Medtronic Sprint Fidelis Leads Class Action
Claims Administrator
P.O. Box 4454, Toronto Station A
25 The Esplanade, Toronto, ON M5W 4B1

MRQ

Robinson v. Medtronic, Inc.
and Medtronic of Canada, Ltd.

ONTARIO SUPERIOR
COURT OF JUSTICE

Case No. 07-CV-341755 CP

Must Be Postmarked No Later Than September 28, 2020

CANADIAN MEDTRONIC SPRINT FIDELIS ICD LEADS SETTLEMENT
Claim Package

CLAIMANT INFORMATION

First Name | M.I. | Last Name

Primary Address

Primary Address Continued

City

Province | Postal Code | Country Name/Abbreviation

This Claim Package contains:

- A Privacy Statement;
- Instructions for Claimants; and
- A Claim Form.

PRIVACY STATEMENT

Personal Information regarding Claimants is collected, used, and retained by the Claims Administrator pursuant to the Personal Information Protection and Electronic Documents Act. S.C. 2000, c.5 (PIPEDA):

- For the purpose of operating and administering the Canadian Medtronic Sprint Fidelis ICD Leads Settlement Agreement ("Settlement");
- To evaluate and consider the Claimant's eligibility under the Settlement; and
- Is strictly private and confidential and will not be disclosed without the express written consent of the Claimant except as provided for in the Settlement.

INSTRUCTIONS FOR CLAIMANTS

These instructions provide basic guidelines for submitting claims under the Settlement. In the case of any disagreement between these instructions and the Settlement, the Settlement shall prevail. For more detailed information, please refer to the Settlement Agreement that can be viewed or downloaded at http://www.medtronicleadsettlement.ca.

To establish your right to benefits under the terms and conditions of the Settlement, a completed Claim Package must be submitted to the Claims Administrator which shall consist of:

- A completed and signed Claim Form;
- Medical records and/or a completed and signed Physician Declaration, as set out below; and
- All other required documentation as described herein.

FOR CLAIMS PROCESSING ONLY	OB	CB	DOC / LC / REV	RED / A / B

All completed Claim Packages must be submitted to the Claims Administrator postmarked no later than September 28, 2020, at the following address:

Medtronic Leads Class Action Claims Administrator
P.O. Box 4454, Toronto Station A, 25 The Esplanade, Toronto, ON M5W 4B1
info@medtronicleadsettlement.ca
Attention: Canadian Medtronic Sprint Fidelis ICD Leads Settlement

Claimants who do not submit a completed Claim Package to the Claims Administrator on or before **September 28, 2020**, shall forever forfeit their rights to benefits from the Settlement and will be precluded from ever bringing an action in relation to the Leads against any of the Released Parties.

If you require assistance or advice regarding completion of the Claim Package or have any questions related to your claim, you may retain legal counsel at your own expense, or contact the Claims Administrator, free of charge at 1-888-788-4820, or at www.medtronicleadsettlement.ca. **Claimants who retain lawyers or agents in making their claims under the Settlement shall be solely responsible for the fees and expenses of such lawyers or agents.**

Claimants may communicate with the Claims Administrator and obtain forms in either English or French. Claimants (or their lawyers/agents) **must** advise the Claims Administrator of any changes or corrections in address, name, phone number or legal representation.

Please keep copies of all documentation you send to the Claims Administrator. Completing the documentation process takes time. **ACT NOW**. Do not wait until the last few weeks before the Claim Period expires.

CANADIAN MEDTRONIC SPRINT FIDELIS ICD LEADS SETTLEMENT CLAIM FORM
Strictly Private and Confidential

Section 1 – Claimant Identification

I am making a claim as a:

- ○ **Class Member** (the person who had one or more Sprint Fidelis ICD Leads (with model number(s) 6949, 6948, 6931 and 6930 "the Leads") implanted which was/were prematurely explanted/replaced or caused unintended shocks as a result of a fracture or impending fracture of the Lead)
- ○ **Representative of a Class Member** (a person who is the legal representative of a Class Member who is deceased, a minor and/or otherwise under a legal disability)

Section 2 - Class Member Identification

Class Member Last Name | First Name

Address | P.O. Box

City

Province | Postal Code

Birth Date (Y Y Y Y / M M / D D) | Date of Death (if applicable) (Y Y Y Y / M M / D D) ○ Official Death certificate attached

Home Phone (— — —) | Work Phone (— — —)

Fax (— — —)

Email

Section 3 - Representative Claimant Identification

This section is to be completed only if you are submitting a claim as the Representative of a Class Member. You MUST provide proof of your authority to act as the representative of a Class Member. Before completing this section, you MUST complete Sections 1 and 2 to identify the Class Member that you are representing.

I am applying on behalf of a Class Member who is:

- ○ **A minor (under 18 years of age)**
  Please enclose a copy of your authority to act (i.e. long-form birth certificate, baptismal certificate, court order or other proof of guardianship)
- ○ **A person under legal disability**
  Please enclose a copy of your authority to act (i.e. power of attorney, etc.)
- ○ **Deceased**
  Please enclose a copy of your authority to act (i.e. will, etc.)

Representative Claimant Last Name

First Name

Address

P.O. Box

City

Province

Postal Code

Y Y Y Y / M M / D D
Birth Date

Home Phone

Work Phone

Fax

Email

Section 4 – Legal Representative Identification

This section is to be completed ONLY IF a lawyer or agent is representing the Claimant.

Name of Law Firm or Agency

Lawyer's or Agent's Last Name

First Name

Address

P.O. Box

City

Province

Postal Code

Phone

Fax

Email

Provincial Law Society# (if applicable)

NOTE: If you complete Section 4 above, all correspondence will be sent to your legal representative, who must notify the Claims Administrator of any change in mailing address. If you change your legal representation or cease to retain your legal representative, you must notify your former legal representative and the Claims Administrator in writing.

Section 5 – Proof of Implant and Premature Explant/Replacement of Lead or Unintended Shocks

In order to be eligible for compensation under the Settlement, each Claimant must provide evidence of the Class Member's implantation **AND** premature explantation/replacement of or unintended shocks caused by a fracture or impending fracture of one or more Lead.

To establish that the Class Member was **implanted** with one of the Leads, **one** of the following **must** be submitted:

- ○ if the Class Member previously received a Certification Notice Letter, fill the appropriate section in the Claimant Declaration (Section 7, below); **OR**
- ○ a photocopy of the Class Member's Medtronic Implanted Pacer-Cardioverter-Lead ID Card which reflects the Lead Model number and Implant Date; **OR**
- ○ one of the following medical records which reflects the Class Member's Lead Model number and Implant Date, including, but not limited to:
  - ○ a Medtronic Quick Look Report; **OR**
  - ○ an operative report describing the Class Member's implantation with one of the Leads, including the Lead Model number and Implant Date; **OR**
  - ○ any other medical record reflecting the Class Member's implantation with one of the Leads, which record must include the Lead Model number and Implant Date.

AND

To establish that the Class Member's Lead was **explanted/replaced or caused unintended shocks as a result of a fracture and/or impending fracture of the Lead**, one of the following **must** be submitted:

- ○ contemporaneous medical records from the hospital where the Lead was explanted/replaced which expressly indicate that the reason for the Lead explant/replacement or unintended shocks was/were due to a fracture/impending fracture of the Lead; **OR**
- ○ if the explant/replacement records do not include any medical opinion attributing the explant/replacement or unintended shocks to a fracture/impending fracture of the Lead, a completed and signed Physician Declaration contained in Section 8 below.

Section 6 – Extraordinary Injury Fund Claim

Please complete this section **ONLY** if you are seeking compensation from the Extraordinary Injury Fund. In order to be eligible for compensation from the Extraordinary Injury Fund, a Claimant must satisfy the criteria set out in Section 5 above **and** must also establish that the Class Member suffered from either Minor or Major Complications as set out below **within 45 days** of the premature explant/replacement of their Lead **OR** unintended shocks as a result of the fracture in the Lead. In the case of unintended shocks where the Lead was **NOT** explanted/replaced, an award from the Extraordinary Injury Fund will be made at the discretion of the Claims Administrator, based on severity.

Please indicate the basis for the Extraordinary Injury Fund Claim (fill all that apply):

Minor Complications:

- ☐ Hematomas lasting more than 7 days with tenseness, drainage, or minor dehiscence managed as an outpatient.
- ☐ Hematomas without tenseness but requiring additional outpatient evaluation.
- ☐ Implant related pain lasting more than 7 days requiring prolonged use of narcotic pain medications.
- ☐ Cellulitis treated as an outpatient with oral antibiotics.
- ☐ Stitch abscess.
- ☐ Minor surgical wound findings.
- ☐ Unanticipated device reprogramming resulting from inadequate lead performance with significant patient symptoms or status change, excluding asymptomatic threshold changes.
- ☐ Reversal of sedation for respiratory compromise requiring benzodiazepine or opioid receptor antagonist.
- ☐ Peripheral nerve injury.
- ☐ Superficial phlebitis.

Major Complications:

- ☐ Pneumothorax requiring observation or chest tube placement.
- ☐ Hemothorax.
- ☐ Stroke within 45 days of the explant/replacement procedure.
- ☐ Hemodynamic instability during the procedure requiring unplanned intervention and/or aborting the procedure.
- ☐ Infection requiring intravenous antibiotics and/or system removal/extraction.
- ☐ Generator or lead malfunction requiring reoperation.
- ☐ Pocket revision requiring reoperation.
- ☐ Prolonged hospitalization attributable to the device replacement procedure.
- ☐ Hematoma requiring evacuation, drainage, blood transfusion, hospitalization, or extension of hospital stay to treat hematoma.
- ☐ Hospital readmission directly related to the explant/replacement procedure.
- ☐ Coronary venous dissection with hemodynamic instability.
- ☐ Pulmonary embolus.
- ☐ Peripheral arterial embolus.
- ☐ Deep vein thrombosis.
- ☐ Drug reaction resulting in an aborted procedure.
- ☐ Cardiac valve injury.
- ☐ New atrioventricular conduction block developing as a result of the procedure.

Unintended Shocks

- ☐ unintended shocks due to fractured Lead **WITHOUT** Lead explant/replacement – date(s) and number of shocks:

  Y Y Y Y / M M / D D — Date — Number of shocks

  Y Y Y Y / M M / D D — Date — Number of shocks

  Y Y Y Y / M M / D D — Date — Number of shocks

- ☐ unintended shocks due to fractured Lead **WITH** Lead explant/replacement – date(s) and number of shocks:

  Y Y Y Y / M M / D D — Date — Number of shocks

  Y Y Y Y / M M / D D — Date — Number of shocks

  Y Y Y Y / M M / D D — Date — Number of shocks

You **must** submit with this Claim Package medical records reflecting that the Class Member suffered unintended shocks due to a fractured Lead and/or complication(s) arising directly from the Class Member's explant/replacement surgery.

If you are seeking compensation from the Extraordinary Injury Fund for out of pocket expenses related to the Class Member's unintended shock(s) and/or surgical complication(s), please complete the chart below and attach all relevant supporting documents. If you need more space, please attach a separate page.

Description of Expense	Amount Claimed	Description of Supporting Documentation
	$.	
	$.	
	$.	
	$.	
	$.	
	$.	

If you are seeking compensation from the Extraordinary Injury Fund for income loss allegedly suffered by the Class Member because of the unintended shock(s) and/or surgical complication(s), you must complete the following section and submit the required supporting documentation:

At the time of the Class Member's unintended shock(s) and/or surgical complication(s), s/he was employed by:

Name of Company

Job Description

$.
Rate of pay

Name of Contact Person

— —
Phone Number

The Class Member was off work for days as a result of the unintended shock(s) and/or surgical complication(s).

$.
The Class Member's alleged income loss

You must provide documentation supporting the Class Member's alleged income loss.

Section 7 – Claimant Declaration

The undersigned hereby consent(s) to the disclosure of the information contained herein to the extent necessary to process this claim for benefits. The undersigned acknowledges and understands that this Claim Form is an official Court document sanctioned by the Court that presides over the Settlement, and submitting this Claim Form to the Claims Administrator is equivalent to filing it with a Court.

The undersigned hereby declares under penalty of perjury that the Class Member:

- ○ **did** previously receive a Certification Notice Letter; or
- ○ **did not** previously receive a Certification Notice Letter.

After reviewing the information that has been supplied on this Claim Form, the undersigned declares under penalty of perjury that the information provided in this Claim Form is true and correct to the best of his/her knowledge, information and belief.

Signature of Claimant: _____ Dated (yyyy/mm/dd): _____

Section 8 – Physician Declaration

I solemnly declare that:

1. I am a physician licensed to practice medicine in the province of _____.
2. I am/was a treating physician for _____ (Class Member) who was implanted with one or more of the following Medtronic Lead(s) (indicate all that apply and indicate the date(s) of implant):

	Lead	Model#	Date
○	Sprint Fidelis	6949	Y Y Y Y / M M / D D
○	Sprint Fidelis	6948	Y Y Y Y / M M / D D
○	Sprint Fidelis	6931	Y Y Y Y / M M / D D
○	Sprint Fidelis	6930	Y Y Y Y / M M / D D

3. On _____(date), _____ (Class Member)'s Sprint Fidelis Lead:

○ was explanted/replaced as a result of a fracture in the Lead and/or because there was evidence that there was an impending fracture of the Lead; or

○ caused unintended shocks to _____ (Class Member) as a result of a fracture in the lead and/or there was evidence that there was an impending fracture of the Lead.

Signature of Physician: _____ Dated (yyyy/mm/dd): _____

Name of Physician: _____

Address

City

Province Postal Code

— —

Telephone Number