

Court file #

05-CV-296218 CP

**ONTARIO  
SUPERIOR COURT OF JUSTICE**

**BETWEEN**

**BRIAN FREDERICK FOOTE, RHONDA LYNN LO MONACO,  
ANITA PRAINE, and FRANCINE NOROVZI**

Plaintiffs

and

**MEDTRONIC, INC. and  
MEDTRONIC OF CANADA LTD.**

Defendants

Proceeding under the *Class Proceedings Act, 1992*

**NOTICE OF ACTION**

**TO THE DEFENDANTS**

A LEGAL PROCEEDING HAS BEEN COMMENCED AGAINST YOU by the plaintiffs. The claim made against you is set out in the following pages.

IF YOU WISH TO DEFEND THIS PROCEEDING, you or an Ontario lawyer acting for you must prepare a statement of defence in Form 18A prescribed by the Rules of Civil Procedure, serve it on the plaintiffs' lawyers or, where the plaintiffs do not have a lawyer, serve it on the plaintiffs, and file it, with proof of service, in this court office, **WITHIN TWENTY DAYS** after this statement of claim is served on you, if you are served in Ontario.

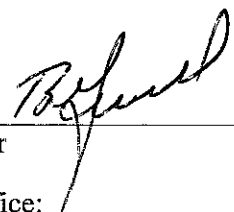
If you are served in another province or territory of Canada or in the United States of America, the period for serving and filing your statement of defence is forty days. If you are served outside Canada and the United States of America, the period is sixty days.

Instead of serving and filing a statement of defence, you may serve and file a notice of intent to defend in Form 18B prescribed by the Rules of Civil Procedure. This will entitle you to ten more days within which to serve and file your statement of defence.

IF YOU FAIL TO DEFEND THIS PROCEEDING, JUDGMENT MAY BE GIVEN AGAINST YOU IN YOUR ABSENCE AND WITHOUT FURTHER NOTICE TO YOU. IF YOU WISH TO DEFEND THIS PROCEEDING BUT ARE UNABLE TO PAY LEGAL FEES, LEGAL AID MAY BE AVAILABLE TO YOU BY CONTACTING A LOCAL LEGAL AID OFFICE.

September 1, 2005

Issued by:

  
\_\_\_\_\_  
Registrar

Address of Court Office:  
393 University Avenue  
10<sup>th</sup> Floor  
Toronto ON M5G 2M2

TO:  
MEDTRONIC, INC.  
710 Medtronic Parkway  
Minneapolis, Minnesota  
55432-5604  
U.S.A.

AND TO:  
MEDTRONIC OF CANADA LTD.  
6733 Kitimat Road  
Mississauga, ON L5N 1W3

**CLAIM**

1. Brian Foote (“Brian”), Rhonda Lynn Lo Monaco (“Rhonda”) and Francine Norovzi (“Francine”) claim on their own behalf and on behalf of all persons who were implanted in Canada with one of the Medtronic Defibrillators defined herein (the “Class”):

- (a) an order certifying this action as a class proceeding and appointing themselves as the representative plaintiffs;
- (b) a declaration that the defendants were negligent in the design, development, testing, manufacture, licensing, assembly, distribution and sale of the Medtronic Defibrillators described herein and that they are liable for damages;
- (c) a declaration that the defendants owed a duty of care to the plaintiffs and to the other Class members;
- (d) special damages, general damages and punitive damages, including the costs of administering the plan of distribution of the recovery in this action, in the sum of \$500,000,000 or such further sum as this Honourable Court may find appropriate, or alternatively, damages assessed equal to the gross revenue, or in the further alternative, damages assessed equal to the net income, received by the defendants as a result of the sale of the Medtronic Defibrillators defined herein, including the costs of administering the plan of distribution of the recovery in this action;
- (e) such further and other special damages as may be incurred from the date hereof until trial, or final disposition of this action, particulars of which will be provided to the defendants;
- (f) an accounting and an order requiring disgorgement of all revenue derived by the defendants from the sale of the Medtronic Defibrillators described herein;
- (g) a reference or such other directions as may be necessary to determine issues not determined at the trial of the common issues;
- (h) pre-judgment interest and post-judgment interest compounded, or pursuant to the *Courts of Justice Act*, R.S.O. 1990, c. C.43;

- (i) costs of this action pursuant to the *Class Proceedings Act, 1992*, S.O. 1992, c. 6 or, alternatively, on a substantial indemnity basis; and
- (j) such further and other relief as to this Honourable Court seems just.

2. Anita Praine (“Anita”) claims on her own behalf and on behalf of the family members entitled to assert a claim pursuant to the *Family Law Act*, R.S.O. 1990, c. F.3, as amended, or equivalent legislation in other provinces (the “Family Class”):

- (a) an order certifying this action as a class proceeding and appointing him as the representative plaintiff of the Family Class;
- (b) damages pursuant to the *Family Law Act*, R.S.O. 1990, c. F.3, or equivalent legislation in other provinces, in the amount of \$25,000,000;
- (c) such further and other special damages as may be incurred from the date hereof until trial, or final disposition of this action, particulars of which will be provided to the defendants;
- (d) pre-judgment interest and post-judgment interest compounded, or pursuant to the *Courts of Justice Act*, R.S.O. 1990, c. C.43;
- (e) costs of this action pursuant to the *Class Proceedings Act, 1992*, S.O. 1992, c. 6 or, alternatively, on a substantial indemnity basis; and
- (f) such further and other relief as to this Honourable Court seems just.

#### THE NATURE OF THE ACTION

3. This class action concerns the defendants’ negligent design, testing, development, manufacturing, assembly, licensing, marketing, distribution and sale of certain implantable cardiac defibrillators (“ICDs”) and cardiac resynchronization therapy defibrillators (“CRIDs”). ICDs and CRIDs are surgically implanted into persons who have heart diseases that create the risk of a life-threatening heart arrhythmia

(abnormal rhythm). ICDs and CRIDs deliver electrical shocks to the heart to restore normal heart rhythm.

4. On February 10, 2005, the defendants notified physicians about the potential for a battery shorting action that may occur in the following ICDs and CRIDs manufactured between April, 2001 and December, 2003:

| <b>DEVICE FAMILY</b> | <b>MODEL NUMBERS</b> |
|----------------------|----------------------|
| Marquis VR           | 7230                 |
| Marquis DR           | 7274                 |
| Maximo VR            | 7232                 |
| Maximo DR            | 7278                 |
| InSync Marquis       | 7277                 |
| InSync II Marquis    | 7289                 |
| InSync III Marquis   | 7279                 |
| InSync III Protect   | 7285                 |

(the “Medtronic Defibrillators”).

5. The Medtronic Defibrillators were subsequently recalled in the U.S.

6. If a Medtronic Defibrillator malfunctions, the Class member may suffer serious personal injury, including death. Class members may be required to have the devices explanted, leading to further risk of serious personal injury, including death.

#### **THE PLAINTIFFS**

7. Brian resides in the City of Windsor, in the Province of Ontario. On or about July 23, 2004, Brian was implanted with a Marquis VR, Model 7230 ICD, serial number PKD116025H.

8. Rhonda is 41 years old and resides in the City of London, in the Province of Ontario. In 1994, Rhonda was diagnosed with idiopathic dilated cardio-myopathy and tachycardia.

9. August 26, 1994, Rhonda was implanted with a Micro Jewel, Model 7221 ICD. On September 3, 1998, the device was replaced with another Micro Jewel ICD as a result of normal battery depletion.

10. On August 13, 2002, Rhonda was implanted with a Marquis VR Model 7230 ICD, serial number PKD600202S. On November 2, 2004, due to problems with the leads, Rhonda's ICD was replaced with a Marquis VR, Model 7239 ICD, serial number PKD119466H.

11. On or about March 2005, Rhonda was contacted by a representative of Medtronic and was invited to attend a meeting at the University Hospital in London, Ontario. Rhonda was informed at the meeting that her ICD had a defect that could result in battery depletion and device malfunction due to a battery shorting problem.

12. After being advised of the defect and after consultations with her physicians, Rhonda decided to have her ICD replaced. On May 31, 2005, Rhonda had her ICD removed and replaced, well before the projected battery life, with an EnTrust VR, Model D154VRC ICD, serial number PNT600246S.

13. Anita resides in the City of Niagara Falls, in the Province of Ontario. Anita is Rhonda's mother.

14. Francine is 47 years-old and resides in the City of Toronto, in the Province of Ontario. In 1992, Francine was diagnosed with hypertrophic cardio myopathy. On August 1, 2003, Francine was implanted with a Marquis DR, Model 7274 ICD, serial number PKC12188OH

15. On or about March 2005, Francine was advised by her cardiologist of a possible defect with her defibrillator that could result in battery depletion and device malfunction due to battery shorting problem. Francine's cardiologist recommended that the ICD be replaced. On July 22, 2005, Francine had her ICD removed and replaced with an EnTrust VR, Model D154VRC ICD, serial number PNR600904S.

#### **THE DEFENDANTS**

16. Medtronic, Inc. ("Medtronic") is a corporation incorporated pursuant to the laws of the State of Minnesota. Medtronic is headquartered in Minneapolis. Medtronic designs, develops, manufactures and markets medical products. Its primary products include those for heart and vascular disease, neurological disorders, chronic pain, spinal disorders, diabetes, urologic and digestive systems disorders and eye, ear, nose and throat disorders. Medtronic employs about 33,000 people and has research, manufacturing, education and sales facilities around the world.

17. Medtronic of Canada Ltd. ("Medtronic Canada") is a corporation incorporated pursuant to the laws of the Province of Ontario with its head office located in the City of Mississauga. Medtronic Canada is a wholly-owned subsidiary of Medtronic.

18. At all material times, the defendants designed, developed, tested, assembled, manufactured, licensed, marketed, distributed and sold the Medtronic Defibrillators for profit in Ontario and elsewhere in Canada. At all material times, each defendant was the agent of the other and each was vicariously liable for the acts and omissions of the other.

#### **THE DEFECTIVE MEDTRONIC DEFIBRILLATORS**

19. On February 10, 2005, the defendants acknowledged that the Medtronic Defibrillators may experience rapid battery depletion due to a battery shorting mechanism. If this occurs, complete battery depletion can take place within a few hours to a few days, after which there will be a complete loss of device function.

20. The U.S. Food and Drug Administration (the "FDA") classified the acknowledgements regarding the Medtronic Defibrillators as a Class I recall. A Class I recall is one in which there is a reasonable probability that, if a particular device is malfunctioning, it may cause serious adverse health consequences or death.



**THE CONSPIRACY**

21. From on or about January 1, 2001 to on or about February 9, 2005 at Minneapolis, Minnesota, Mississauga, Ontario and elsewhere, the defendants by their directors, officers, servants and agents, wrongfully, unlawfully, maliciously and lacking *bona fides*, conspired and agreed together, the one with the other and with persons unknown to:

- (a) submit false, inaccurate and misleading information to Health Canada and the FDA;
- (b) conceal the defects of the Medtronic Defibrillators;
- (c) mislead the Class members and others about the safety of the Medtronic Defibrillators; and
- (d) delay the repairs of the defects.

22. The defendants' were motivated to conspire and their predominant purposes, concerns and motivation were:

- (a) to obtain medical device licenses for the Medtronic Defibrillators;
- (b) to increase or maintain revenue;
- (c) to increase or maintain profit;
- (d) to increase or maintain market share;
- (e) to avoid negative publicity;
- (f) to place corporate revenue and profit above the safety of the Class members; and
- (g) to avoid the costs associated with correcting the defects in the Medtronic Defibrillators.

23. In furtherance of the conspiracy, the following acts, among others, were done by the defendants and their servants, agents and employees:

- (a) they met secretly in the United States and Canada from time to time to discuss the issues giving rise to the conspiracy;
- (b) they directed their servants, agents and employees to perform wrongful or unlawful acts in furtherance of the conspiracy;
- (c) they failed to disclose the defects in the Medtronic Defibrillators to the public and the regulatory authorities in a timely manner;
- (d) they failed to take any steps to cure the defects in the Medtronic Defibrillators after they knew of the defects and the injuries and risks associated with the use of the Medtronic Defibrillators;
- (e) they failed to warn the Class members that the Medtronic Defibrillators were defective;
- (f) they failed to warn health care providers that the Medtronic Defibrillators were defective;
- (g) they concealed the fact that the Medtronic Defibrillators were defective from the public, health care providers and the regulatory authorities, including the FDA and Health Canada; and
- (h) they concealed adverse information regarding the testing and safety of the Medtronic Defibrillators from the public, health care providers and regulatory authorities, including the FDA and Health Canada; and
- (i) they continued to sell the defective Medtronic Defibrillators after the design change in 2003 in order to use up an existing inventory.

24. The defendants' conduct was unlawful because they knowingly caused the dangerous and defective Medtronic Defibrillators to be marketed, sold and implanted into the Class members and they failed to disclose the defects to the Class members and the regulatory authorities.

**THE DEFENDANTS' NEGLIGENCE**

25. The defendants owed a duty of care to the plaintiffs and the other Class members.

26. The plaintiffs plead that the defendants breached the standard of conduct expected of them in the circumstances because, among other things, they:

- (a) failed to adequately design, manufacture and/or test the Medtronic Defibrillators to ensure that they were free from defects;
- (b) knew or ought to have known that the Medtronic Defibrillators were defective and that they would not properly perform the functions for which they were intended;
- (c) failed to report the defects in the Medtronic Defibrillators to the appropriate regulatory authorities in a timely manner; and
- (d) failed to warn the Class members that the Medtronic Defibrillators were defective.

**DAMAGES**

27. Brian, Rhonda and Francine plead that they and the Class members would not have had the Medtronic Defibrillators implanted had the defendants not acted negligently and had they disclosed the defects that were known to them in a timely manner.

28. As a result of the defendants' conduct described above, Brian, Rhonda, Francine and the other Class members have suffered damages and loss, including, but not limited to:

- (a) enduring or having to endure painful medical procedures to implant the Medtronic Defibrillators;
- (b) enduring or having to endure painful medical procedures to explant the Medtronic Defibrillators;
- (c) enduring painful medical procedures to implant new defibrillators that are defect-free;
- (d) personal injury, including adverse effects of the diseases which necessitated the implant of the Medtronic Defibrillators in the first place;
- (e) the risk of death or other serious injuries;
- (f) costs associated with replacing the Medtronic Defibrillators;
- (g) costs associated with monitoring the Medtronic Defibrillators;
- (h) out-of-pocket expenses incurred by the Class members or for their benefit; and
- (i) loss of income

29. As a result of the defendants' conduct described above, Anita and the other Family Class members have suffered, including, but not limited to:

- (a) actual expenses reasonably incurred for the benefit of the Class members;
- (b) traveling expenses incurred while visiting the Class members during treatment or recovery;
- (c) loss of income or the value of services provided for the Class member where services, including nursing and housekeeping, have been provided; and
- (d) compensation for loss of support, guidance, care and companionship that they might reasonably have expected to receive from the Class member.

**PUNITIVE DAMAGES**

30. Brian, Rhonda and Francine plead that the defendants' conduct in the design, development, testing, manufacturing, licensing, assembly, distribution, marketing and sale of the Medtronic Defibrillators, the delayed recall and/or the failure to recall and the facts pleaded above was high-handed, outrageous, reckless, wanton, entirely without care, deliberate, callous, disgraceful, wilful, in intentional disregard of the plaintiffs' rights and safety and the rights and safety of the Class members, indifferent to the consequences and motivated by economic considerations such as the maintaining of revenue and market share. Such conduct renders the defendants liable to pay punitive damages.

**WAIVER OF TORT**

31. As a result of the conduct described above, the plaintiffs reserve to themselves the right to elect at the trial of the common issues to waive the tort and to have damages assessed equal to the gross revenue received by the defendants, or alternatively, the net income received by the defendants, as a result of the sale of the Medtronic Defibrillators.

**REAL AND SUBSTANTIAL CONNECTION WITH ONTARIO**

32. The plaintiffs plead that this action has a real and substantial connection with Ontario because, among other things:

- (a) the defendants carry on business in Mississauga, Ontario and elsewhere in Canada;
- (b) the defendants market their products in Ontario;
- (c) the plaintiffs' damages were sustained in Ontario;
- (d) the defendants made application to Health Canada in Ottawa, Ontario for permission to market implantable medical devices in Canada; and
- (e) the defendants advertised their products in Ontario.

**PLACE OF TRIAL**

33. The plaintiffs propose that this action be tried in the City of Toronto in the Province of Ontario.

**SERVICE**

34. This originating process may be served without court order outside Ontario because the claim is:

- (a) in respect of a tort committed in Ontario (rule 17.02(g));
- (b) in respect of damages sustained in Ontario arising from a tort or breach of contract however committed (rule 17.02(h));
- (c) against a person outside Ontario who is a necessary and proper party to this proceeding properly brought against another person served in Ontario (rule 17.02(o)); and

(d) against a person carrying on business in Ontario (rule 17.02(p)).

September 1, 2005

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FOOTE et al.

Plaintiffs

vs. MEDTRONIC INC. et al.

Defendants

Court File No.

**ONTARIO  
SUPERIOR COURT OF JUSTICE**

PROCEEDINGS COMMENCED AT TORONTO

**NOTICE OF ACTION**

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