AMENDED THIS June 29, 2017 / PURSUANT TO
MODIFIÉ CE CONFORMÉMENT A
☑ RULE/LA RÈGLE 26.02 (a)
☐ THE ORDER OF
L'ORDONNANCE DU
DATED / FAIT LE (in Brantford)
REGISTRAR GREFFIER
SUPERIOR COURT OF JUSTICE COUR SUPÉRIEURE DE JUSTICE

Court File No. CV-17-512508 - 00CP

ONTARIO
SUPERIOR COURT OF JUSTICE

BETWEEN:

SHIRLEY HOULE and ROLAND HOULE

Plaintiffs

and

ST. JUDE MEDICAL, INC., and ST. JUDE MEDICAL CANADA, INC.

Defendants

Proceeding under the Class Proceedings Act, 1992

AMENDED STATEMENT OF CLAIM

TO THE DEFENDANTS:

A LEGAL PROCEEDING HAS BEEN COMMENCED AGAINST YOU by the plaintiff. 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 plaintiff's lawyer or, where the plaintiff does not have a lawyer, serve it on the plaintiff, 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.

TAKE NOTICE: THIS ACTION WILL AUTOMATICALLY BE DISMISSED if it has not been set down for trial or terminated by any means within five years after the action was commenced unless otherwise ordered by the court.

Date March 30, 2017 Issued by "D. Rhoden"

Local Registrar

Address of court office: 393 University Ave. - 10th Fl.
Toronto, Ontario
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TO: **ST. JUDE MEDICAL, INC.**
One St. Jude Medical Drive
St. Paul, Minnesota
55117-9983
U.S.A.

AND
TO: **ST. JUDE MEDICAL CANADA, INC.**
6975 Creditview Road #1
Mississauga, ON
L5N 8E9

CLAIM

1. The Plaintiffs, Shirley Houle and Roland Houle, claim on behalf of themselves and the Patient Class and FLA Class (as those terms are defined below):

(a) an order certifying this action as a class proceeding;

(b) an order defining the Class as:

(i) every person resident in Canada that has been implanted with one of the following of models St. Jude Defibrillator, manufactured between January 2010 and May 23, 2015:

(1) Fortify;

(2) Fortify Assura;

(3) Forify Assura MP;

(4) Unify;

(5) Unify Assura; and,

(6) Unify Quadra (together, the "Defibrillators")

(the Patient Class); and

(ii) all dependants of members of the Patient Class, as defined by section 61 of the *Family Law Act* R.S.O. 1990 c.F.3 s.61 and similar legislation in other Provinces as listed in Schedule "A" where applicable (the FLA Class);

(c) an order appointing Shirley Houle as the Representative Plaintiff on behalf of the Patient Class and appointing Roland Houle as the Representative Plaintiff on behalf of the FLA Class;

(d) a declaration that the Defendants owed a duty of care to the Plaintiffs and the Class members with respect to their research, development, pre-market testing, manufacturing, and representations to Health Canada and medical practitioners regarding the Defibrillators;

(e) a declaration that the Defendants owed a duty of care to the Plaintiffs and the Class members with respect to the post-market monitoring and surveillance of the functionality of the Defibrillators;

(f) a declaration that the Defendants breached their duty of care to the Plaintiffs and the Class members with respect to their research, development, pre-market testing, manufacturing, and representations to regulators regarding the Defibrillators;

(g) a declaration that the Defendants breached their duty of care to the Plaintiffs and the Class members with respect to the post-market monitoring and surveillance of the functionality of the Defibrillators;

(h) a declaration that the Defendants owed a duty to warn to the Plaintiffs, the Class, Health Canada and medical practitioners of any known dangers associated with the ordinary use of the Defibrillators, and of any identified change in the functionality of the Defibrillators;

(i) a declaration that the Defendants breached their duty to warn the Plaintiffs, the Class, Health Canada and medical practitioners:

(i) by failing to warn that the batteries in the Defibrillators were prone to forming lithium ion clusters that could cause the batteries to deplete rapidly; and

(ii) by failing to issue a further warning when the Defibrillators did exhibit at tendency to early failure without reasonable or sufficient warning due to lithium clusters forming in the battery resulting in rapid battery depletion;

(j) a declaration that the Defendants breached their duty of care to the Plaintiffs and the Class members by failing to promptly recall the Defibrillators after the Defendants discovered that the lithium battery in the Defibrillators was prone to early failure without reasonable or sufficient warning due to lithium clusters forming in the battery causing rapid battery depletion;

(k) an order that the Defendants pay the costs of all Ontario Health Insurance Plan (OHIP) subrogated claims and all other provincial healthcare subrogated claims related to the implantation of the Defibrillators and all resulting medical treatments of the Plaintiff and the Patient Class;

(l) the costs of providing notice of certification of this action as a class proceeding to the Class, and the costs of distributing the proceeds of any judgment to all Class members;

(m) punitive, aggravated and exemplary damages in the amount of $50,000,000.00;

(n) pre-judgment interest in accordance with the provisions of s. 127 of the *Courts of Justice Act*, R.S.O. 1990, c. C.43, as amended;

(o) post-judgment interest in accordance with the provisions of s. 128 of the *Courts of Justice Act*, R.S.O. 1990, c. C.43, as amended;

(p) costs of this action on a substantial indemnity basis, including applicable HST;

(q) such further and other relief as to this Honourable Court may seem just and proper;

on behalf of Shirley and the Patient Class:

(r) non-pecuniary damages in the amount of $800,000,000 to be assessed either in the aggregate or individually for each Patient Class Member;

(s) special damages including out of pocket expenses, lost income, and impairment of future earning capacity in an amount to be assessed either in the aggregate or individually for each Patient Class Member;

(t) an order directing a reference for the assessment of the special damages suffered by the Patient Class members, if required;

(u) the future costs of monitoring for those members of the Patient Class who do not wish to have their Defibrillators replaced; and,

on behalf of Roland and the FLA Class:

(v) non-pecuniary damages for loss of care, guidance and companionship, including damages for wrongful death of the Patient Class members who have died as a

result of the failure of the Defibrillator with which they were implanted in the amount of 10,000,000 or such other amount as fixed by the court, and special damages in an amount to be assessed pursuant to s. 61 of the *Family Law Act*, R.S.O. 1990 c.F.3 s.61 and similar legislation in other Provinces as listed in Schedule "A" where applicable (together, the *FLA*), in an amount to be assessed in the aggregate or individually for each *FLA* class member; and,

(w) an order directing a reference for the assessment of the special damages suffered by the FLA Class members, if required.

NATURE OF THE CLASS ACTION

2. This action is brought on behalf of: (a) all people in Canada who ~~between January 2010 and May 23 2015~~ were implanted with one of the Defibrillators manufactured between January 2010 and May 23, 2015 (the "Patient Class"), and, (b) on behalf of all dependants of members of the Patient Class, as defined by section 61 of the *Family Law Act* R.S.O. 1990 c.F.3 and similar legislation in other Provinces as listed in Schedule "A" where applicable (the "*FLA* Class").

3. The claim pertains to the Defendants' negligent research, development, pre-market testing, manufacturing, representation to regulators, post-market monitoring and surveillance, as well as the negligent failure to give timely warning and recall of the Defibrillator models known as:

a. Fortify;

b. Fortify Assura;

c. Forify Assura MP;

d. Unify;

e. Unify Assura; and,

f. Unify Quadra

that were manufactured in the period from January 2010 to May 23, 2015.

4. The Defibrillators are medical devices implanted under the skin that provide pacing for slow heart rhythms (bradycardia), and electrical shock or pacing to stop dangerously fast heart rhythms (tachycardia). Defects in the Defibrillators are inherently dangerous and can cause death or injury to the individuals who rely upon them to maintain a steady heartbeat. "Unanticipated battery depletion can have life-threatening consequences." [Pokorney et al., *Novel mechanism of premature battery failure due to lithium cluster formation in implantable cardioverter-defibrillators*, Duke Division of Electrophysiology, Duke University Medical Center, HeartRythm, December 2014, Vol. 11, Issue 12 pp. 2190-2195, http://dx.doi.org/10.1016/j.hrthm.2014.07.038 (the "Duke Study")]

5. The Plaintiffs assert that the Defendants were negligent in the research, development, pre-market testing, manufacturing, representations to regulators, post-market monitoring and surveillance, warning and recall of the Defibrillators because the Defibrillators were manufactured by the Defendants containing a lithium battery that was (to their knowledge) prone to lithium ion deposits (known as lithium clusters) that could cause a short circuit between the battery terminals resulting in the unpredictable and rapid draining of battery power. The Defendants knew or ought reasonably to have known that the batteries were susceptible to rapid depletion without warning,

leaving the Patient Class vulnerable to injury and death as a result of the failure of the Defibrillator to perform its life-saving functions.

6. Once the Defendants knew of the dangerous and life-threatening defect in the Defibrillators, they failed to warn the Class of the defect, failed to recall the Defibrillators, and continued to sell their existing stock of defective devices into the stream of commerce for at least another 17 months after the publication of the Duke Study, and after making a design change correcting the dangerous defect, without a warning about the battery defect in the old stock, callously putting the Patient Class at risk of death or serious and permanent injury.

7. Between January 1, 2010 and November 30, 2013 the Defendants were notified of, and had confirmed at least 48 premature battery depletions in the Defibrillators. Other cases had been reported and were suspected, but the devices were not returned to the manufacturer for inspection.

8. Even when the Defibrillators were subject to a Class 1 Recall by the US Food and Drug Administration - which is the highest and/or most serious level, and involves products that can predictably cause severe health problems including injury or death - the Defendants refused to recall the Defibrillators in Canada, merely issuing a warning on October 11, 2016, and leaving to individual medical care practitioners the onus of advising the Patient Class of the defect, and encouraging the Patient Class instead to use another device manufactured by the Defendants – the Merlin@Home remote monitoring system.

9. There have, in fact, been deaths associated with Defibrillators that could not provide the needed shock therapy due to premature battery depletion, as well as injuries from fainting and dizziness arising from the failure of Defibrillators to prove needed pacing therapy due to premature battery depletion.

THE PARTIES

10. Shirley Houle ("Shirley") is an individual who resides in the Town of Port Hope, in the Province of Ontario. Shirley brings this action on her own behalf and on behalf of the Patient Class.

11. Roland Houle ("Roland") is an individual who resides in the Town of Port Hope, in the Province of Ontario and is the husband to Shirley. Roland, brings this action pursuant to the provisions of s. 61 of the *Family Law Act*, R.S.O. C. F.8, as amended, for the pecuniary and non-pecuniary damages he has suffered arising as a result of the injuries and losses sustained by Shirley. Roland brings this action on his own behalf and on behalf of the *FLA* Class.

12. The Defendant, St. Jude Medical Canada, Inc., is a corporation incorporated pursuant to the laws of Canada and carried on business in the development, design, manufacture, distribution, marketing and sale of heart defibrillators, including the Defibrillators.

13. The Defendant, St. Jude Medical, Inc., was at all material times a corporation incorporated pursuant to the laws of the State of Minnesota and at all material times carried on business in the development, design, manufacture, distribution, marketing and sale of heart defibrillators, including the Defibrillators. St. Jude Medical, Inc. has been acquired by Abbott Laboratories, effective January 4, 2017.

FACTS

14. On January 31, 2014, Shirley was implanted with a single chamber Fortify Assura Defibrillator, model # 1359-40c, bearing serial number 1108598. She was hospitalized from January 31, 2014 to February 3, 2014 for the procedure and recovery.

15. Shirley is completely dependent on this Defibrillator for her physical health, as she is both pacemaker dependent and is diagnosed with an atrial flutter.

16. Shortly after being implanted with the Defibrillator, Shirley experienced multiple episodes of presyncope ('grey out' spells of near fainting), and was admitted to her local hospital, but then discharged. On February 15, 2014 she experienced an abrupt syncopal episode and was brought to the emergency department at University Health Network, Toronto. The cause of the syncopal episode was a lead dislodgment, which was corrected by surgery on February 18, 2014, and she was discharged on February 21, 2014.

17. Had the Defendants provided a timely warning about the defective Defibrillators, then Shirley would not have been implanted with a St. Jude Defibrillator, and would not have had to suffer the pain and anguish and suffering of further surgeries, or the syncopal or near-syncopal episodes, and the additional pain, anguish and suffering arising from the subsequent warning of potential battery failure in her Defibrillator.

18. Had the Defendants provided a timely warning about the defective Defibrillators, then the Defibrillator implanted in Shirley could have been removed and replaced during the February 2014 surgery, thereby saving Shirley the additional pain, anguish and suffering arising from the subsequent warning of potential battery failure in her Defibrillator and further surgeries for lead revision and then to remove and replace the defective device.

19. By January and February 2014, the Defendants had actual knowledge of the defect in the Defibrillators, as numerous defective devices had been returned to St. Jude Medical, Inc. for testing; but the Defendants had issued no warnings or recalls.

20. In the fall of 2015 Shirley experienced 6 consecutive days of recurrent near-synocope. In October, 2015, Shirley underwent semi-urgent defibrillation lead revision surgery. The Defibrillator was not replaced. Shirley was hospitalized from October 5 – 9, 2015 for this surgery.

21. Had the Defendants provided a timely warning about the defective Defibrillators, then the Defibrillator implanted in Shirley could have been removed and replaced during the October 2015 surgery, thereby saving Shirley the additional pain, anguish and suffering arising from the subsequent warning of potential battery failure in her Defibrillator and further surgery to remove and replace the defective device. By October 2015, the Defendants had actual knowledge of the defect in the Defibrillators ~~for a full year~~ since at least September 12, 2011; but had issued no warnings or recalls.

22. On or about November 5, 2015, Shirley underwent a procedure to set up wireless transmission of data from the Defibrillator. On or about May 4, 2015, Shirley attended at the Peterborough Regional Cardiac Device Clinic where a Merlin@Home Remote Monitor was provided to Shirley, which she was subsequently able to use to receive remote monitoring of the function of her Defibrillator.

23. The Merlin@Home Remote Monitor was sold to clinics such as the Peterborough Regional Cardiac Device Clinic by the Defendants to provide remote monitoring services to patients implanted with St. Jude defibrillators, including the Defibrillators. The Defendants directly or indirectly encouraged clinics and the Patient Class to obtain these monitors to increase the Defendants' profits, and because the Defendants knew that the Patient Class were at risk of rapid and unexpected battery depletion. However, prior to October 2016, the Defendants did not explain to the clinics or the Patient Class that the reason they were encouraging the use of the home

monitoring devices was because the Defendants knew that the Defibrillators were defective, and prone to rapid battery depletion.

24. By letter dated October 16, 2016, the Peterborough Regional Cardiac Device Clinic advised Shirley that it had recently learned that there was a problem identified in Defibrillators manufactured before May 23, 2015, which included her device. Shirley also received warning letters from the University Health Network in Toronto and the Canadian Health Rhythm Society, Device Committee.

25. The identified issue was premature battery depletion. The root cause had been identified by the Defendants as a formation of lithium clusters on the battery. The formation of the clusters can result in an electrical short, whereby the battery may deplete in anywhere from hours to a few days and high voltage therapies will not be delivered. The time course of the depletion was said to appear to be two to three years after the implantation of the device, i.e. the very age of the device implanted in Shirley. The warning letters stated that there is no advance warning that a premature battery depletion is imminent, and any Defibrillator could be affected.

26. Upon receipt of this warning, Shirley became enormously distraught and anxious, suffering symptoms analogous to post-traumatic shock. She feared that her Defibrillator would stop functioning without adequate notice, and because she is entirely dependent upon the device, that she was at risk of injury or death. Shirley became fearful of travelling because of the risk that the battery in her Defibrillator might fail while in transit, when she would be unable to reach a cardiac centre to address the emergency. Shirley became fearful of driving anywhere by herself, other than short distances, for fear that the battery in her Defibrillator might fail, causing injury or death not only to herself or any passengers in the vehicle, but also to other travellers on the roadways.

Shirley suffered from stress-related insomnia, generalized anxiety and distress, all of which negatively affected her relationship with Roland and her other family members.

27. As a result of the warning issued by the Defendants, the Plaintiffs were obliged to cancel a planned winter vacation to Florida because they feared to travel while Shirley's Defibrillator was at risk of rapid depletion at any time. Shirley became dependent upon Roland to drive her to meetings and appointments where previously Shirley would have transported herself, causing additional expense and inconvenience to Roland.

28. On February 8, 2017 Shirley's condition, including her high levels of anxiety and distress, was reviewed at the University Health Network, at which time it was determined that Shirley should be scheduled for immediate replacement of the defective Defibrillator.

29. On March 9, 2017 Shirley was admitted to University Health Network Hospital in Toronto, and on March 12, 2017 the defective Defibrillator was removed and replaced with a new defibrillator. She was released from hospital on March 13, 2017.

30. Shirley suffered pain and suffering as a result of the surgery to replace the defective Defibrillator. If the Defibrillator had not been defective, Shirley would not have required replacement surgery for at least 4 or more years. She has now been subjected to an additional surgery with the attendant pain and suffering which she would not have otherwise experienced but for the fact that the Defibrillator was defective.

THE DEVICES

31. At all material times, the Defendants were responsible for the development, design, manufacturing, sale and distribution of the Defibrillators, either directly or indirectly, to members of the general public living in Canada, including Shirley.

32. The Defibrillators are class VI devices under the *Food and Drugs Act*, R.S.C. 1985, c. F-27. They may only be sold in Canada with the license and approval of Health Canada. The Defendants represented to Health Canada that the Defibrillators were safe and effective for their intended purpose, and based on the Defendants' representations the Defibrillators were licenced and approved for sale in Canada by Health Canada.

33. Defibrillators function by automatically monitoring and, when necessary, providing an electric shock to the heart if the heart rate rises above a certain number (ventricular fibrillation). The shock to the heart is intended to restore normal rhythm and prevent sudden cardiac death. Under normal circumstances batteries in a defibrillator will last between 6-10 years. Defibrillators allow a patient to continue living a relatively normal life including work, exercise, travel and other leisure activities.

34. The Defibrillators were powered by lithium-based batteries. Lithium batteries are generally capable of functioning without need for replacement for approximately seven or eight years. Following implantation, the battery power slowly begins to deplete until it reaches a certain charge level at which point it sends a notification to the patient informing them it's time to have the battery replaced.

35. This notification, known as an Elective Replacement Indicator ("ERI") is a vibration, is sent when the battery reaches approximately three months-worth of remaining battery life,

providing the patient with sufficient time to see a physician for battery replacement. However, to the knowledge of the Defendants, not all patients are able to sense the ERI vibration; therefore the Defendants also recommend regular monitoring of the Defibrillators by cardiac specialists.

36. The Defendants marketed the Defibrillators in Canada as a safe and effective internal heart defibrillator. However, from the outset, lithium cluster formation was a known phenomenon in the type of battery the Defendants used in manufacturing the Defibrillators. This defect was not disclosed by the Defendants to Health Canada, or to the Patient Class or their health care providers.

37. Shirley's surgeon relied on these representations in choosing the Defibrillator for implantation in Shirley.

38. The business of the Defendants are interwoven with each other so much that each Defendant is the agent of the other for the purposes of research, design, testing, development, manufacturing, assembly, licensing, marketing, distribution, importation and the sale of the devices in Canada.

ALLEGATIONS OF NEGLIGENCE

39. The Defendants owed the Plaintiffs and the class a duty of care because the Defibrillators are extremely high-risk medical devices. They are implanted in patients with a history of cardiac disease and are intended to protect against events of bradycardia or tachycardia. Failure of these devices can lead to serious injury or death. The Patient Class is placed in a special relationship with the Defendants who know that the Patient Class is dependent upon the successful operation of the Defibrillators for their health and life.

40. The Defendants owed the Plaintiffs and the class a duty to warn them of all the dangers inherent in the ordinary use of the Defibrillators of which they were aware, or of which they became aware. The Defendants' duty included the duty to provide clear, complete and current information concerning all the dangers inherent in the ordinary use of the Defibrillators.

41. The Defendants knew that the Patient Class and their health care providers relied upon the Defendants to provide full and frank disclosure to them and their medical advisors of all potential risks inherent in the ordinary use of the Defibrillators in deciding which type or brand of defibrillator with which to be implanted, and that the Patient Class would rely upon the device to keep them alive.

42. The Defendants were negligent in the research, development, pre-market testing, and manufacturing of the Defibrillators and in the representations that they made to Health Canada and to the health care providers of the Patient Class with respect to the reliability of the Defibrillators, the particulars of which are as follows:

(a) prior to placing the Defibrillators on the market, they knew that the risks to patients were extremely high by implanting them with the Defibrillators, as the Patient Class was dependent upon the Defibrillators to maintain a steady heart beat;

(b) they knew or ought to have known that the lithium batteries they used for the Defibrillators were susceptible to forming lithium clusters which would lead to rapid battery depletion and they failed to do the requisite research and testing to determine if the batteries in the Defibrillators would therefore suffer from premature battery depletion;

(c) they were negligent in the design of the battery in the Defibrillators by failing to include a necessary layer of insulation to avoid the formation of lithium clusters or to prevent the clusters from causing rapid battery depletion;

(d) they failed to exercise due care and skill in the pre-market testing, manufacturing and marketing of the Defibrillators;

(e) they knew or should have known that the Defibrillators would suffer from premature battery depletion after forming lithium ion clusters, and therefore the batteries were not an appropriate choice or design for a life sustaining medical device;

(f) they knew that the Duke Study published in December 2014 identified the problem with the Defibrillators that could lead to premature battery depletion, and that the Duke Study confirmed that the Defendants had knowledge of the defect in the Defibrillators, and disclosed that the Defendants had redesigned their defibrillators to replace the defective battery; but the Defendants still took no action to warn the Patient Class of the defect in the Defibrillators;

(g) they knew, or ought to have known, that the risk of formation of lithium clusters on battery terminals leading to premature battery depletion had been identified in the literature as far back as 1991;

(h) they knew that 39 cases of premature battery depletion in the Defibrillators had been reported to the Food and Drug Administration by November 31, 2013, and in fact the Defendants had confirmed the defects were due to lithium cluster

formation, yet they failed to warn the Patient Class and failed to remove the Defibrillators from the stream of commerce;

(i) Between 2011 and 2014 St. Jude Medical Inc. conducted at least 42 product analyses of failed Defibrillators, which showed in each instance that its supplier's analysis provided evidence of lithium cluster bridging which had prematurely drained the battery, yet it repeatedly and negligently concluded that the cause of the premature depletion could not be determined;

(j) they manufactured, marketed, distributed and sold the Defibrillators which were not safe for their intended use;

(k) they failed to conduct adequate follow up studies and product analyses on the possibility of premature battery depletion;

(l) they knew or ought to have known that the Defibrillators were not designed to their own internal specifications, i.e. with a battery that would last for more than seven years;

(m) they knew or ought have known that the Defibrillators posed a danger to patients as a result of the premature battery depletion; and

(n) they failed to establish and maintain procedures to identify the premature battery depletion issue as quickly as possible and to correct the issue a quickly as possible.

43. Further, once the Defendants were aware of the design defect of the battery in the Defibrillators:

(a) they failed to provide proper or any warnings to the Patient Class;

(b) they failed to give Health Canada complete and accurate information, including information regarding the premature battery depletion;

(c) they knew that their warnings to doctors had to be accurate and up to date and yet failed to notify the Patient Class' doctors of the premature battery depletion issue for over 2 years from the date the Defendants first confirmed the design defect; and

(d) they knew that they had a continuing obligation to conduct testing and studies to continually update the medical community as to the safety and efficacy of the batteries within the devices, yet they failed to do so.

44. The Defendants have conducted themselves in a high handed, wanton, reprehensible manner, without regard to the safety and well-being of the Patient or *FLA* Classes. This conduct warrants an award of aggravated, punitive and/or exemplary damages. The particulars of which are as follows:

(a) the Defendants failed to conduct proper trials and testing on the battery of the devices before it was introduced into the market;

(b) the Defendants knew that the Defibrillator batteries were prone to premature depletion and despite this, failed to advise Health Canada or physicians when they first knew of the defect in the design of the Defibrillators, and continued to sell the defective Defibrillators for implantation in Class members without any warning of

the issue and without regard to the safety and well-being of the Class, even after they had corrected the defect in new models of the devices;

(c) they knew that the premature battery depletion could cause death or serious injury and with wanton disregard for the classes, they still placed the defective Defibrillators into the stream of commerce; and,

(d) the Defendants placed their own economic interests over that of the safety and wellbeing of the Patient Class.

45. As a result of the negligence of the Defendants, Shirley and other Patient Class Members have suffered the following:

(a) anxiety, depression and psychological stress, along with a loss of enjoyment of life;

(b) undergone and/or will undergo additional surgery to replace the Defibrillator;

(c) loss of ability to participate in recreational, social, and household activities to the extent they would otherwise have been able to participate in such activities;

(d) suffered and continue to suffer from personal injuries, pain and suffering, which may only be overcome through additional surgery;

(e) pecuniary losses;

(f) the Ontario Health Insurance Plan, and equivalent Provincial health care plans have incurred expenses on behalf of the Patient Class; and

(g) some class members have died as a result of the battery failure in the Defibrillators.

46. As a result of the Defendants' actions, Roland and the *FLA* class members have suffered damages recoverable pursuant to s. 61 of the *Family Law Act*., R.S.O. 1990, c. F.3, and similar legislation in other Provinces as listed in Schedule "A" where applicable including:

(a) loss of care, guidance and companionship;

(b) provision of nursing and housekeeping services to injured family members; and,

(c) out-of-pocket expenses, including travel, parking and telephone expenses, loss of present and future income and funeral expenses.

47. The Plaintiffs plead and rely upon the following statues:

(a) *Class Proceedings Act, 1992*, S.O. 1992, c.6, as amended; and

(b) *Family Law Act,* R.S.O. 1990, c. F.3, as amended and corresponding similar legislation in other Provinces as listed in Schedule "A" where applicable.

48. The Plaintiffs rely on sub rule 17.02 (g) and (p) of the Ontario *Rules of Civil Procedure*, a tort committed in Ontario, and a person carrying on business (the supply of Defibrillators) in Ontario in support of service of this originating process on St. Jude Medical, Inc. outside of Ontario.

49. The Plaintiffs propose that this action be tried in the City of Toronto in the Province of Ontario.

Schedule A

Province	**Legislation**
Ontario	s. 61, *Family Law Act,* R.S.O. 1990, c. F.3
Manitoba	ss.3(2), 3.1(2) *The Fatal Accidents Act*, C.C.S.M. c. F50
Saskatchewan	s.4.1(2) *Fatal Accidents Act,* R.S.S. 1978, c.F-11
Alberta	s.8(2) *Fatal Accidents Act*, R.S.A. 2000, c F-8
British Columbia	*Family Compensation Act*, R.S.B.C. 1996, c. 126
Newfoundland	s.6 *Fatal Accidents Act,* R.S.N.L. 1990, cF-6
Nova Scotia	s.5 *Fatal Injuries Act,* R.S.N.S. 1989, c. 163
Prince Edward Island	s. 6(3) *Fatal Accidents Act*, R.S.P.E.I. 1988, c.F-5
New Brunswick	s. 10 *Fatal Accidents Act,* S.N.B. 2012, c 104

March 30, 2017

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Court File No. CV-17-512508 -00CP

ONTARIO
SUPERIOR COURT OF JUSTICE

PROCEEDING COMMENCED AT
TORONTO

AMENDED STATEMENT OF CLAIM

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