leads. Plaintiffs shall notify Medtronic of said retention and shall not, unless otherwise agreed by Medtronic, conduct any destructive testing or analysis of the surgically removed Sprint Fidelis Leads, until and unless Plaintiffs: (i) provide Medtronic with a protocol for conducting the destructive testing or analysis; (ii) allow representatives of 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) preserve the results of said testing and analysis.

b. Medtronic has a right to perform an in-person inspection of Sprint Fidelis Leads following any testing done by or on behalf of Plaintiffs or their agents and a right to conduct its own analysis and testing of any such leads upon reasonable notice, and subject to the provisions of Sections C.1 and C.4 above or as otherwise agreed by the Parties.

c. Plaintiffs, at their option, can return to Medtronic any surgically removed Sprint Fidelis Leads. Such Leads should be returned to a representative of Medtronic whom Medtronic designated pursuant to Order No. 2. Plaintiff shall take reasonable efforts to maintain chain of custody information for such Leads up to and including their return to Medtronic's designee. Once received by Medtronic, such Leads will be governed by the terms and conditions of this Order.

**6. Return to Medtronic of Other Surgically Removed Devices in Plaintiffs' Possession**

a. Any Plaintiff in possession of surgically removed Medtronic products, other than those surgically removed Sprint Fidelis Leads described in Paragraph C.5 above, that were implanted together with Sprint Fidelis Leads, shall return such devices, if they have not already done so, within thirty (30) days of the date of this Order, to the Medtronic representative identified pursuant to Order No. 2. Plaintiff shall take reasonable efforts to maintain chain of custody information for such leads and devices.

b. Each device received by Medtronic's designee pursuant to Section C.6.a, above, shall be considered to be Returned Implanted Products, as defined above in Section B and will be subject, as appropriate, to the testing and analysis provisions detailed and the notice provisions detailed in this Order.

c. Any Plaintiff who was, but no longer is, in possession of surgically removed Medtronic products that were implanted together with Sprint Fidelis Leads, must provide to Medtronic, within thirty (30) days of the date of this Order, any and all information related to the current whereabouts or status of that lead or product, unless the lead or product is in Medtronic's possession.

7. **Permitted Demonstrative Use of Other Sprint Fidelis Leads**

Notwithstanding the terms of this Order, Medtronic shall be permitted to provide to physicians, upon a physician's request, Other Sprint Fidelis Leads for their use as demonstrative aids in connection with the care and treatment of patients.

8. **Other Leads, Devices, Components, and Materials**

Except as specifically limited by this Order, Medtronic may continue its ordinary course of business regarding the use, reuse, testing, analysis, and disposal without limitation, of any tangible thing, such as raw materials, components, subassemblies, non-Fidelis leads (i.e., leads designated with model numbers different than those set forth in Section A of this Order), and devices. However, Medtronic shall retain samples of raw materials, components, and subassemblies that were unique to the production of Sprint Fidelis leads and not consumed in Sprint Fidelis lead manufacture.

**D. Preservation of Documents, Electronically Stored Information, and Tangible Things**

The parties shall take good faith reasonable steps, including due diligence, to preserve all documents, electronically stored information, and tangible things within their possession, custody, or control that contain information that is relevant to the claims, defenses, or subject matter of this litigation. Unless otherwise agreed to by the parties, relevant electronically stored information will be preserved in electronic format, including any relevant metadata. Notwithstanding the foregoing, a party may continue routine erasures of computerized data pursuant to existing programs that contain information relevant to the claims, defenses, or subject matter of this litigation providing that the programs have been disclosed and discussed at the meet and confer sessions among the parties and that adequate, good faith assurances or provisions have been made to ensure that the only copy of relevant information is not erased by such programs.

**E. Preservation Obligations Separate from Production Obligations**

The preservation of electronically stored information, documents, and tangible things in accordance with the terms of this Order does not address or mandate the production of any such information in discovery and no requests for or objections to discovery are affected by this Order.

With respect the electronically stored information, documents, and tangible things being preserved pursuant to Section C of this Order, no such information need be made available until, and unless, the present discovery stay

as entered by Order No. 4 is lifted by the Court. The parties will meet and confer promptly following any such lifting of the present discovery stay regarding the production of such electronically stored information, documents, and tangible things.

Notwithstanding the stay of discovery, Plaintiffs' Lead Counsel may request that Medtronic produce the results of testing and analysis of (a) Returned Implanted Products and (b) Explanted Sprint Fidelis Leads (identified above in sections C.3.a and C.4.c respectively) for each Named Plaintiff and represented Plaintiff identified by Plaintiffs' Lead counsel in the production request. Upon such request, Medtronic will produce said results in a timely manner to Plaintiffs' lead counsel or his designee.

Dated: June 20, 2008

*s/ Janie S. Mayeron*  
JANIE S. MAYERON  
United States Magistrate Judge