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

# ONTARIO SUPERIOR COURT OF JUSTICE

THE HONOURABLE	)	THURSDAY, THE	1 <sup>ST</sup>
JUSTICE PAUL M. PEREL BETWEEN:	L ) ) )	DAY OF AUGUST, 2	019
	RLEY HOULE and ROLAND HO		nintiffs
PERIEURE DE	- and -		

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

**Defendants** 

Proceeding under the Class Proceedings Act, 1992

#### SETTLEMENT APPROVAL ORDER

**THIS MOTION**, made by the Plaintiffs, on consent, for an order approving the settlement of this action pursuant to s. 29(2) of the *Class Proceedings Act*, 1992, SO 1992, c 6 (the "*CPA*"), in accordance with the terms of the Settlement Agreement between the Plaintiffs and Defendants dated February 15, 2019 (the "Settlement Agreement");

AND THIS MOTION, made by Class Counsel for approval of their fees and disbursements payable under a contingency fee agreement between the Plaintiffs and Class Counsel dated December 20, 2016 in the total amount of \$1,371,675.00 inclusive of disbursements and HST, in accordance with s. 32(2) *CPA*, and for an order granting the payment of an honourarium to the Plaintiffs on a *quantum meruit* basis in the amount of \$5,000 each for their efforts in prosecuting this action,

were heard this day at Osgoode Hall Courthouse, 130 Queen Street West, Toronto, Ontario.

ON READING the affidavit of Shirley and Roland Houle, sworn July 5, 2019, and the affidavits of John Kingman Phillips sworn July 12, 22 and 30, 2019, the factum and briefs of authorities of the Plaintiffs and Class Counsel, filed, including the **Settlement Agreement**, attached to this Order as **Appendix 1**, and on hearing the submissions of Class Counsel and the lawyers for the Defendants, and certain Class Members who objected to the terms of the Settlement or Class Counsel fees;

AND ON BEING ADVISED that the Provincial Health Insurers consent to this Order;

**AND ON BEING ADVISED** that the parties consent to this Order, without any admission of liability by the Defendants whatsoever;

- 1. **THIS COURT ORDERS** that the **Settlement Agreement**, **Appendix 1**, is incorporated by reference into this Order and that unless otherwise defined in this Order, capitalized terms in this Order shall have the meanings set out in the Settlement Agreement.
- 2. **THIS COURT ORDERS** that the Settlement Agreement is fair and reasonable and in the best interests of the Class and is hereby approved, and shall be implemented in accordance with its terms.
- 3. **THIS COURT ORDERS** that the Defendants shall pay to and for the benefit of the Class \$4,250,000 CAD, plus \$750,000 CAD for costs in full and final settlement of the Released Claims.

- 4. **THIS COURT ORDERS AND DECLARES** that the Releasors forever and absolutely release the Releasees from the Released Claims.
- 5. THIS COURT ORDERS AND DECLARES that the Releasors agree not to make any claim or take or continue any proceedings arising out of or relating to the subject matter of the Released Claims, including the alleged harm or damages from the use, purchase, implantation, replacement, or explantation of a Defibrillator in a Patient Class Member against any other person, corporation or entity (including, without limitation, any health care professionals, heath care providers, or health care facilities) which might claim damages and/or contribution and indemnity and/or other relief under the provisions of the *Negligence Act* or other comparable provincial or territorial legislation and any amendments thereto, the common law, Québec civil law, or any other statute, for any relief whatsoever, including relief of a monetary, declaratory or injunctive nature, from one or more of the Releasees.
- 6. THIS COURT ORDERS AND DECLARES that in consideration of the payments made to the Provincial Health Insurers set out in the Settlement Agreement, the Provincial Health Insurers are deemed to forever and absolutely release the Releasees from the Released Claims and the Provincial Health Insurers shall be bound by the Settlement Agreement.
- 7. THIS COURT ORDERS AND DECLARES that each Class Member, whether or not he or she submits a claim or otherwise receives an award, and each Provincial Health Insurer, is deemed to have completely and unconditionally released and forever discharged the Releasees from any and all Released Claims.
- 8. **THIS COURT ORDERS AND DECLARES** that each Class Member, whether or not he or she submits a claim or otherwise receives an award, and each Provincial Health Insurer, is

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forever barred and enjoined from continuing, commencing, instituting or prosecuting any action, litigation, investigation or other proceeding in any court of law or equity, arbitration, tribunal, proceeding, governmental forum, administrative forum or any other forum, directly, representatively or derivatively, asserting against any of the Defendants or Releasees any claims that relate to or constitute any Released Claims.

- 9. THIS COURT ORDERS AND DECLARES that this Order, including the Settlement Agreement, is binding upon the Plaintiffs and each Class Member, whether or not they submit a claim to participate in the distribution of the Settlement Fund, including those persons who are minors or are mentally incapable, and the requirements of Rule 7.04(1) and 7.08(4) of the *Rules of Civil Procedure* are dispensed with in respect of this Action.
- 10. **THIS COURT ORDERS AND DECLARES** that any other action or proceeding commenced in Ontario by a Class Member relating to the Released Claims shall be and is hereby dismissed against the Defendants, without costs and with prejudice.
- 11. **THIS COURT ORDERS** that the Claims Administrator shall be Epiq Class Action Services.
- 12. **THIS COURT ORDERS** that the Referee shall be the Honourable Colin Campbell, and that he may appoint such designates as he deems fit, and who are qualified to assist him in fulfilling the role of Referee.
- 13. **THIS COURT ORDERS** that the Claims Administrator and the Referee shall provide notice of this Order pursuant to the Notice Protocol, facilitate the claims administration process, and report to the Court and the Parties in accordance with the terms of the Settlement Agreement.

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- 14. THIS COURT ORDERS that the Claims Administrator and the Referee shall maintain confidentiality over and shall not share the information provided pursuant to this Order with any other person, including but not limited to any lawyer (except any lawyers retained by the Claims Administrator or the Referee), unless doing so is necessary for effecting the Notice Protocol (in the case of the Claims Administrator) and facilitating the claims administration process in accordance with the Settlement Agreement (in the cases of both the Claims Administrator and the Referee).
- 15. **THIS COURT ORDERS** that this Order constitutes an Order compelling the production of information by the Defendants within the meaning of applicable privacy laws, including that it satisfies the requirements of section 7(3)(c) of the *Personal Information Protection and Electronic Documents Act*, SC 2000, c 5 and section 41(1)(d)(i) of the *Personal Health Information Protection Act*, 2004, SO 2004 c 3.
- 16. **THIS COURT ORDERS** that this Order does and is deemed to comply with any requirement under applicable privacy laws for the Defendants to provide any notice to persons of disclosure of the information required by this Order without consent.
- 17. **THIS COURT ORDERS** that the Defendants be and are hereby released from any and all obligations pursuant to any and all applicable privacy laws, including common law, statutes and regulations in relation to the disclosure of personal information or personal health information required by this Order.
- 18. **THIS COURT ORDERS AND DECLARES** that no person may bring any action or take any proceeding against the Claims Administrator or the Referee or any of their employees, agents, partners, associates, representatives, successors or assigns for any matter in any way

relating to the Settlement Agreement, the implementation of this Order or the administration of the Settlement Agreement and this Order except with leave of this Court.

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- 19. **THIS COURT ORDERS** that the Releasees have no responsibility for and no liability whatsoever with respect to the administration of the Settlement Agreement.
- 20. **THIS COURT ORDERS** that the Long Form and Short Form Notice of Settlement Approval are hereby approved substantially in the form attached as Schedule E to the Settlement Agreement, and the Notice of Settlement Approval shall be disseminated in accordance with the Notice Protocol set out at Schedule C of the Settlement Agreement.
- 21. THIS COURT ORDERS that the claim deadline is set at January 10, 2020, and any claim forms submitted after that date shall be invalid, subject only to the Claims Administrator reasonably exercising its discretion to accept late claim forms for up to 15 days after January 10, 2020 where the Class Member submitting a late claim form has a reasonable explanation for the late delivery of the claim.
- 22. **THIS COURT ORDERS** that the fees and disbursements of Class Counsel are hereby fixed at \$1,371,675.00, being \$1,147,500 for fees, \$149,175 for HST and \$75,000 for disbursements inclusive of taxes, which are a first charge upon the Settlement Fund, and may be deducted from the Settlement Fund before the balance is transferred to the Claims Administrator.
- 23. **THIS COURT ORDERS** that the Plaintiffs are awarded an honorarium of \$5,000.00 CAD each on a *quantum meruit* basis for the contributions that they made in the prosecution of this action for the benefit of the Class as a whole, and this amount shall be paid from the Settlement

Fund by Class Counsel before the transferring the net Settlement Fund to the Claims Administrator.

- 24. **THIS COURT ORDERS** that Class Counsel shall, within 10 days of this Order becoming final, transfer the Settlement Fund including the accrued interest and less Class Counsel's fees and the Plaintiffs' honoraria, to the Claims Administrator to be held in trust for the benefit of the Class, pending distribution to the Class Members in accordance with the Distribution Protocol at Schedule G to the Settlement Agreement.
- 25. **THIS COURT ORDERS AND ADJUDGES** that, save as aforesaid, the Action be and is hereby dismissed, without costs and with prejudice.
- 26. THIS COURT ORDERS that there will be no costs of this motion.

JUSTICE P. PERELL

ENTERED AT / INSCRIPT A TORONTO ON / BOOK NO: LE / DANS LE REGISTRE NO:

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## APPENDIX 1

# SETTLEMENT AGREEMENT

Made as of April 1, 2019

Between

SHIRLEY HOULE AND ROLAND HOULE

(the "Plaintiffs")

and

ST. JUDE MEDICAL INC. AND ST. JUDE MEDICAL CANADA INC.

(the "Defendants")

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#### SETTLEMENT AGREEMENT

#### RECITALS

- A. WHEREAS the Plaintiffs commenced the Action which alleges that the Defibrillators distributed by the Defendants are defective;
- B. AND WHEREAS the Plaintiffs have brought a motion to certify the Action as a class proceeding;
- C. AND WHEREAS the Defendants intend to oppose certification of this Action as a class proceeding;
- D. AND WHEREAS the Defendants deny the allegations in the Action and believe they have good and reasonable defences to the Plaintiffs' claims;
- E. AND WHEREAS the Defendants assert that they would actively pursue these defences through trials and, if necessary, on appeals, if the Plaintiffs continued the Action against them;
- F. AND WHEREAS the Parties have negotiated and entered into this Settlement Agreement to avoid the further expense, inconvenience, and burden of this litigation and to achieve final resolutions of all claims that have been asserted, or which could have been asserted, against the Releasees by the Plaintiffs on their own behalf and on behalf of the Proposed Class, and to avoid the risks inherent in uncertain, complex and protracted litigation, and thereby to put to rest this controversy;
- G. AND WHEREAS counsel for the Defendants and Class Counsel have engaged in extensive arm's-length settlement discussions and negotiations in respect of this Settlement Agreement;
- H. AND WHEREAS as a result of these settlement discussions and negotiations, the Parties have entered into this Settlement Agreement, which embodies all of the terms and conditions of the settlement between the Parties, both individually and on behalf of the Class, subject to approval of the Ontario Court;
- I. AND WHEREAS the Plaintiffs have agreed to accept this settlement in part because of the Settlement Fund to be provided by the Defendants under this Settlement Agreement, as well as the attendant risks of litigation in light of the defences that may be asserted by the Defendants;
- J. AND WHEREAS Class Counsel have engaged in extensive consultations with the Provincial Health Insurers, negotiated their entitlement to compensation separately from that for the Class, and the Provincial Health Insurers have authorized Class Counsel to enter into this Settlement Agreement and agree to be bound by this Settlement Agreement;
- K. AND WHEREAS the Parties and their counsel agree that neither this Settlement Agreement nor any statement made in the negotiations leading to this Settlement Agreement shall be deemed or construed as an admission by or evidence against the Releasees or evidence of the truth of any of the Plaintiffs' allegations;

- L. AND WHEREAS the Plaintiffs and their counsel have reviewed and fully understand the terms of this Settlement Agreement and, based on a thorough analysis of the applicable facts and law, and having regard to the burden and expense in prosecuting the Action, including the risks and uncertainties associated with trials and appeals, the Plaintiffs and their counsel have concluded that this Settlement Agreement is fair, reasonable and in the best interests of the Plaintiffs and the Proposed Class;
- M. AND WHEREAS the Defendants are entering into this Settlement Agreement in order to achieve a final and nation-wide resolution of all claims in respect of Defibrillators which have been asserted, or which could have been asserted, against the Releasees by the Plaintiffs and the Provincial Health Insurers in the Action, and to avoid further expense, inconvenience and the distraction of burdensome and protracted litigation;
- N. AND WHEREAS the Parties therefore wish to, and hereby do, fully and finally resolve on a national basis, without admission of liability, the Action against the Defendants;
- O. AND WHEREAS for the purposes of settlement only and contingent on orders by the Court as provided for in this Settlement Agreement, the Plaintiffs have consented to a dismissal of the Action against the Defendants;

NOW THEREFORE, in consideration of the covenants, agreements and releases set forth herein and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, it is agreed by the Parties that the Action be dismissed against the Defendants on the merits with prejudice, subject to the approval of the Ontario Court, on the following terms and conditions:

#### **SECTION 1 – DEFINITIONS**

- 1. For the purpose of this Settlement Agreement only, including the Recitals and Schedules hereto:
  - (a) Account means an interest bearing trust account under the control of the Claims Administrator at a Schedule 1 chartered Canadian bank. All interest accrued in the Account will be added to, and become part of the Settlement Fund.
  - (b) Action means the action issued in the Ontario Superior Court: Shirley Houle and Ronald Houle v. St. Jude Medical Inc. and St. Jude Medical Canada Inc. bearing Court File No. CV-17-572508.
  - (c) Administration Expenses means all fees, disbursements, expenses, costs, taxes, and any other amounts incurred or payable by the Plaintiffs, Class Counsel, or otherwise for the approval, implementation and operation of this Settlement Agreement, including the costs of notices, the costs of translation of the notices, and the fees and expenses of the Claims Administrator and the Referce, but excluding Class Counsel Fees.
  - (d) Approval Hearing means the hearing of the motion before the Ontario Court for the approval of this Settlement Agreement.

- (e) Claims Administrator means the entity appointed by the Court to administer the settlement and disseminate the notices pursuant to the terms of this Settlement Agreement.
- (f) Claims Deadline means the date that is 150 (one hundred and fifty) days from the date on which the notice of settlement approval is first disseminated.
- (g) Claims Period means the 150 (one hundred and fifty) day period from the date that the notice of settlement approval is first disseminated until the Claims Deadline.
- (h) Class Counsel Fees means the fees, disbursements, HST, and other applicable taxes or charges of Class Counsel.
- (i) Class Counsel means Waddell Phillips Professional Corporation and Howie Sacks and Henry LLP.
- (j) Class or Class Members means all members of both the Patient Class and the Derivative Class who do not validly opt out of the Action.
- (k) Costs means a payment towards the costs of the Action incurred by the Plaintiffs on behalf of the Class, as described herein.
- (1) Defendants means St. Jude Medical, Inc. and St. Jude Medical Canada, Inc.
- (m) Defibrillator means the implantable cardioverter defibrillators or cardiac resynchronization therapy defibrillators manufactured by the Defendants between January 2010 and May 23, 2015 listed below:

Trade Name	Model	Trade Name	Model
Fortify Assura™ DR	CD2259-40Q	Quadra Assura MP™	CD3371-40C
Fortify Assura™ DR	CD2259-40	Quadra Assura MP™	CD3371-40QC
Fortify Assura™ DR	CD2359-40C	Quadra Assura™	CD3265-40Q
Fortify Assura™ DR	CD2359-40QC	Quadra Assura™	CD3367-40QC
Fortify Assura™ VR	CD1359-40QC	Quadra Assura™	CD3267-40
Fortify Assura™ VR	CD1259-40	Quadra Assura™	CD3267-40Q
Fortify Assura™ VR	CD1259-40Q	Quadra Assura™	CD3367-40C
Fortify Assura™ VR	CD1359-40C	Unify Assura™	CD3261-40Q
Fortify™ DR	CD2233-40Q	Unify Assura™	CD3361-40QC
Fortify™ DR	CD2233-40	Unify Assura™	CD3261-40
Fortify™ ST DR	CD2235-40	Unify Assura™	CD3361-40C
Fortify™ ST DR	CD2235-40Q	Unify Quadra™	CD3251-40
Fortify™ ST VR	CD1235-40	Unify Quadra™	CD3251-40Q
Fortify™ ST VR	CD1235-40Q	Unify™	CD3231-40
Fortify™ VR	CD1233-40	Unify™	CD3235-40
Fortify™ VR	CD1231-40	Unify™	CD3235-40Q
Fortify™ VR	CD1233-40Q		

- (n) Derivative Class or Derivative Class Members means all dependents of Patient Class Members asserting the right to sue the Releasees independently or derivatively by reason of their familial relationship to a Patient Class Member, including pursuant to the Family Law Act, RSO 1990 c.F.3 or similar legislation in any other Province or Territory in Canada.
- (o) Effective Date means the date on which the Final Order takes effect.
- (p) Eligible Claimants means Class Members eligible to receive compensation under this Settlement.
- (q) Eligible Explant Claimants means Patient Class Members who either (i) had a Defibrillator replaced due to premature battery depletion where the battery depletion occurred earlier than expected based on the Defibrillator usage and there was no indication that the depletion was related to a cause other than a short circuit that may have been due to the formation of lithium clusters, or (ii) had a Defibrillator replaced between October 10, 2016 and August 8, 2017 on an elective basis in response to the St. Jude advisory issued in Canada on October 10, 2016 provided that the electively replaced Defibrillator had been implanted for less than five years at the time of the replacement.
- (r) Eligible Extraordinary Injury Fund Claimants means Eligible Claimants entitled to receive compensation from the Extraordinary Injury Fund as set out in Schedule F.

- (s) Eligible Non-Explant Claimants means Patient Class Members who are not Eligible Explant Claimants.
- of this Settlement Agreement, once the time to appeal such order has expired without any appeal being taken, if a right of appeal exists, or, if an appeal from a final order is taken, once there has been affirmation of the approval of this Settlement Agreement upon a final disposition of all appeals.
- (u) Net Settlement Fund means the Settlement Fund, less legal fees payable to Class Counsel as approved by the Court, all Administration Expenses, and any honorarium payable to the Plaintiffs as approved by the Court.
- (v) Notice of Certification, Proposed Settlement and Approval Hearing means the form of notice, agreed to by the Parties, or such other form as may be approved by the Court, which informs the Class that the Action has been certified, the process for opting out, of the date and location of the Approval Hearing, the principal elements of this Settlement Agreement and the process by which they may object to the Settlement.
- (w) Notice of Settlement Approval means the form of notice, agreed to by the Parties, or such other form as may be approved by the Court, which informs the Class of the approval of this Settlement Agreement, and how to make a claim.
- (x) Ontario Court or Court means the Ontario Superior Court of Justice.
- (y) Parties means the Plaintiffs and the Defendants.
- (z) Patient Class or Patient Class Members means (i) all persons who are resident in Canada as at the date of the Certification Order or, if deceased at or before the date of the Certification Order, who were residents in Canada at the date of death, (ii) who were implanted in Canada with one or more of the Defibrillators, and (iii) who do not opt out of the Action.
- (aa) Plaintiffs means Shirley Houle and Roland Houle.
- (bb) Proposed Class or Proposed Class Members means the proposed Patient Class and Derivative Class, including those who opt out of the Action.
- (cc) Provincial Health Insurers means all provincial and territorial Ministries of Health or equivalents, and/or provincial and territorial plans funding medical services throughout Canada, who are entitled to make a claim pursuant to any of the relevant legislation set out in Schedule H.
- (dd) Recitals means the recitals to this Settlement Agreement.
- (ee) Referee means the person appointed by the Ontario Court to assess the claims for compensation from the Extraordinary Injury Fund as set out in the Distribution

Protocol, and to make a final determination of Eligible Class Members in the event of any dispute of the Claims Administrator's decision with respect to eligibility, and his or her designate.

- Released Claims means: (a) any and all manner of claims, demands, actions, suits, (ff) Québec civil law and statutory liabilities, and causes of action which have been asserted or which could have been asserted in the Action, whether direct or indirect, class, individual, or otherwise in nature, whether personal or subrogated, damages whenever incurred, liabilities of any nature whatsoever, including interest, costs, expenses, penalties, and lawyers' fees that the Releasors (other than the Provincial Health Insurers), or any one of them, whether directly, indirectly, representatively, derivatively, or in any other capacity, ever had, now have, or hereafter can, shall, could, or may have against the Releasees, whether known or unknown, relating in any way to any conduct by the Releasees prior to the execution of this Settlement Agreement concerning alleged harm or damages from the use, purchase, implantation, replacement, or explantation of a Defibrillator in a Patient Class Member; and (b) as it relates to the Provincial Health Insurers, any and all manner of claims which a Provincial Health Insurer ever had, now has or hereafter can, shall or may have pursuant to provincial or territorial legislation that permits the recovery of healthcare costs or medical expenses from third parties, whether known or unknown, direct or indirect, subrogated or otherwise, relating in any way to any conduct by the Releasees prior to the execution of this Settlement Agreement concerning alleged harm or damages from the use, purchase, replacement, implantation, or explantation of a Defibrillator in a Patient Class Member.
- (gg) Releasees means, jointly and severally, the Defendants and their respective present and former parents, subsidiaries, affiliates, officers, directors, employees, insurers, agents, attorneys, servants, contractors, suppliers, representatives and the successors, heirs, executors, administrators, trustees, and assigns of each of the foregoing.
- (hh) Releasors means, jointly and severally, individually and collectively, the Plaintiffs and the Class Members, and their respective successors, heirs, executors, administrators, trustees, and assigns, and the Provincial Health Insurers.
- (ii) Schedules has the meaning set out in Section 12.12.
- (jj) Settlement Agreement or Settlement means this agreement, including the Recitals and Schedules.
- (kk) Settlement Fund means the total of all amounts paid pursuant to this Settlement Agreement as set out in Section 4.1(2), plus any interest accrued thereon.

## SECTION 2 - CONDITION PRECEDENT: COURT APPROVAL

2. Subject to section 8.3 below, this Settlement Agreement shall be null and void and of no force or effect unless the Ontario Court approves this Settlement Agreement.

## SECTION 3 - COURT APPROVAL

#### 3.1 Best Efforts

The Parties shall use their best efforts to effect this Settlement and to secure the prompt, complete and final dismissal with prejudice of the Action against the Defendants.

# 3.2 Motion Approving Certification and Notice

- (a) At a time mutually agreed to by the Parties after this Settlement Agreement is executed, the Plaintiffs shall bring a motion before the Court for an order, substantially in the form attached hereto as Schedule "A", certifying the Action, on consent, for settlement purposes only, and for an order approving the short and long-form Notices of Certification, Proposed Settlement and Approval Hearing in the forms attached at Schedule "B".
- (b) In the event that the Court indicates that an order certifying the Action may not be granted in a form that is conditional on eventual settlement approval, the Parties shall immediately withdraw the motion referred to in section 3.2(a), and the Parties shall instead seek a date to proceed with the hearing of a contested certification motion.
- (c) The Notice of Certification, Proposed Settlement and Approval Hearing shall be disseminated to Proposed Class Members by the means outlined in the Notice Protocol set out in Schedule "C" or in such manner as may be ordered by the Court.

## 3.3 Motion for Settlement Approval

- (a) As soon as practicable after the Notice of Certification, Proposed Settlement and Approval Hearing has been disseminated, the Plaintiffs shall file a motion in the Ontario Court for an order approving this Settlement Agreement. The order sought shall be substantially in the form attached at Schedule "D".
- (b) The short and long-form Notices of Settlement Approval shall be substantially in the form attached at Schedule "E", and shall be disseminated to Class Members in accordance with the Notice Protocol approved by the Court in the Certification Order.

## **SECTION 4 – SETTLEMENT BENEFITS**

#### 4.1 Payment of Settlement Fund

(1) Within thirty days of the execution of this Settlement Agreement, the Defendants will pay \$5,000,000 CAD to Waddell Phillips Professional Corporation, in trust, for the benefit of the Class, in full satisfaction of all of the Released Claims against the Releasees, contingent on the issuance of the Final Order, including dismissal of the Action as of the Effective Date.

- (2) Class Counsel shall hold the Settlement Fund in trust in an interest bearing trust account, and shall transfer to the Account of the Claims Administrator the Settlement Fund, less Class Counsel Fees as approved by the Court and any costs incurred by Class Counsel in respect of the Court-approved notices to the Class, within ten business days after the Effective Date. Class Counsel will provide an accounting to the Claims Administrator of the Fees and notice expenses deducted from the Settlement Fund, including supporting documentation.
- (3) Class Counsel shall not otherwise pay out any of the Settlement Fund from the trust account, except in accordance with this Settlement Agreement or in accordance with an order of the Court obtained on notice to the Defendants.
- (4) The Settlement Fund shall, at first instance, be allocated as follows, subject to the Court's determination of the total legal fees and disbursements to be paid to Class Counsel, and the total actual Administration Expenses incurred:
  - (a) \$4,000,000 CAD to the Class Members and Provincial Health Insurers, to be distributed in accordance with the Distribution Protocol attached as Schedule "G";
  - (b) \$250,000 CAD towards the Administration Expenses relating to the Settlement, including the notice programs set out in the Notice Protocol as approved by the Court; and
  - (c) \$750,000 CAD for Costs of the Action, to be applied towards the total legal fees payable to Class Counsel as determined by the Court in accordance with the contingency fee agreement between the Plaintiffs and Class Counsel.
- (5) The Claims Administrator will invest the Settlement Fund in the Account. All interest accrued in the Account will be added to the Settlement Fund.
- (6) The Defendants shall have no obligation to pay any amount in addition to the Settlement Fund.
- (7) The Claims Administrator shall maintain the Account as provided for in this Settlement Agreement and shall not pay out any monies from the Account, except in accordance with the provisions of this Settlement Agreement, without an order of the Court made on notice to or on the consent of the Defendants and Class Counsel.

## 4.2 Appointment and Role of Claims Administrator and Referee

- (1) The Ontario Court shall appoint a Claims Administrator for the purpose of administering the Settlement, and a Referee for the purpose of the determination of awards from the Extraordinary Injury Fund, and any appeals from the Claims Administrator's determination of eligibility.
- (2) The Claims Administrator and the Referee shall sign and adhere to a confidentiality agreement, in a form satisfactory to the Parties, by which they agree to keep confidential any information concerning Class Members or the Releasees. Further, the Claims Administrator and Referee shall institute and maintain procedures to ensure that the identity of all Class Members

and all information regarding any claims and submissions will be kept strictly confidential. At the conclusion of the claims administration process, any information obtained by the Claims Administrator and the Referce shall be securely deleted and destroyed.

- (3) The Claims Administrator shall disseminate the notices, process all claims, and administer the payment of the Settlement Fund to the Eligible Claimants in accordance with the terms of this Settlement Agreement.
- (4) The Claims Administrator and Referee shall offer their services in both French and English.
- (5) Class Counsel, together with counsel for the Defendants, may meet with the Claims Administrator and/or Referee to discuss the criteria for eligibility of Patient Class Members to recover from the Settlement Fund.
- (6) The Claims Administrator and the Referee shall report to the Court, Class Counsel and to Defendants' counsel on the total number of claims received and the decisions made by them in respect of any claim no later than 60 days after the Claims Deadline. The Claims Administrator and Referee shall update their reports to the Court, Class Counsel and to Defendants' counsel when all of the Eligible Claimants have been paid. The Claims Administrator will deliver a final report upon the distribution of any cy-près payment after the six month stale date has passed for all payments made to Eligible Claimants.
- (7) The Releasees shall have no responsibility for and no liability whatsoever with respect to the actions of the Claims Administrator, the Referee, or the administration of the Settlement Agreement.

#### 4.3 Claims and Claimants

- (1) The Defendants have estimated and identified from their records 340 potential Eligible Explant Claimants and 8,597 potential Eligible Non-Explant Claimants. The Defendants will provide to the Claims Administrator and to Class Counsel, to the extent known, a list of the Patient Class Members, including their names, last known addresses, the type of Defibrillator implanted, and the serial numbers of the implanted Defibrillators. The Defendants will also identify for the Claims Administrator and Class Counsel, to the extent known, any Defibrillators that were replaced due to premature battery depletion where the battery depletion occurred earlier than expected based on the Defibrillator usage and there was no indication that the depletion was related to a cause other than a short circuit that may have been due to the formation of lithium clusters. These lists will be used to verify Class Members' eligibility to receive a payment from the Settlement Fund, and may be used by the Claims Administrator to prepopulate claim forms.
- (2) The Defendants will provide the information described in 4.3(1) only pursuant to orders from the Ontario Court obtained in accordance with this Settlement Agreement.
- (3) The Claims Administrator and Referee shall use the information solely for the purpose permitted by valid Court orders and applicable privacy laws, and not for any other purpose. The Claims Administrator and Referee shall maintain confidentiality over and shall not share the information with any other person, including but not limited to any lawyer (except any lawyers retained by the Claims Administrator or the Referee), unless doing so is necessary for effecting

the Notice Protocol (in the case of the Claims Administrator) and facilitating the claims administration process in accordance with the Settlement Agreement (in the cases of both the Claims Administrator and the Referce).

- (4) In order to receive a payment from the Settlement Fund, each Patient Class Member must deliver, mail, email, fax or complete a web-based claim form, which shall be in a form to be prepared by the Claims Administrator in consultation with Class Counsel, and approved by the Court, along with any required supporting documentation, which must be received by the Claims Administrator no later than 11:59 pm EST on the Claims Deadline. Supporting documentation may include doctor's or hospital records or such other documentation satisfactory to the Claims Administrator demonstrating that the Class Member is an Eligible Claimant. Mailed claim forms will be deemed to have been received by the Claims Administrator on a timely basis if they are stamped as received by Canada Post by 11:59 pm EST on the Claims Deadline.
- (5) The Claims Administrator shall determine, in its sole discretion, whether a claim form has been properly completed and whether a claim has been validly asserted by a Class Member. The decision of the Claims Administrator as to whether a claim has been validly asserted shall be final and not subject to review. The Claims Administrator shall notify each Class Member who delivers an incomplete claim form of the nature of the deficiencies, and provide the claimant Class Member 30 days to submit a complete claim form before deciding if their claim is invalid. Each claimant Class Member whose claim is deemed invalid shall be notified of that fact in writing by the Claims Administrator.
- (6) If the Claims Administrator determines that a Class Member is not an Eligible Claimant, the Class Member may appeal the decision to the Referee. Any such appeal must be made in writing no later than 20 days after the Claims Administrator delivers its decision on the invalidity of the claim, with a copy to Class Counsel, who may also make submissions to the Referee within another 10 days of receipt of the Class Member's submissions. The Referee shall then rule on whether the claim is valid or invalid within 20 business days of receipt of all submissions, and there shall be no further right of appeal therefrom.
- (7) In order to qualify as an Eligible Explant Claimant, a Class Member must submit with their claim form supporting documentation demonstrating that they meet the criteria described in section 1(q). If the Claims Administrator determines that a Class Member is not an Eligible Explant Claimant, any appeal therefrom shall be in accordance with the Referce Guidelines attached as Schedule "F".
- (8) In order to recover from the Extraordinary Injury Fund, a Class Member must submit with their claim form supporting documentation demonstrating entitlement to additional compensation including, if necessary, medical records, an attending physician's report, death certificate of the Patient Class Member, or such other documentation acceptable to the Referee to demonstrate that the Class Member qualifies as an Eligible Extraordinary Injury Fund Claimant.
- (9) If the Claims Administrator determines that a Class Member is an Eligible Extraordinary Injury Fund Claimant, the Claims Administrator shall forward to the Referee the Class Member's claim form and supporting documentation for the determination of the award, if any, to be paid to the Class Member from the Extraordinary Injury Fund. The Referee may request additional

documentation or submissions from the Class Member, if he or she reasonably requires further information in order to fairly assess the claim. The determination of any award from the Extraordinary Injury Fund shall be made in accordance with the Referee Guidelines attached as Schedule "F". Any determination of an award from the Extraordinary Injury Fund by the Referee shall be final and not subject to review. If the Referee decides to deny compensation from the Extraordinary Injury Fund, the Class Member will have ten (10) business days from the delivery of the Referee's decision to seek a review of the decision by the case management judge in the Action by filing written submissions with the Court, not to exceed 3 pages in length without leave of the Court.

# SECTION 5 - DISTRIBUTION OF THE SETTLEMENT FUND AND ACCRUED INTEREST

#### 5.1 Settlement Distribution

The Settlement Fund shall be held in trust by Class Counsel, and then the Claims Administrator and shall only be disbursed by them in accordance with the provisions of this Settlement Agreement.

## 5.2 Order of Distribution of Settlement Fund

The Claims Administrator will pay the funds out of the Settlement Fund in accordance with the Referee Guidelines attached as Schedule "F" and the Distribution Protocol attached as Schedule "G".

### 5.3 Cy-près

(1) If, six months following the conclusion of the distribution of the Settlement Fund to all Eligible Claimants there remain any unallocated amounts, or distributed Settlement Fund cheques have become stale dated without being cashed, then such amounts remaining in the Settlement Fund shall be paid cy-près to the Heart and Stroke Foundation of Canada.

#### 5.4 Taxes

- (1) All Settlement Funds held by the Claims Administrator shall remain subject to the jurisdiction of the Ontario Court until they are distributed pursuant to the Final Order.
- (2) Subject to section 5.4(4), all taxes payable on any interest that accrues on the Settlement Fund shall be the responsibility of the Class. The Claims Administrator shall be solely responsible to fulfill all tax reporting and payment requirements arising from the Settlement Fund, including any obligation to report taxable income and make tax payments. All taxes (including interest and penalties) due with respect to the income earned by the Settlement Fund shall be paid from the Account.
- (3) Subject to section 5.4(4), the Releasees shall have no responsibility to make any tax filings relating to the Settlement Fund and shall have no responsibility to pay tax on any income earned by the Settlement Fund or to pay any taxes on the monies in the Account.

(4) In the event that this Settlement Agreement is terminated, the interest earned on the Settlement Fund while on deposit in Class Counsel's trust account shall be paid to the Defendants as directed in writing by the Defendants, and in such case, each Defendant shall be responsible for the payment of all taxes on its proportionate share of such interest received by it.

#### SECTION 6 - OPT OUTS

## 6.1 Procedure to Opt Out

(1) A Proposed Class Member may opt out of the Action by sending a written notice, by email, fax, mail or courier to the Claims Administrator at:

**Epiq Class Action Services** 

Attention: St. Jude ICD Settlement Nelson P.O. 20187 – 322 Rideau Street Ottawa Ontario K1N 5Y5

Fax: 1-866-262-0816

Email: info@stjudeICDclaim.ca

- (2) An opt out notice must be received by the Claims Administrator by no later than 11:59 p.m. EST on the date that is 60 (sixty) days after the date the Notice of Certification, Proposed Settlement and Approval Hearing is first disseminated in accordance with the Notice Protocol attached as Schedule "C".
- (3) The notice of opt out shall contain:
  - (a) the full name, mailing address, and telephone number of the Proposed Class Member:
  - (b) the Provincial Health Insurance number of the Proposed Class Member;
  - (c) the make, model and serial number of the Defibrillator of the Proposed Class Member;
  - (d) the date and location where the Proposed Class Member's Defibrillator was implanted;
  - (e) a statement indicating whether the Proposed Class Member's Defibrillator was explanted, and if so, the location where it was explanted and the date on which it was explanted; and
  - (f) in the case of a Derivative Class Member whose Patient Class Member relative is deceased, the Patient Class Member's information set out in 3(a) to (e) above, along with the Patient Class Member's date of death and a statement of whether they believe the Patient Class Member's death was related to premature battery depletion.

(4) The Claims Administrator shall provide to Class Counsel and counsel for the Defendants the names of the persons who have delivered opt out notices and a copy of the opt out notices, by no later than 11:59 p.m. EST on the date that is 70 (seventy) days after the Notice of Certification, Proposed Settlement and Approval Hearing is first disseminated.

#### SECTION 7 – RELEASES AND DISMISSALS

## 7.1 Release of Releasees

- (1) Upon the Effective Date, and in consideration of the payment of the Settlement Fund and for other valuable consideration set forth in the Settlement Agreement, the Releasors forever and absolutely release the Releasees from the Released Claims. And for the consideration provided herein, the Releasors agree not to make any claim or take or continue any proceedings arising out of or relating to the subject matter of the Released Claims, including the alleged harm or damages from the use by, purchase, implantation, replacement, or explantation of a Defibrillator in a Patient Class Member against any other person, corporation or entity (including, without limitation, any health care professionals, health care providers, or health care facilities) which might claim damages and/or contribution and indemnity and/or other relief under the provisions of the Negligence Act or other comparable provincial or territorial legislation and any amendments thereto, the common law, Québec civil law, or any other statute, for any relief whatsoever, including relief of a monetary, declaratory or injunctive nature, from one or more of the Releasees.
- (2) An Order will be sought at the hearing for approval of the Settlement Agreement which shall include a term releasing the claims of the Provincial Health Insurers in substantially the following form:

In consideration of the payments made to the Provincial Health Insurers set out in the Settlement Agreement, the Provincial Health Insurers are deemed to forever and absolutely release the Releasees from the Released Claims and the Provincial Health Insurers shall be bound by the Settlement Agreement.

- (3) Without limiting any other provisions herein, each Class Member, whether or not he or she submits a claim or otherwise receives an award, and each Provincial Health Insurer, will be deemed by this Settlement Agreement completely and unconditionally to have released and forever discharged the Releasees from any and all Released Claims.
- (4) Each Class Member, whether or not he or she submits a claim or otherwise receives an award, and each Provincial Health Insurer, will be forever barred and enjoined from continuing, commencing, instituting or prosecuting any action, litigation, investigation or other proceeding in any court of law or equity, arbitration, tribunal, proceeding, governmental forum, administrative forum or any other forum, directly, representatively or derivatively, asserting against any of the Defendants or Releasees any claims that relate to or constitute any Released Claims.

#### 7.2 Dismissal of the Action

The Final Order shall include a term that the Action is dismissed with prejudice and without costs against the Defendants.

#### SECTION 8 – TERMINATION OF SETTLEMENT AGREEMENT

#### 8.1 Right of Termination

- (1) The Defendants, the Plaintiffs and Class Counsel shall have the right to terminate this Settlement Agreement, in the event that:
  - (a) the Ontario Court declines to approve this Settlement Agreement or any material term or part thereof; or
  - (b) the form and content of the Final Order approved by the Ontario Court fails to comply in any material respect with the terms of this Settlement Agreement.
- (2) The Defendants shall have the right to terminate this Settlement Agreement in the event that there are more than a total of 30 (thirty) valid notices of opt out from:
  - (a) Proposed Class Members who stated that their Defibrillator was explanted; and
  - (b) Derivative Class Members whose Patient Class Member relatives are deceased.
- (3) To exercise a right of termination, a terminating party shall deliver a written notice of termination by no later than 15 (fifteen) days after the triggering event with respect to section 8.1(1), or 15 (fifteen) days from delivery of the opt out report by the Claims Administrator. Upon delivery of such a written notice, this Settlement Agreement shall be terminated and, except as provided for in sections 8.2, 8.3, and 11, it shall be null and void and have no further force or effect, shall not be binding on the Parties, and shall not be used as evidence or otherwise in any litigation.

## 8.2 If Settlement Agreement is Terminated

- (1) If this Settlement Agreement is terminated in accordance with its terms or otherwise fails to take effect for any reason, any order certifying this Action as a class proceeding or approving any aspect of this Settlement Agreement shall be set aside and declared null and void and of no force or effect, and anyone shall be estopped from asserting otherwise.
- (2) If this Settlement Agreement is terminated in accordance with its terms or otherwise fails to take effect for any reason, Class Counsel shall transfer the Settlement Fund, plus interest accrued, to counsel for the Defendants, less any costs incurred by Class Counsel or Claims Administrator in respect of the Court-approved notices to the Class. Class Counsel will provide an accounting to the Defendants of these costs, including supporting documentation.
- (3) If this Settlement Agreement is terminated in accordance with its terms or otherwise fails to take effect for any reason, all negotiations, statements and proceedings relating to the settlement and the Settlement Agreement shall be deemed to be without prejudice to the rights of the Parties, and the Parties shall be deemed to be restored to their respective positions existing immediately before it was executed.

(4) The Parties expressly reserve all of their respective rights if the Ontario Court does not approve this Settlement Agreement.

## 8.3 Survival of Provisions After Termination

If this Settlement Agreement is terminated or otherwise fails to take effect for any reason, the provisions of this section and sections 4.2(2), 4.3(2), 4.3(3), 8.2, 11 and the Recitals, Schedules and Definitions applicable thereto shall survive the termination and continue in full force and effect.

## **SECTION 9 – LEGAL FEES**

- (1) Class Counsel will bring a motion to the Ontario Court for approval of Class Counsel Fees. The Defendants will not take any position with respect to the amount of fees requested by Class Counsel.
- (2) Class Counsel Fees may be paid out of the Settlement Fund in their trust account or the Account only after Class Counsel obtain the approval of their fees and disbursements from the Ontario Court.
- (3) Class Members who retain lawyers to assist them in making their individual claims in this Settlement shall be responsible for the legal fees and expenses of such lawyers.

# SECTION 10 - ADMINISTRATION AND IMPLEMENTATION

## 10.1 Mechanics of Administration

Except to the extent provided for in this Settlement Agreement, the mechanics of the implementation and administration of this Settlement Agreement shall be supervised by the Ontario Court. The Claims Administrator, Referee, or the Parties may seek directions from the case management judge, on notice to the other Parties at any time, as may be required.

## SECTION 11 - NO ADMISSION OF LIABILITY

- (1) The Parties agree that, whether or not this Settlement Agreement is finally approved or is terminated, this Settlement Agreement and anything contained herein, and any and all negotiations, documents, discussions, and proceedings associated with this Settlement Agreement, and any action taken to carry out this Settlement Agreement, shall not be deemed, construed, or interpreted to be an admission of any violation of any statute of law, or of any wrongdoing or liability by the Releasees, or of the truth of any of the claims or allegations made in the Action.
- (2) The Parties further agree that, whether or not this Settlement Agreement is finally approved or is terminated, neither this Settlement nor any document relating to it shall be offered in evidence in any action or proceeding in any court, agency or tribunal as an admission of any violation of any statute of law, or of any wrongdoing or liability by the Releasees, or of the truth of any of the claims or allegations made in the Action. Nothing in this section shall prevent the Parties from filing the Settlement Agreement or any document related thereto in evidence in order to seek Court

approval of this Settlement Agreement or to give effect to and enforce the provisions of this Settlement Agreement.

#### SECTION 12 - MISCELLANEOUS

## 12.1 Headings, etc.

In this Settlement Agreement:

- (a) the division of the Settlement Agreement into sections and the insertion of headings are for convenience of reference only and shall not affect the construction or interpretation of this Settlement Agreement; and
- (b) the terms "this Settlement Agreement", "the Settlement Agreement", "Settlement", "hereof", "herein", "herein", "hereto", and similar expressions refer to this Settlement Agreement and not to any particular section or portion of this Settlement Agreement.

## 12.2 Ongoing Jurisdiction

The Ontario Court shall retain exclusive jurisdiction over all matters relating to the implementation and enforcement of this Settlement Agreement.

## 12.3 Governing Law

This Settlement Agreement shall be governed by, construed and interpreted in accordance with the laws of the Province of Ontario.

### 12.4 Entire Agreement

This Settlement Agreement constitutes the entire agreement among the Parties, and supersedes all prior and contemporaneous understandings, undertakings, negotiations, representations, communications, promises, agreements, agreements in principle, and memoranda of understanding in connection herewith. The Parties agree that they have not received or relied on any agreements, representations, or promises other than as contained in this Settlement Agreement. None of the Parties shall be bound by any prior obligations, conditions, or representations with respect to the subject matter of this Settlement Agreement, unless expressly incorporated herein. This Settlement Agreement may not be modified or amended except in writing and on consent of all Parties hereto, and any such modification or amendment must be approved by the Ontario Court.

## 12.5 Binding Effect

Once the Settlement Agreement is approved by the Ontario Court and the approval order becomes a Final Order, this Settlement Agreement shall be binding upon, and inure to the benefit of, the Releasers, the Releasers, Class Counsel, the Claims Administrator, and the Referee.

## 12.6 Counterparts

This Settlement Agreement may be executed in counterparts, all of which taken together will be deemed to constitute one and the same agreement, and a facsimile signature shall be deemed an original signature for purposes of executing this Settlement Agreement. This Settlement Agreement may be delivered and is fully enforceable in either original, faxed or other electronic form provided that it is duly executed.

## 12.7 Negotiated Agreement

This Settlement Agreement has been the subject of negotiations and discussions among the Parties, each of which has been represented and advised by competent counsel, so that any statute, case law, or rule of interpretation or construction that would or might cause any provision to be construed against the drafter of this Settlement Agreement shall have no force and effect. The Parties further agree that the language contained or not contained in previous drafts of this Settlement Agreement, or any agreement in principle, shall have no bearing upon the proper interpretation of this Settlement Agreement.

### 12.8 Language

The Parties acknowledge that they have required and consented that this Settlement Agreement and all related documents be prepared in English; les parties reconnaissent avoir exigé que la présente convention et tous les documents connexes soient rédigés en anglais. A French translation of all notices pursuant to this Settlement Agreement shall be paid for as an Administration Expense.

#### 12.9 Dates

Dates referred to in this Settlement Agreement may be altered with the written consent of the Parties and with the approval of the Ontario Court.

### 12.10 Confidentiality

- (1) The Parties agree that no public statements shall be made regarding this Action or their Settlement which are in any way inconsistent with the terms of the Settlement Agreement. In particular, the Parties agree that any public statements regarding this Action will indicate clearly that the Settlement has been negotiated, agreed and approved by the Ontario Court without any admissions or findings of liability or wrongdoing, and without any admissions or conclusions as to the truth of any of the facts alleged in the Action, all of which are specifically denied by the Defendants.
- (2) Each Party agrees not to disparage the opposite Parties or their counsel with respect to any of the matters in issue in the Action or the manner in which the Action were conducted or settled, or the Defendants' products. The Parties agree that any public statements that are inconsistent with the terms of this Settlement Agreement could cause irreparable harm, including harm to the business and reputation of the Releasees.

#### 12.11 Recitals

The recitals to this Settlement Agreement are true and form part of the Settlement Agreement.

#### 12.12 Schedules

The Schedules annexed hereto form part of this Settlement Agreement and are:

- (a) Schedule A Certification Order;
- (b) Schedule B Notices of Certification, Proposed Settlement and Approval Hearing (short and long form);
- (c) Schedule C Notice Protocol;
- (d) Schedule D Approval Order;
- (e) Schedule E Notice of Settlement Approval (short and long form);
- (f) Schedule F Referce Guidelines;
- (g) Schedule G Distribution Protocol; and
- (h) Schedule H Table of Provincial and Territorial Health Insurance statutes.

#### 12.13 Acknowledgements

Each of the Parties hereby affirms and acknowledges that:

- (a) he, she, or a representative of the Party with the authority to bind the Party with respect to the matters set forth herein has read and understands the Settlement Agreement;
- (b) the terms of this Settlement Agreement and the effects thereof have been fully explained to him, her, or the Party's representative by his, her, or its counsel; and
- (c) no Party has relied upon any statement, representation, or inducement (whether material, false, negligently made, or otherwise) of any other Party with respect to the first Party's decision to execute this Settlement Agreement.

#### 12.14 Authorized Signature

Each of the undersigned represents that he or she is fully authorized to enter into the terms and conditions of, and to execute, this Settlement Agreement.

#### 12.15 Notice

Where this Settlement Agreement requires a Party to provide notice or any other communication or document to another, such notice, communication, or document shall be provided by email, facsimile, or letter by overnight delivery to the representatives for the Party to whom notice is being provided, as identified below:

## For Plaintiffs and for Class Counsel:

Margaret Waddell

Waddell Phillips Professional Corporation

36 Toronto Street

Suite 1120

Toronto ON M5C 2C5

Telephone: (416) 477-6979

Facsimile: (416) 477-1657

Email:

marg@waddellphillips.ca

Paul Miller

Howie Sacks & Henry LLP

20 Oueen Street West

Suite 3500

Toronto ON M5H 3R3

Telephone: (416) 646-3901

Facsimile: (416) 361-0083

Email:

pmiller@hshlawyers.com

#### For Defendants:

Caroline Zayid / Eric Block / Byron Shaw McCarthy Tétrault LLP Toronto Dominion Bank Tower Suite 5300, Box 48 Toronto ON M5K 1E6

Telephone: 416-601-7768 / 7792

Facsimile: 416-868-0673

Email:

czayid@mccarthy.ca / eblock@mccarthy.ca / bdshaw@mccarthy.ca

The Parties, by their counsel, have executed this Settlement Agreement as of the date on the cover page.

Dated at Toronto this 16th day of April, 2019

Waddl

Waddell Phillips Professional Corporation

Margaret L. Waddell

Lawyer for the Plaintiffs, Shirley Houle and Roland Houle

Dated at Toronto this 16th day of April, 2019

Howie Sacks & Henry LLP

Paul Miller

Lawyers for the Plaintiffs Shirley Houle and Roland Houle

Dated at Toronto this 18th day of April, 2019

McCatthy Tétrault LLP

Caroline Zayid

Lawyers for the Defendants, St. Jude Medical,

Inc. and St. Jude Medical Canada, Inc.

## Schedule "A"

Court File No. CV-17-572508-00CP

# ONTARIO SUPERIOR COURT OF JUSTICE

THE HONOURABLE	)	TUESDAY, THE ●TE
JUSTICE PAUL M. PERELL	).	DAY of ●, 2019

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

## **CERTIFICATION ORDER**

THIS MOTION, made by the Plaintiffs, on consent, for an order certifying this action as a class proceeding for settlement purposes, fixing the date of a settlement approval motion, and approving the form, content, and method of dissemination of a notice of certification and of a pending settlement approval hearing (the Notice of Certification, Proposed Settlement and Approval Hearing) was heard this day at Osgoode Hall, 130 Queen Street West, Toronto, Ontario.

ON READING the certification motion record of the Plaintiffs, the responding motion record of the Defendants, and the supplementary motion records of the Plaintiffs and the Defendants, including the Settlement Agreement dated •, 2019 (the "Settlement Agreement"), the facta and books of authorities of the parties, and on hearing the submissions of Class Counsel and the lawyers for the Defendants;

AND ON BEING ADVISED that the Defendants consent to this Order;

**AND ON BEING ADVISED** that the Provincial Health Insurers consent to this Order;

AND ON BEING ADVISED that Epiq Class Action Services has consented to its appointment as the Claims Administrator pursuant to the Settlement Agreement;

- 1. **THIS COURT ORDERS** that this action is certified as a class proceeding, pursuant to sections 2 and 5 of the *Class Proceedings Act*, 1992 for settlement purposes only.
- 2. THIS COURT ORDERS that the classes are defined as:
  - a. Patient Class means (i) all persons who are resident in Canada as at the date of the Certification Order or, if deceased at or before the date of the Certification Order, who were residents in Canada at the date of death, (ii) who were implanted in Canada with one or more of the Defibrillators, and (iii) who do not opt out of this action; and
  - b. *Derivative Class* means all dependants of Patient Class Members asserting the right to sue the Releasees independently or derivatively by reason of their familial relationship to a Patient Class Member, including pursuant to the *Family Law Act*, RSO 1990 c F 3 or similar legislation in any other Province or Territory in Canada (together, the Patient Class and the Derivative Class are the "Class"), and
- 3. THIS COURT ORDERS THAT, for the purposes of this Order:
  - a. *Defibrillator* means the implantable cardioverter defibrillators or cardiac resynchronization therapy defibrillators manufactured by the Defendants between January 2010 and May 23, 2015 listed below:

Trade Name	Model	Trade Name	Model
Fortify Assura™ DR	CD2259-40Q	Quadra Assura MP™	CD3371-40C
Fortify Assura™ DR	CD2259-40	Quadra Assura MP™	CD3371-40QC
Fortify Assura™ DR	CD2359-40C	Quadra Assura™	CD3265-40Q
Fortify Assura™ DR	CD2359-40QC	Quadra Ássura™	CD3367-40QC
Fortify Assura™ VR	CD1359-40QC	Quadra Assura™	CD3267-40
Fortify Assura™ VR	CD1259-40	Quadra Assura™	CD3267-40Q
Fortify Assura™ VR	CD1259-40Q	Quadra Assura™	CD3367-40C
Fortify Assura™ VR	CD1359-40C	Unify Assura™	CD3261-40Q
Fortify™ DR	CD2233-40Q	Unify Assura™	CD3361-40QC
Fortify™ DR	CD2233-40	Unify Assura™	CD3261-40
Fortify™ ST DR	CD2235-40	Unify Assura™	CD3361-40C
Fortify™ ST DR	CD2235-40Q	Unify Quadra™	CD3251-40
Fortify™ ST VR	CD1235-40	Unify Quadra™	CD3251-40Q
Fortify™ ST VR	CD1235-40Q	Unify™	CD3231-40
Fortify™ VR	CD1233-40	Unify™	CD3235-40
Fortify™ VR	CD1231-40	Unify™	CD3235-40Q
Fortify™ VR	CD1233-40Q		

- b. Proposed Class or Proposed Class Members means the proposed Patient Class and Derivative Class, including those who opt out of this action.
- 4. **THIS COURT ORDERS** that the following causes of action are asserted on behalf of the Class: negligence and derivative actions under Section 61 of the *Family Law Act*, RSO 1990, c F 3 and similar legislation in other provinces and territories, and under the provincial health legislation of each province and territory in Canada.
- 5. THIS COURT ORDERS that Shirley Houle shall be appointed as the Representative Plaintiff on behalf of the Patient Class, and Roland Houle shall be appointed as the Representative Plaintiff on behalf of the Derivative Class.

- 6. **THIS COURT ORDERS** that solely pursuant to ss. 2 and 5 of the *Class Proceedings Act* the following common issues shall be certified for settlement purposes only:
  - a. were the Defendants negligent in failing to ensure that there were no defects in the
     Defibrillators:
  - b. were the Defendants negligent in failing to warn the Class of a risk of premature battery depletion with the Defibrillators in a timely fashion; and
  - c. if so, are the Defendants liable in damages to the Patient Class, the Derivative Class or the Provincial Health Insurers?
  - 7. THIS COURT ORDERS that Class members may opt out of this class proceeding by delivering a written request to opt out to the Claims Administrator which must be postmarked, if sent by mail, or received, if sent by fax, e-mail or courier, on or before •, 2019 at 11:59 pm E.S.T. (the "Opt Out Deadline"). [NTD: date is 60 days after the date the Notice of Certification, Proposed Settlement and Approval Hearing is first disseminated] Opt out forms received after this date will not be accepted or valid. The notice of opt out must contain:
    - a. the full name, mailing address, and telephone number of the Proposed Class
       Member;
    - b. the Provincial Health Insurance number of the Proposed Class Member;
    - c. the make, model and serial number of the Defibrillator of the Proposed Class Member;

- d. the date and location where the Proposed Class Member's Defibrillator was implanted;
- e. a statement indicating whether the Proposed Class Member's Defibrillator was explanted, and if so, the location where it was explanted and the date on which it was explanted; and
- f. in the case of a Derivative Class Member whose Patient Class Member relative is deceased, the Patient Class Member's information set out in paragraphs (a) to (e) above, along with the Patient Class Member's date of death and a statement of whether they believe the death was related to premature battery depletion.
- 8. **THIS COURT ORDERS** that any putative members of the Class who validly opt out of this action by the Opt Out Deadline, in accordance with paragraph 7 of this Order are not bound by the Settlement Agreement and shall no longer participate in or have the opportunity in the future to participate in this action or the Settlement Agreement.
- 9. THIS COURT ORDERS that within 10 days of the Opt Out Deadline, the Claims
  Administrator shall provide to Class Counsel and counsel for the Defendants the names of
  persons who have delivered valid opt out notices and a copy of the opt out notices.
- 10. THIS COURT ORDERS that the short form Notice of Certification, Proposed Settlement and Approval Hearing shall be in a form attached hereto as Appendix 1 and the long form Notice of Certification, Proposed Settlement and Approval Hearing shall be in a form attached hereto as Appendix 2.

- 11. **THIS COURT ORDERS** that the Notice Protocol with respect to the publication of the Notice of Certification, Proposed Settlement and Approval Hearing is approved in the form attached hereto as **Appendix 3**, and that the Notice of Certification, Proposed Settlement and Approval Hearing shall be disseminated in accordance with the Notice Protocol.
- 12. THIS COURT ORDERS that Epiq Class Action Services is appointed as the Claims Administrator for the purposes of disseminating the Notice of Certification, Proposed Settlement and Approval Hearing (Schedules 1 and 2) in accordance with the Notice Protocol and for receiving any opt out forms, and reporting to the court and the parties with respect to those opt outs in accordance with the terms of the Settlement Agreement.
- 13. **THIS COURT ORDERS** that within 15 days of this Order, the Defendants will provide to the Claims Administrator and to Class Counsel, to the extent known, a list of the Patient Class Members, including their names, last known addresses, the type of Defibrillator implanted, and the serial numbers of the implanted Defibrillators. The Defendants will also identify for the Claims Administrator and Class Counsel, to the extent known, any Defibrillators that were replaced due to premature battery depletion where the battery depletion occurred earlier than expected based on the Defibrillator usage and there was no indication that the depletion was related to a cause other than a short circuit that may have been due to the formation of lithium clusters.
- 14. **THIS COURT ORDERS** that the Claims Administrator shall use the information provided pursuant to paragraph 13 of this Order for the sole purpose of effecting the Notice Protocol and facilitating the claims administration process in accordance with the Settlement Agreement, and for no other purpose.

- 15. THIS COURT ORDERS that the Claims Administrator shall maintain confidentiality over and shall not share the information provided pursuant to paragraph 13 with any other person, including but not limited to any lawyer (except any lawyers retained by the Claims Administrator), unless doing so is necessary for effecting the Notice Protocol and facilitating the claims administration process in accordance with the Settlement Agreement.
- 16. THIS COURT DECLARES AND ORDERS that this Order constitutes an Order compelling the production of information by the Defendants within the meaning of applicable privacy laws, including that it satisfies the requirements of section 7(3)(c) of the Personal Information Protection and Electronic Documents Act, SC 2000, c 5 and section 41(1)(d)(i) of the Personal Health Information Protection Act, 2004, SO 2004 c 3.
- 17. THIS COURT ORDERS that this Order does and is deemed to comply with any requirement under applicable privacy laws for the Defendants to provide any notice to persons of disclosure of the information required by this Order without consent.
- 18. THIS COURT ORDERS that the Defendants be and are hereby released from any and all obligations pursuant to any and all applicable privacy laws, including common law, statutes and regulations in relation to the disclosure of personal information or personal health information required by this Order.
- 19. **THIS COURT ORDERS** that this Order is binding upon each member of the Class who does not validly opt out from this actions on or prior to the Opt Out Deadline in accordance with paragraph 7 of this Order, whether or not they submit a claim to participate in the

distribution of the Settlement Fund, if the Settlement Agreement is approved, including those persons who are minors or mentally incapable, and the requirements of Rules 7.04(1) and 7.08(4) of the *Rules of Civil Procedure* are dispensed with in respect of this action.

- 20. THIS COURT ORDERS that the hearing of the settlement approval motion and the motion for approval of Class Counsel fees shall take place on •, 2019.
- 21. THIS COURT ORDERS that any Class Members who wish to file with the Court an objection to, or comment on the settlement of this action, or the request for approval of Class Counsel fees, shall deliver a written statement to Class Counsel, at the address indicated in the Notice of Certification, Proposed Settlement and Approval Hearing, no later than ●, 2019.
- 22. **THIS COURT ORDERS** that this Order shall be set aside, declared null and void and of no force and effect on a subsequent motion made on notice to the parties in the event that the Settlement Agreement is terminated in accordance with its terms.
- 23. THIS COURT ORDERS that there shall be no costs of this motion.

The Honourable Justice P. M. Perell

HOULE et al. -and- ST. JUDE | Plaintiffs

ST. JUDE MEDICAL, INC. et al. Defendants

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

# ONTARIO SUPERIOR COURT OF JUSTICE PROCEEDING COMMENCED AT TORONTO

# CERTIFICATION ORDER

# WADDELL PHILLIPS PROFESSIONAL CORPORATION

36 Toronto St., Suite 1120 Toronto, Ontario M5C 2C5 Margaret L. Waddell (29860U) marg@waddellphillips.ca

Tel: (647) 261-4486 Fax: 416-477-1657 HOWIE, SACKS & HENRY LLP 20 Queen Street West, Suite 3500 Toronto, Ontario M5H 3R3

**Paul Miller** (LSO #39202A) pmiller@hshlawyers.com Tel: (416) 361-5990 Fax: (416) 361-0083

Lawyers for the Plaintiffs

# NOTICE OF CLASS ACTION CERTIFICATION and NOTICE OF HEARING FOR SETTLEMENT APPROVAL of ST. JUDE DEFIBRILLATOR CLASS ACTION

# READ THIS NOTICE CAREFULLY. IT MAY AFFECT YOUR RIGHTS.

This Notice is for all persons who were implanted in Canada with an implantable cardioverter defibrillator or cardiac resynchronization therapy defibrillator (a "Defibrillator") manufactured by St. Jude Medical, Inc. between January 2010 and May 23, 2015 listed below, and their immediate family members (the "Class"):

Trade Name	Model	Trade Name	Model
Fortify Assura™ DR	CD2259-40Q	Quadra Assura MP™	CD3371-40C
Fortify Assura™ DR	CD2259-40	Quadra Assura MP™	CD3371-40QC
Fortify Assura™ DR	CD2359-40C	Quadra Assura™	CD3265-40Q
Fortify Assura™ DR	CD2359-40QC	Quadra Assura™	CD3367-40QC
Fortify Assura™ VR	CD1359-40QC	Quadra Assura™	CD3267-40
Fortify Assura™ VR	CD1259-40	Quadra Assura™	CD3267-40Q
Fortify Assura™ VR	CD1259-40Q	Quadra Assura™	CD3367-40C
Fortify Assura™ VR	CD1359-40C	Unify Assura™	CD3261-40Q
Fortify™ DR	CD2233-40Q	Unify Assura™	CD3361-40QC
Fortify™ DR	CD2233-40	Unify Assura™	CD3261-40
Fortify™ ST DR	CD2235-40	Unify Assura™	CD3361-40C
Fortify™ ST DR	CD2235-40Q	Unify Quadra™	CD3251-40
Fortify™ ST VR	CD1235-40	Unify Quadra™	CD3251-40Q
Fortify™ ST VR	CD1235-40Q	Unify™	CD3231-40
Fortify™ VR	CD1233-40	Unify™	CD3235-40
Fortify™ VR	CD1231-40	Unify™	CD3235-40Q
Fortify™ VR	CD1233-40Q		

# CERTIFICATION OF ACTION AS A CLASS PROCEEDING

A class action has been certified by the Ontario Superior Court of Justice against St. Jude Medical, Inc. and St. Jude Medical Canada, Inc. (together, "St. Jude") on behalf of the Class, for the purpose of effecting a proposed settlement of the action.

In the action, the Plaintiffs assert that the batteries in the Defibrillators were faulty as they were subject to forming lithium clusters that could cause the batteries to deplete prematurely, and that the Defendants allegedly failed to warn the Class about this defect in a timely manner. The Defendants dispute these allegations.

# Schedule "B" (Short Form)

# THE PROPOSED SETTLEMENT

The parties have reached a proposed settlement of the class action. Before it is effective, the Court must approve it. The Settlement Agreement is a compromise of disputed claims, without any admission or findings of liability or wrongdoing against St. Jude.

# SUMMARY OF THE SETTLEMENT

If the Settlement Agreement is approved by the Court, St. Jude will pay \$5,000,000 CAD in full and final settlement of all claims against them, in return for a release and a dismissal of the class action. The Settlement Fund, less administration costs and lawyers' fees as approved by the court, will be distributed to the Class in accordance with a Court-approved and supervised Distribution Protocol.

The Settlement Agreement, including the proposed Distribution Protocol (Schedule G) can be reviewed at <a href="https://waddellphillips.ca/class-actions/st-jude-defibrillator-class-action/">https://waddellphillips.ca/class-actions/st-jude-defibrillator-class-action/</a> or <a href="https://www.hshlawyers.com/expertise/mass-tort-litigation/st-jude-defibrillator-pacemaker/">https://www.hshlawyers.com/expertise/mass-tort-litigation/st-jude-defibrillator-pacemaker/</a> or <a href="https://www.hshlawyers.com/expertise/mass-tort-litigation/st-jude-defibrillator-pacemaker/">https://www.hshlawyers.com/expertise/mass-tort-litigation/st-jude-defibrillator

# HEARING TO APPROVE SETTLEMENT AGREEMENT AND CLASS COUNSEL FEES

On •, 2019, at 10:00 am EST there will be a Court hearing (the "Settlement Approval Motion") at which Class Counsel will ask the Court to approve (i) the Settlement Agreement; and (ii) their legal fees and expenses. The hearing will be held at Osgoode Hall, 130 Queen Street West, Toronto, Ontario.

At the Settlement Approval Motion, the Court will determine whether the Settlement Agreement is fair, reasonable, and in the best interest of the Class. Class Counsel will also seek court approval of their fees in the amount of up to \$1,300,000 CAD plus disbursements and taxes to be paid from the Settlement Fund. Class Counsel have been working under a contingency fee agreement, and have not been paid as the matter has proceeded, and have paid all the expenses of conducting the litigation for the Class.

Any Class Member may attend at the Settlement Approval Motion and ask to make submissions regarding the proposed settlement. Persons intending to object to the Settlement Agreement should provide their objection in writing to Class Counsel at the address below by •.

# YOUR OPTIONS

# 1. Stay in the Class Action and Do Nothing:

You do not have to do anything to stay in the class action. You will be legally bound by all orders and judgments of the Court, and you will not be able to sue the Defendants regarding the legal claims made in this case. If the Court approves the Settlement Agreement, the Settlement Fund, less approved deductions, will be distributed to those Class Members who make valid claims. You will be notified about how to claim a portion of the Settlement Fund if the Settlement is approved.

2. Stay in the Class Action and Object to the Settlement Agreement or Class Counsel Fees:

# Schedule "B" (Short Form)

If you want to object to the proposed Settlement or to the payment of Class Counsel's fees and expenses, you should do so by setting out your objection in writing addressed to Class Counsel at the address below by XXXX

# 3. Opt Out of the Class Action

All Class Members will be bound by the decisions of the Court regarding this action, including terms of the Settlement Agreement, if it is approved, unless they opt out. Any Class Member who wishes to exclude themselves from this action must opt out by delivering a written notice of their intent to opt out to:

**Epiq Class Action Services** 

Attention: St. Jude ICD Settlement Nelson P.O. 20187 – 322 Rideau Street Ottawa Ontario K1N 5Y5

Fax: 1-866-262-0816

Email: info@stjudelCDclaim.ca

The Opt Out notice must include your full name, address and telephone number, as well as your Provincial Health insurance number, the make, model and serial number of your Defibrillator, the date and location where you were implanted with the Defibrillator, and, if it was explanted, the date and location of the explant surgery. If you are the family member of a deceased relative who had a Defibrillator, the Opt Out notice must also include your relative's date of death and an indication as to whether their death was related to premature battery depletion with the Defibrillator.

The Opt Out notice must be postmarked, if sent by mail, or received, if sent by fax, e-mail or courier, on or before XXXX, 2019 at 11:59 p.m. EST. Opt out forms received after this date will not be accepted or valid.

# **MORE INFORMATION:**

Go to <a href="https://waddellphillips.ca/class-actions/st-jude-defibrillator-class-action/">https://www.hshlawyers.com/expertise/mass-tort-litigation/st-jude-defibrillator-pacemaker/</a> to review a copy of the Certification Order, the Settlement Agreement, or to obtain additional information about this class action.

Questions for Class Counsel should be directed to:

St. Jude Defibrillator Class Action 36 Toronto St., Suite 1120 Toronto, ON M5C 2C5 Email: reception@waddellphillips.ca

> Phone: 647-261-4486 Fax: 416-477-1657

# Schedule "B" (Short Form)

The Ontario Superior Court of Justice has authorized distribution of this Notice.

Questions about this Notice should NOT be directed to the Court.

# NOTICE OF CLASS ACTION CERTIFICATION and NOTICE OF HEARING FOR SETTLEMENT APPROVAL of ST. JUDE DEFIBRILLATOR CLASS ACTION

# READ THIS NOTICE CAREFULLY, AS IT MAY AFFECT YOUR LEGAL RIGHTS.

This Notice is for: All persons who were implanted in Canada with an implantable cardioverter defibrillator or cardiac resynchronization therapy defibrillator (a "Defibrillator") manufactured by St. Jude Medical, Inc. between January 2010 and May 23, 2015 listed below, and their immediate family members (the "Class"):

Trade Name	Model	Trade Name	Model
Fortify Assura™ DR	CD2259-40Q	Quadra Assura MP™	CD3371-40C
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Fortify™ DR	CD2233-40	Unify Assura™	CD3261-40
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Fortify™ ST VR	CD1235-40	Unify Quadra™	CD3251-40Q
Fortify™ ST VR	CD1235-40Q	Unify™	CD3231-40
Fortify™ VR	CD1233-40	Unify™	CD3235-40
Fortify™ VR	CD1231-40	Unify™	CD3235-40Q
Fortify™ VR	CD1233-40Q		

In 2017, a proposed class action was commenced by Shirley Houle and Roland Houle of Port Hope, Ontario, (the Representative Plaintiffs) against St. Jude Medical, Inc. and St. Jude Medical Canada, Inc. (together, "St. Jude"), in the Ontario Superior Court of Justice, Court File No. CV-17-572508-00CP. In the action, the Plaintiffs assert that that the batteries in the Defibrillators were faulty as they were subject to forming lithium clusters that could cause the batteries to prematurely deplete, and that the Defendants allegedly failed to warn the Class about this defect in a timely manner. The Defendants contest and would refute these allegations if the matter went to trial.

The parties have reached a proposed settlement of the class action (the "Settlement Agreement"). The Settlement Agreement can be viewed at: <a href="https://waddellphillips.ca/class-actions/st-jude-defibrillator-class-action/">https://www.hshlawyers.com/expertise/mass-tort-litigation/st-jude-defibrillator-pacemaker/</a> or [NTD add Epiq website, if available]

The Settlement is a compromise of disputed claims, without any admission or findings of liability or wrongdoing against St. Jude by the Court. St. Jude denies any liability.

The Court has made an Order allowing the action to be prosecuted as a class action. The Order was made on consent, solely for the purposes of facilitating the Settlement. Before the Settlement Agreement will be effective, it must be approved by the Court. If the Settlement is not approved by the Court, then the certification Order will be set aside, and the Plaintiffs' motion for certification will be argued at a later date.

The common issues that have been certified on consent solely pursuant to the *Class Proceedings Act*, 1992, S.O. 1992, c. 6, are:

- a. were the Defendants negligent in failing to ensure that there were no defects in the Defibrillators;
- b. were the Defendants negligent in failing to warn the Class of a risk of premature battery depletion with the Defibrillators in a timely fashion; and
- c. if so, are the Defendants liable in damages to the Patient Class, the Derivative Class or the Provincial Health Insurers?

By consenting to these common issues for the purpose of settlement, St. Jude has not admitted that any of these issues would be certified by the Court if the motion for certification was argued on a contested basis.

The hearing for approval of the Settlement Agreement and setting Class Counsel's legal fees will be on [DATE], at the Osgoode Hall Court House, 130 Queen Street West, Toronto, at 10:00 am.

As a Class Member, your legal rights are affected as you will be bound by any orders of the Court, including the Court's approval of the Settlement Agreement, the release of St. Jude from any liability in respect of the matters that were raised or that could have been raised in the class action, or any other Court orders, if the Settlement Agreement is not approved.

If you do not wish to be included in the class action, you have a choice to exclude yourself from the lawsuit ("Opt Out"). If you Opt Out, you will not be bound by any court decision, nor will you be able to participate in the Settlement.

# WHAT THIS NOTICE CONTAINS

# **BASIC INFORMATION**

- 1. Why was this Notice issued?
- 2. What are the Settlement benefits?
- 3. What is this lawsuit about?
- 4. Who is a member of the Class?
- 5. What are the Plaintiffs asking for?
- 6. Is there any money available now?

# YOUR OPTIONS

- 7. What happens if I do nothing?
- 8. What if I don't agree with the Settlement Agreement or Class Counsel's fees or disbursements?
- 9. What if I don't want to be in the Class?

# THE LAWYERS REPRESENTING YOU

- 10. Do I have a lawyer in the case?
- 11. How will the lawyers be paid?

# **GETTING MORE INFORMATION**

12. How do I get more information?

# **YOUR OPTIONS:**

# DO NOTHING - Stay in the lawsuit

If you do nothing, you will automatically be included as a member of the Class. You do not need to take any further action to stay in the lawsuit.

Await the outcome. You will be bound by the terms of the Court-approved Settlement. If the Settlement Agreement is not approved, then you will be bound by any future orders of the Court.

Give up certain rights. By doing nothing, you are choosing to stay in the class action. You will keep your right to share in the settlement, however, you will also be bound by any negative results. You are giving up the right to sue St. Jude on your own in connection with the allegedly defective Defibrillators and St. Jude's alleged failure to warn.

# OPT OUT Remove yourself from the lawsuit

If you choose to Opt Out of the class action, then you will not be bound by any court orders. This means that you will get no money or benefits from the Settlement Agreement. This also means that you will not be bound by any potential negative results.

If you exclude yourself, you keep the right to sue St. Jude on your own.

If you intend to Opt Out and sue St. Jude on your own, you should be aware that there will be limitation periods that apply to your claim, and the time within which an action may be started. You should consult a lawyer to obtain advice about your rights to bring an individual action.

To Opt Out, you must act by •, 2019.

Follow the instructions below, at p. 8.

## **BASIC INFORMATION**

# 1. Why is there a Notice?

This lawsuit has been approved by the Court to proceed as a class action against St. Jude for the purpose of effecting the Settlement Agreement reached between the parties. If you are included in the Class, this Notice explains your legal rights.

### 2. What are the settlement benefits?

If the Court approves the Settlement Agreement, St. Jude will pay \$5,000,000 CAD in full and final settlement of all claims in the class action against it, including Class Counsel's fees and administration costs, in return for releases and a dismissal of the class action. The Settlement Fund, less administration costs and lawyers' fees, will be distributed to the Class in accordance with the Court-approved and supervised Distribution Protocol, which can be reviewed at Schedule G of the Settlement Agreement found at: <a href="https://waddellphillips.ca/class-actions/st-jude-defibrillator-class-action/">https://www.hshlawyers.com/expertise/mass-tort-litigation/st-jude-defibrillator-pacemaker/</a> or [add Epiq website if available]. The Distribution Protocol anticipates that the Settlement Fund will be paid on the following basis:

- An amount for each Eligible Explant Claimant<sup>1</sup>, depending upon a number of factors, including the number of Eligible Explant Claimants and the number of claimants who have experienced complications arising from surgery to replace their Defibrillator who make valid claims;
- Additional compensation for Eligible Explant Claimants who have experienced complications arising from surgery to replace a Defibrillator as awarded by the Referee in accordance with guidelines approved by the Court;
- up to \$100 CAD to those Patient Class Members who (i) had their Defibrillator implanted prior to December 1, 2013; and (ii) are not an Eligible Explant Claimant;
- up to \$500 CAD to those Patient Class Members who (i) had their Defibrillator implanted on or after December 1, 2013; and (iii) are not an Eligible Explant Claimant;

<sup>&</sup>lt;sup>1</sup> "Eligible Explant Claimants" means Patient Class Members who either (i) had a Defibrillator replaced due to premature battery depletion where the battery depletion occurred earlier than expected based on the Defibrillator usage and there was no indication that the depletion was related to a cause other than a short circuit that may have been due to the formation of lithium clusters, or (ii) had a Defibrillator replaced between October 10, 2016 and August 8, 2017 on an elective basis in response to the St. Jude advisory issued in Canada on October 10, 2016 provided that the electively replaced Defibrillator had been implanted for less than five years at the time of the replacement.

- Payments to the Derivative Class Members of deceased Patient Class Members as approved by the Referee in accordance with guidelines approved by the Court; and,
- All out of pocket expenses, up to \$500 CAD, incurred by Class Members in the amounts approved by the Referee in accordance with guidelines approved by the Court.

## 3. What is this lawsuit about?

In 2017, a proposed class action was commenced against St. Jude. The claim alleged that during the Class Period, the batteries in the Defibrillators were faulty as they were subject to forming lithium clusters that could cause the batteries to prematurely deplete, and that the Defendants allegedly failed to warn the Class about this defect in a timely manner. The Defendants dispute these allegations.

# 4. Who is a member of the Class?

The Class is defined solely under Canadian law as all persons who were implanted in Canada with an implantable cardioverter defibrillator or cardiac resynchronization therapy defibrillator (a "Defibrillator") that was manufactured by St. Jude between January 2010 and May 23, 2015 listed above, and their immediate family members.

# 5. What are the plaintiffs asking for?

The claim asks for money for Class Members for physical and psychological injuries as a result of St. Jude allegedly failing to warn that the batteries in the Defibrillators were subject to forming lithium clusters that could cause the batteries to prematurely deplete. The Representative Plaintiffs are also asking for an honorarium of \$5,000 CAD each, payment of their lawyers' fees and costs, the costs of administering the settlement, and interest.

# 6. Is there any money available now?

At the Settlement Approval Motion, the Court will determine whether the Settlement Agreement is fair, reasonable, and in the best interest of the Class.

If the Settlement Agreement is approved by the Court, the Settlement Amount of \$5,000,000 CAD, less administration costs and lawyers' fees, as approved by the Court, will be distributed in accordance with the Court-approved and supervised Distribution Protocol.

At the hearing, Class Counsel will also seek court approval of their request for fees equal to no more than 30% of the Settlement Fund plus expense reimbursement. Class Counsel has not been paid as the matter has proceeded, and has funded the out-of-pocket expenses of conducting the litigation for the Class. Class Counsel will be requesting the fees and disbursements to be deducted from the Settlement Fund.

# 7. What happens if I do nothing at all?

You do not have to do anything to stay in the class action. If the Settlement Agreement is approved by the Court, then the Settlement Amount of \$5,000,000 CAD less legal fees, disbursements and administration costs will be distributed to qualifying Class Members. You will be notified about how to ask for a portion of the net Settlement Fund in a separate notice.

As a Class Member, you will be legally bound by all orders and judgments of the Court, including a release to be granted in favour of St. Jude, and you will not be able to sue St. Jude regarding the legal claims made in this case.

# 8. What if I don't agree with the Settlement Agreement or Class Counsel's requested fees and disbursements?

The Settlement Agreement is posted on Class Counsel's website: <a href="https://waddellphillips.ca/class-actions/st-jude-defibrillator-class-action/">https://waddellphillips.ca/class-actions/st-jude-defibrillator-class-action/</a> or <a href="https://www.hshlawyers.com/expertise/mass-tort-litigation/st-jude-defibrillator-pacemaker/">https://www.hshlawyers.com/expertise/mass-tort-litigation/st-jude-defibrillator-pacemaker/</a> or and [add Epiq website if available].

Once filed with the Court, the materials explaining why Class Counsel and the Representative Plaintiffs say that this settlement is in the best interests of the Class will also be posted on the websites.

Class Counsel will also post the court documents explaining and supporting their request for approval of their fees and disbursements. Class Counsel entered into a contingency fee agreement with the Representative Plaintiffs that would permit Class Counsel to be paid 1/3 of the recovery achieved for the class, exclusive of any amount paid by St. Jude as a contribution to court costs. Class Counsel will be asking the Court to approve fees payable to them of no more than \$1,300,000 CAD, plus disbursements and taxes.

On \_\_\_ 2019, at \_\_EST, the Court will hear the Representative Plaintiffs' motion for Settlement Approval, and Class Counsel's Motion for approval of their contingency fee agreement.

The hearing will be held at Osgoode Hall, 130 Queen Street West, Toronto, Ontario, starting at 10:00 am.

If you want to remain in the Class, but object to the terms of the Settlement Agreement or object to the amount of fees requested by Class Counsel, you should do so by setting out your objection in writing addressed to the Class Counsel at their address below. Written objections will be filed with the Court, but must be delivered by no later than • [2 business days prior to hearing]

You may also attend at the hearing in person or with your own lawyer to raise any objection.

Objections should be sent to:

St. Jude Defibrillator Class Action
Waddell Phillips Professional Corporation
36 Toronto St., Suite 1120
Toronto, ON M5C 2C5
(f) 416-477-1657
(e) reception@waddellphillips.ca

# 9. What if I don't want to be in the Class?

If you decide you do not want to participate in the lawsuit, you must remove yourself - this is referred to as "opting-out". If you remove yourself, you will not receive any money or benefit from the Settlement Agreement, if it is approved. You will not be bound by any Court orders and you keep your right to sue St. Jude regarding the issues raised in this case. You cannot change your mind later and opt back into the class action.

To remove yourself, you must send a written Opt Out notice to the Claims Administrator by registered mail or certified mail at:

# **Epiq Class Action Services**

Attention: St. Jude ICD Settlement Nelson P.O. 20187 – 322 Rideau Street Ottawa Ontario K1N 5Y5 Fax: 1-866-262-0816

Email: info@stjudeICDclaim.ca

The Opt Out notice must include your full name, address and telephone number, as well as your Provincial Health insurance number, the make, model and serial number of your Defibrillator, the date and location where you were implanted with the Defibrillator, and, if it was explanted, the date and location of the explant surgery. If you are a family member of a deceased relative who had a Defibrillator, the Opt Out notice must also include your relative's date of death and an indication as to whether their death was related to premature battery depletion with the Defibrillator. You may use the form set out below.

The Opt Out notice must be postmarked, if sent by mail, or received, if sent by fax, e-mail or courier, on or before XXXX, 2019 at 11:59 pm E.S.T. Opt Out forms received after this date will not be accepted or valid, and you will be remain a Class Member.

# THE LAWYERS REPRESENTING YOU

# 10. Do I have a lawyer in the case?

Waddell Phillips Professional Corporation and Howie, Sacks and Henry LLP are the lawyers for the Representative Plaintiffs, and are Class Counsel.

# 11. How will the lawyers be paid?

You will not have to pay any of the fees and expenses of Class Counsel, directly. If the Court grants their request, Class Counsel's fees and expenses will be deducted from the Settlement Amount.

# **GETTING MORE INFORMATION**

# 12. How do I get more information?

You can obtain more information about this case, including assistance in determining if you are a member of the Class, or about Opting Out by contacting Class Counsel or the Claims Administrator using the contact details listed below:

### **Claims Administrator:**

# **Epiq Class Action Services**

Attention: St. Jude ICD Settlement
Nelson P.O. 20187 – 322 Rideau Street
Ottawa Ontario
K1N 5Y5
Fax: 1-866-262-0816

Email: info@stjudeICDclaim.ca

### Class Counsel:

Waddell Phillips Professional Corporation 36 Toronto St., Suite 1120 Toronto, ON M5C 2C5 Email: reception@waddellphillips.ca Phone: 647-261-4486 Fax: 416-477-1657

Attn. St. Jude Defibrillator Class Action

Howie Sacks & Henry LLP 20 Queen Street West, Suite 3500 Toronto, ON M5H 3R3 Email: pmiller@hshlawyers.com Phone: 416-361-5990 Fax: 416-361-0083

# ST. JUDE DEFIBRILLATOR CLASS ACTION OPT OUT FORM

This is NOT a claim form. Completing this OPT OUT FORM will <u>exclude you from the lawsuit and you will not receive any compensation arising out of any settlement or judgment in the class action.</u>

To:

**Epiq Class Action Services** 

Attention: St. Jude ICD Settlement Nelson P.O. 20187 – 322 Rideau Street Ottawa Ontario

K1N 5Y5

Fax: 1-866-262-0816

Email: info@stjudeICDclaim.ca

I understand that by Opting Out, I am confirming that <u>I do not wish to participate</u> in the St. Jude Defibrillator class action.

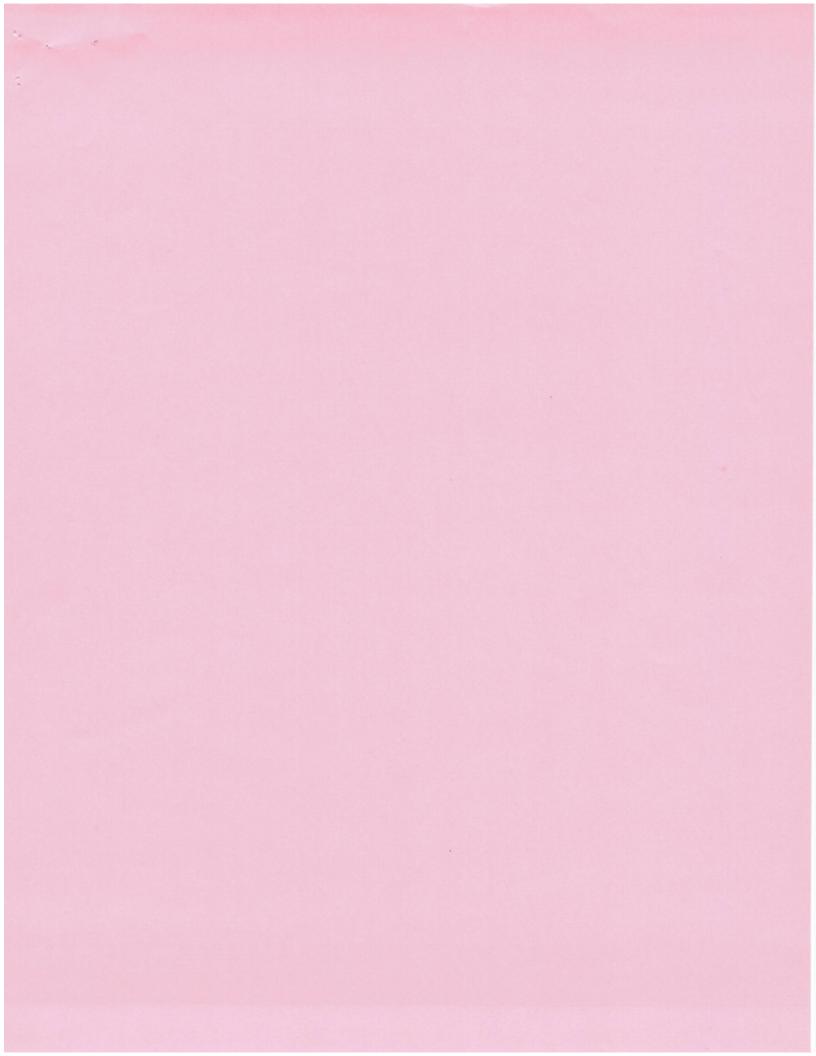
I understand that if I wish to commence my own action, it must be commenced within a specified limitation period or it will be legally barred, and that a recommendation has been made to me to seek independent legal advice about my rights in this respect.

I understand that the limitation period was stopped from the time the class proceeding was filed on March 30, 2017, but the limitation period will start running against me if I Opt Out of this class action.

I understand that by Opting Out, I take full responsibility for the resumption of the running of any relevant limitation period and for taking all necessary legal steps to protect any claim I may have against the Defendants.

Name of Person Implanted with a	
Defibrillator	
Name of Next-of-Kin of a Deceased	
Name of Next-of-Kin of a Deceased	
Person who was Implanted with a	
Defibrillator, Family Relationship	
(e.g. spouse, child, parent), and date of	
death	
If your Next-of-Kin who was Implanted	
with a Defibrillator is deceased, was	
their death related to premature	

battery depletion with the Defibrillator?	
Mailing Address	
Phone Number	
Email Address (optional)	
Provincial Health Insurance Number of Person Implanted with a Defibrillator	
Make, Model and Serial Number of the Defibrillator	
Date and Location of Implant	
If applicable, Date and Location of when/where the Defibrillator was replaced or removed.	
Optional: Reason for Opting-Out: Please	explain your reason(s) for opting-out.
Date	
Signature of Witness	Signature of Class Member or Next-of-Kin Opting-Out
Name:	Name:
Print Name	Print Name
Note: To opt out, this form must be propertulater than	ly completed and received at the above address <u>no</u>



## APPENDIX 3

### NOTICE PROTOCOL

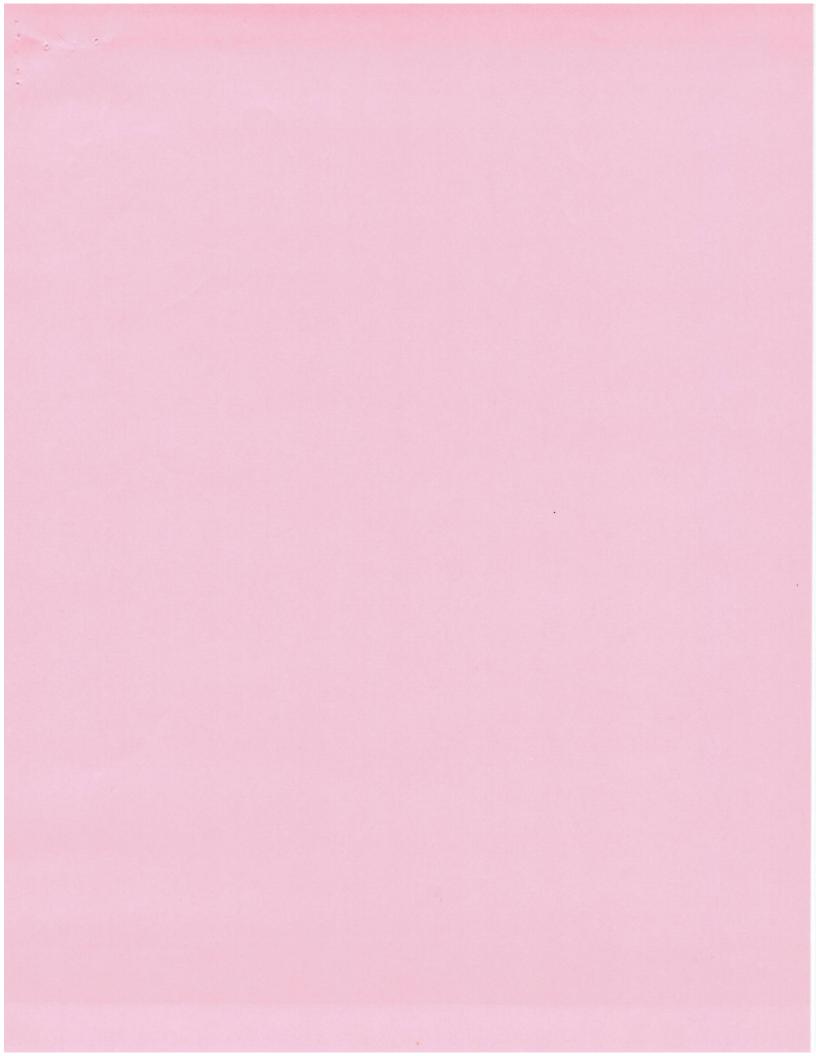
- A. Notice of Certification, Proposed Settlement and Approval Hearing (Certification Notice)
- 1. Within 15 (fifteen) days of the date that the Order certifying the Action as a class proceeding for settlement takes effect, the Defendants will provide to the Claims Administrator and to Class Counsel lists of Patient Class Members including their names, last known addresses, the type of Defibrillator implanted and the serial numbers of the implanted Defibrillators, to the extent such information is available to the Defendants (the "Patient Class Member List").
- 2. Class Counsel will publish a national press release in English and in French advising of the consent certification of the action as a class proceeding for settlement purposes, briefly outlining the key features of the settlement, advising of opt out rights, and include links to the short and long form Notices on Class Counsels' web pages dedicated to the proceeding. The content of the press release will be in a form agreed between the Parties and, if they are unable to agree, then in a form approved by the Court.
- 3. The Claims Administrator will deliver the Certification Notice:
  - a) by mail to the Patient Class Members (as updated from other sources, including information provided by Class Counsel and from the Patient Class List);
  - b) by email to any Class Member who has provided their contact information to Class Counsel; and
  - c) by mail or email to any person requesting a copy from Class Counsel or the Claims Administrator.
- 4. Class Counsel will post an update to their firm websites advising of the certification of the action for settlement purposes and explaining its import, setting out the key terms of the proposed settlement, explaining the procedure for opting out of the Action, and explaining the process for objecting to the proposed settlement. Class Counsel will post a link to a copy of the long form and short form Certification Notices, and the executed Settlement Agreement. Once filed with the court, Class Counsel will also post a link to the Plaintiffs' motion for settlement approval and Class Counsel's motion for fee approval.
- 5. The Defendants will post the long form Certification Notice on Abbott's website.

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## APPENDIX 3

# NOTICE PROTOCOL

- B. Notice of Settlement Approval (Settlement Notice)
- 1. Class Counsel will publish a national press release in English and in French advising of the settlement approval, and include links to the short and long form Notices on Class Counsels' web pages dedicated to the proceeding. The content of the press release will be in a form agreed between the Parties and, if they are unable to agree, then in a form approved by the Court.
- 2. The Claims Administrator will deliver the Settlement Notice, including a paper copy of the Claim Form, and instructions on how to access and complete a web-based claim form:
  - a) by mail to Patient Class Members (as updated from other sources, including information provided by Class Counsel, and updated contact information received from Class Members and the Patient Class List);
  - b) by email to any Class Member who has provided their contact information to Class Counsel; and
  - c) by mail or email to any person requesting a copy from Class Counsel or the Claims Administrator.
- 3. Class Counsel will post an update to their firm websites advising of the settlement approval and explaining its import, setting out the key terms of the settlement, explaining the procedure for making a claim for part of the Settlement Fund, including how to contact the Claims Administrator. Class Counsel will post a link to a copy of the long form and short form Settlement Notices, and the executed Settlement Agreement.
- 4. The Defendants will post the long form Settlement Notice and Claim Form on Abbott's website.
- 5. The short form Settlement Notice will be published twice in the Metro Newspaper, including the French version of the Settlement Notice in the Montreal edition of the Metro, and twice in the Globe and Mail and in La Presse+ or in le journal de Montréal and le journal du Québec.



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

# ONTARIO SUPERIOR COURT OF JUSTICE

THE HONOURABLE	)	•, THE •
JUSTICE PAUL M. PERELL	) ) )	DAY OF ●, 2019

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

## SETTLEMENT APPROVAL ORDER

**THIS MOTION**, made by the Plaintiffs, on consent, for an order approving the settlement of this action solely pursuant to s. 29(2) of the *Class Proceedings Act*, 1992, SO 1992, c 6 (the "*CPA*"), in accordance with the terms of the Settlement Agreement between the Plaintiffs and Defendants dated February 15, 2019 (the "Settlement Agreement");

AND THIS MOTION, made by Class Counsel for approval of their fees and disbursements payable under a contingency agreement between the Plaintiffs and Class Counsel dated December 20, 2016 in the total amount of ●, plus HST, in accordance with s. 32(2) *CPA*, and for an order granting the payment of an honourarium to the Plaintiffs in the amount of \$5,000 CAD each for their efforts in prosecuting this action on a *quantum meruit* basis,

were heard this day at Osgoode Hall Courthouse, 130 Queen Street West, Toronto, Ontario.

ON READING the parties' motion records, and facta and briefs of authorities of the Plaintiffs and Class Counsel, filed, including the Settlement Agreement, attached to this Order as Appendix 1, and on hearing the submissions of Class Counsel and the lawyers for the Defendants;

AND ON BEING ADVISED that the Provincial Health Insurers consent to this Order;

AND ON BEING ADVISED that the parties consent to this Order, without any admission of liability by the Defendants whatsoever;

- 1. THIS COURT ORDERS that the Settlement Agreement, Appendix 1, is incorporated by reference into this Order and that unless otherwise defined in this Order, capitalized terms in this Order shall have the meanings set out in the Settlement Agreement.
- 2. THIS COURT ORDERS that the Settlement Agreement is fair and reasonable and in the best interests of the Class and is hereby approved, and shall be implemented in accordance with its terms.
- 3. **THIS COURT ORDERS** that the Defendants shall pay to and for the benefit of the Class \$4,250,000 CAD, plus \$750,000 CAD for Costs in full and final settlement of the Released Claims.
- 4. THIS COURT ORDERS AND DECLARES that the Releasors forever and absolutely release the Releasees from the Released Claims.
- 5. THIS COURT ORDERS AND DECLARES that the Releasors agree not to make any claim or take or continue any proceedings arising out of or relating to the subject matter of the

Released Claims, including the alleged harm or damages from the use, purchase, implantation, replacement, or explantation of a Defibrillator in a Patient Class Member against any other person, corporation or entity (including, without limitation, any health care professionals, heath care providers, or health care facilities) which might claim damages and/or contribution and indemnity and/or other relief under the provisions of the *Negligence Act* or other comparable provincial or territorial legislation and any amendments thereto, the common law, Québec civil law, or any other statute, for any relief whatsoever, including relief of a monetary, declaratory or injunctive nature, from one or more of the Releasees.

- 6. THIS COURT ORDERS AND DECLARES that in consideration of the payments made to the Provincial Health Insurers set out in the Settlement Agreement, the Provincial Health Insurers are deemed to forever and absolutely release the Releasees from the Released Claims and the Provincial Health Insurers shall be bound by the Settlement Agreement.
- 7. THIS COURT ORDERS AND DECLARES that each Class Member, whether or not he or she submits a claim or otherwise receives an award, and each Provincial Health Insurer, is deemed to have completely and unconditionally released and forever discharged the Releasees from any and all Released Claims.
- 8. THIS COURT ORDERS AND DECLARES that each Class Member, whether or not he or she submits a claim or otherwise receives an award, and each Provincial Health Insurer, is forever barred and enjoined from continuing, commencing, instituting or prosecuting any action, litigation, investigation or other proceeding in any court of law or equity, arbitration, tribunal, proceeding, governmental forum, administrative forum or any other forum, directly,

representatively or derivatively, asserting against any of the Defendants or Releasees any claims that relate to or constitute any Released Claims.

- 9. THIS COURT ORDERS AND DECLARES that this Order, including the Settlement Agreement, is binding upon the Plaintiffs and each Class Member, whether or not they submit a claim to participate in the distribution of the Settlement Fund, including those persons who are minors or are mentally incapable, and the requirements of Rule 7.04(1) and 7.08(4) of the Rules of Civil Procedure are dispensed with in respect of this Action.
- 10. THIS COURT ORDERS AND DECLARES that any other action or proceeding commenced in Ontario by a Class Member relating to the Released Claims shall be and is hereby dismissed against the Defendants, without costs and with prejudice.
- 11. THIS COURT ORDERS that the Claims Administrator shall be Epiq Class Action Services.
- 12. **THIS COURT ORDERS** that the Referee shall be the Honourable Colin Campbell, and that he may appoint such designates as he deems fit, and who are qualified to assist him in fulfilling the role of Referee.
- 13. **THIS COURT ORDERS** that the Claims Administrator and the Referee shall provide notice of this Order pursuant to the Notice Protocol, facilitate the claims administration process, and report to the Court and the Parties in accordance with the terms of the Settlement Agreement.
- 14. THIS COURT ORDERS that the Claims Administrator and the Referee shall maintain confidentiality over and shall not share the information provided pursuant to this Order with any other person, including but not limited to any lawyer (except any lawyers retained by the Claims

Administrator or the Referee), unless doing so is necessary for effecting the Notice Protocol (in the case of the Claims Administrator) and facilitating the claims administration process in accordance with the Settlement Agreement (in the cases of both the Claims Administrator and the Referee).

- 15. THIS COURT ORDERS that this Order constitutes an Order compelling the production of information by the Defendants within the meaning of applicable privacy laws, including that it satisfies the requirements of section 7(3)(c) of the *Personal Information Protection and Electronic Documents Act*, SC 2000, c 5 and section 41(1)(d)(i) of the *Personal Health Information Protection Act*, 2004, SO 2004 c 3.
- 16. THIS COURT ORDERS that this Order does and is deemed to comply with any requirement under applicable privacy laws for the Defendants to provide any notice to persons of disclosure of the information required by this Order without consent.
- 17. THIS COURT ORDERS that the Defendants be and are hereby released from any and all obligations pursuant to any and all applicable privacy laws, including common law, statutes and regulations in relation to the disclosure of personal information or personal health information required by this Order.
- 18. THIS COURT ORDERS AND DECLARES that no person may bring any action or take any proceeding against the Claims Administrator or the Referee or any of their employees, agents, partners, associates, representatives, successors or assigns for any matter in any way relating to the Settlement Agreement, the implementation of this Order or the administration of the Settlement Agreement and this Order except with leave of this Court.

- 19. **THIS COURT ORDERS** that the Releasees have no responsibility for and no liability whatsoever with respect to the administration of the Settlement Agreement.
- 20. **THIS COURT ORDERS** that the Long Form and Short Form Notice of Settlement Approval are hereby approved substantially in the form attached as Schedule E to the Settlement Agreement, and the claim deadline is set at •, and the Notice of Settlement Approval shall be disseminated in accordance with the Notice Protocol set out at Schedule C of the Settlement Agreement.
- THIS COURT ORDERS that the fees and disbursements of Class Counsel are hereby fixed at \$• CAD, being \$• CAD for fees and \$• CAD for HST and \$• for disbursements and applicable taxes, which are a first charge upon the Settlement Fund, and may be deducted from the Settlement Fund before the balance is transferred to the Claims Administrator.
- 22. **THIS COURT ORDERS** that the Plaintiffs are awarded an honorarium of \$5,000.00 CAD each on a *quantum meruit* basis for the contributions that they made in the prosecution of this action for the benefit of the Class as a whole, and this amount shall be paid from the Settlement Fund by Class Counsel before the transferring the net Settlement Fund to the Claims Administrator.
- 23. THIS COURT ORDERS that Class Counsel shall, within 10 days of this Order becoming final, transfer the Settlement Fund including the accrued interest and less Class Counsel's fees and the Plaintiffs' honoraria, to the Claims Administrator to be held in trust for the benefit of the Class, pending distribution to the Class Members in accordance with the Distribution Protocol at Schedule G to the Settlement Agreement.

- 24. THIS COURT ORDERS AND ADJUDGES that, save as aforesaid, the Action be and is hereby dismissed, without costs and with prejudice.
- 25. THIS COURT ORDERS that there will be no costs of this motion.

JUSTICE P. PERELL

Shirley Houle et al St. Jude Medical Inc. et al Plaintiff and Defendant

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

# ONTARIO SUPERIOR COURT OF JUSTICE

Proceeding commenced at TORONTO

# ORDER

# WADDELL PHILLIPS PROFESSIONAL CORPORATION

36 Toronto St., Suite 1120 Toronto, Ontario M5C 2C5 Margaret L. Waddell (29860U) marg@waddellphillips.ca

Tel: (647) 261-4486 Fax: 416-477-1657

# HOWIE, SACKS & HENRY LLP 20 Queen Street West, Suite 3500 Toronto, Ontario M5H 3R3

**Paul Miller** (LSO #39202A) pmiller@hshlawyers.com Tel: (416) 361-5990 Fax: (416) 361-0083

# Lawyers for the Plaintiffs

# NOTICE OF SETTLEMENT APPROVAL ST. JUDE DEFIBRILLATOR CLASS ACTION

# READ THIS NOTICE CAREFULLY. IT MAY AFFECT YOUR RIGHTS.

This Notice is for all persons who were implanted in Canada with an implantable cardioverter defibrillator or cardiac resynchronization therapy defibrillator (a "Defibrillator") manufactured by St. Jude Medical, Inc. between January 2010 and May 23, 2015 listed below, and their immediate family members (the "Class"):

Trade Name	Model	Trade Name	Model
Fortify Assura™ DR	CD2259-40Q	Quadra Assura MP™	CD3371-40C
Fortify Assura™ DR	CD2259-40	Quadra Assura MP™	CD3371-40QC
Fortify Assura™ DR	CD2359-40C	Quadra Assura™	CD3265-40Q
Fortify Assura™ DR	CD2359-40QC	Quadra Assura™	CD3367-40QC
Fortify Assura™ VR	CD1359-40QC	Quadra Assura™	CD3267-40
Fortify Assura™ VR	CD1259-40	Quadra Assura™	CD3267-40Q
Fortify Assura™ VR	CD1259-40Q	Quadra Assura™	CD3367-40C
Fortify Assura™ VR	CD1359-40C	Unify Assura™	CD3261-40Q
Fortify™ DR	CD2233-40Q	Unify Assura™	CD3361-40QC
Fortify™ DR	CD2233-40	Unify Assura™	CD3261-40
Fortify™ ST DR	CD2235-40	Unify Assura™	CD3361-40C
Fortify™ ST DR	CD2235-40Q	Unify Quadra™	CD3251-40
Fortify™ ST VR	CD1235-40	Unify Quadra™	CD3251-40Q
Fortify™ ST VR	CD1235-40Q	Unify™	CD3231-40
Fortify™ VR	CD1233-40	Unify™	CD3235-40
Fortify™ VR	CD1231-40	Unify™	CD3235-40Q
Fortify™ VR	CD1233-40Q		

The Ontario Superior Court of Justice has approved the settlement of a class action against St. Jude Medical, Inc. and St. Jude Medical Canada, Inc. (together, "St. Jude") on behalf of the Class.

The class action alleged that during the Class Period, the batteries in the Defibrillators were faulty as they were subject to forming lithium clusters that could cause the batteries to deplete prematurely, and that the Defendants allegedly failed to warn the Class about this defect in a timely manner. The Defendants dispute these allegations. St. Jude has agreed to pay the all-inclusive amount of \$5,000,000 CAD to settle the claim. The Settlement Agreement is a compromise of disputed claims, without any admission or findings of liability or wrongdoing against St. Jude.

To be eligible to receive part of the Settlement Fund, Class Members must submit a completed Claim Form to the Claims Administrator, **Epiq Class Action Services** by no later than •, 2019.

# Schedule "E" (Short Form)

For more information, to see the Long Form Notice of Settlement Approval, and to obtain a copy of the Claim Form go to: <a href="https://www.XXXXXX.com">www.XXXXXX.com</a>

Or contact the Claims Administrator at:

**Epiq Class Action Services** 

Attention: St. Jude ICD Settlement
Nelson P.O. 20187 – 322 Rideau Street
Ottawa Ontario
K1N 5Y5

Fax: 1-866-262-0816 Email: info@stjudeICDclaim.ca

Questions for Class Counsel should be directed to:

St. Jude Defibrillator Class Action 36 Toronto St., Suite 1120 Toronto, ON M5C 2C5 Email: reception@waddellphillips.ca

> Phone: 647-261-4486 Fax: 416-477-1657

The Ontario Superior Court of Justice has authorized distribution of this Notice.

Questions about this Notice should NOT be directed to the Court.

# NOTICE OF SETTLEMENT APPROVAL of ST. JUDE DEFIBRILLATOR CLASS ACTION and CLAIMS PROCESS

This Notice is for all persons who were implanted in Canada with an implantable cardioverter defibrillator or cardiac resynchronization therapy defibrillator (a "Defibrillator") manufactured by St. Jude Medical, Inc. between January 2010 and May 23, 2015 listed below, and their immediate family members (the "Class"):

Trade Name	Model	Trade Name	Model
Fortify Assura™ DR	CD2259-40Q	Quadra Assura MP™	CD3371-40C
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Fortify™ DR	CD2233-40	Unify Assura™	CD3261-40
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Fortify™ ST VR	CD1235-40	Unify Quadra™	CD3251-40Q
Fortify™ ST VR	CD1235-40Q	Unify™	CD3231-40
Fortify™ VR	CD1233-40	Unify™	CD3235-40
Fortify™ VR	CD1231-40	Unify™	CD3235-40Q
Fortify™ VR	CD1233-40Q		

# READ THIS NOTICE CAREFULLY, IT MAY AFFECT YOUR LEGAL RIGHTS.

# YOU MAY NEED TO TAKE PROMPT ACTION.

The Ontario Superior Court of Justice has approved the settlement of a class action against St. Jude Medical, Inc. and St. Jude Medical Canada, Inc. (together, "St. Jude") on behalf of the Class in the action Houle v. St. Jude, Court File No. CV-17-572508-00CP.

The Settlement Agreement is a compromise of disputed claims, without any admission or findings of liability or wrongdoing against St. Jude. The class action alleged that during the Class Period, the batteries in the Defibrillators were faulty as they were subject to forming lithium clusters that could cause the batteries to deplete prematurely, and that the Defendants

allegedly failed to warn the Class about this defect in a timely manner. The Defendants dispute these allegations.

St. Jude has agreed to pay the all-inclusive amount of \$5,000,000 CAD (the "Settlement Fund") to settle the class action, in return for releases and a dismissal of the class action. The Settlement Fund includes \$750,000 CAD for court costs, which will be allocated towards Class Counsel's legal fees. The Court has approved payment of Class Counsel's legal fees in the amount of •, which is •% of the Settlement Amount, exclusive of the court costs paid by St. Jude. Class Counsel will also be reimbursed for the disbursements and expenses they incurred. These amounts will be deducted from the Settlement Fund. The total fees, disbursements and taxes paid to Class Counsel, as approved by the Court, is XX\$\$ CAD.

This Notice provides a summary of the Settlement Agreement. The full Settlement Agreement may be viewed at: [Epiq's website address]

or at: https://waddellphillips.ca/class-actions/st-jude-defibrillator-class-action/

or at: https://www.hshlawyers.com/expertise/mass-tort-litigation/st-jude-defibrillator-pacemaker/

# **BASIC INFORMATION**

# 1. Why is there a Notice?

This action was previously certified for settlement purposes by Court Order dated •. The Court has now determined that the Settlement Agreement is fair, reasonable, and in the best interest of the Class, and it has been approved.

Eligible Class Members may now make a claim to receive a portion of the Settlement Fund.

# 2. What are the settlement benefits?

St. Jude will pay the Settlement Amount of \$5,000,000 CAD in full and final settlement of all claims against it, including class counsel fees and administration costs, in return for a comprehensive release from the Class and the Provincial Health Insurers, and a dismissal of the class action. The Settlement Amount, less administration costs and class counsel fees, will be distributed in accordance with the Court-approved and supervised Distribution Protocol, which is Schedule "G" to the Settlement Agreement, and can be viewed at: [Epiq's website address]

or at: https://waddellphillips.ca/class-actions/st-jude-defibrillator-class-action/

or at: <a href="https://www.hshlawyers.com/expertise/mass-tort-litigation/st-jude-defibrillator-pacemaker/">https://www.hshlawyers.com/expertise/mass-tort-litigation/st-jude-defibrillator-pacemaker/</a>

In broad terms, Class Members who complete a valid claim form before the Claims Deadline of •, will be eligible to receive the following:

- 1. If you are an Eligible Explant Claimant, you will be eligible to receive an amount that depends upon a number of factors, including the number of Eligible Explant Claimants and the number of claimants who have experienced complications arising from surgery to replace their Defibrillator who make valid claims. Eligible Explant Claimants means Patient Class Members who either (i) had a Defibrillator replaced due to premature battery depletion where the battery depletion occurred earlier than expected based on the Defibrillator usage and there was no indication that the depletion was related to a cause other than a short circuit that may have been due to the formation of lithium clusters, or (ii) had a Defibrillator replaced between October 10, 2016 and August 8, 2017 on an elective basis in response to the St. Jude advisory issued in Canada on October 10, 2016 provided that the electively replaced Defibrillator had been implanted for less than five years at the time of the replacement.
- 2. If you are an immediate family member of a Patient Class Member who has died and you are able to demonstrate to the Referee on the balance of probabilities that the death was caused or contributed to by premature battery depletion where the battery depletion occurred earlier than expected based on the Defibrillator usage and there was no indication that the depletion was related to a cause other than a short circuit that may have been due to the formation of lithium clusters, you will be eligible for:
  - a. \$60,000 CAD if you are the spouse of the deceased Patient Class Member;
  - b. \$45,000 CAD if you are the minor child of the deceased Patient Class Member; or
  - c. In the event that there is no spouse or minor children of the Patient Class Member, \$20,000 CAD if you are an adult child or parent of the deceased Patient Class Member up to \$100,000 CAD in the aggregate.
- 3. If you are an Eligible Explant Claimant who has experienced complications arising from surgery to replace your Defibrillator, in addition to any amount under #1 above, you will be eligible for:
  - a. \$12,500 CAD for hospitalization exceeding 3 days;
  - b. \$5,000 CAD for hospitalization from 1-3 days; or
  - c. \$1,000 CAD for same day treatment in hospital, clinic, or doctor's office, including for prescription of medications to treat the complication.
- 4. If you are a Patient Class Member that has incurred, and has documented proof of out of pocket expenses that exceed \$100.00 CAD in the aggregate arising from actions taken in response to the receipt of the St. Jude advisory released on October 10, 2016, including but not limited to additional clinic attendances, hospital visits or surgery, you will be eligible to claim those out of pocket expenses, up to \$500.00 CAD.
- 5. If you are a Patient Class Member whose Defibrillator was implanted on or after December 1, 2013, but you are not an Eligible Explant Claimant, you will be eligible to receive up to \$500 CAD.

6. If you are a Patient Class Member and you do not fall within #1 or #5 above, you will be eligible to receive up to \$100 CAD.

# 3. What is this lawsuit about?

In 2017, a proposed class action was commenced against St. Jude. The Plaintiffs allege that during the Class Period, the batteries in the Defibrillators were subject to forming lithium clusters that could cause the batteries to prematurely deplete, and that the Defendants allegedly failed to warn the Class about this defect in a timely manner. The Defendants dispute these allegations.

# 4. Who is a member of the Class?

If you meet the Class definition set out above, then you are a member of the Class.

# **HOW TO MAKE A CLAIM**

To be eligible to receive part of the Settlement Fund, Class Members must submit a completed Claim Form, attached to this Notice, to Epiq Class Action Administration by no later than XXXX, 2019

# **Epiq Class Action Services**

Attention: St. Jude ICD Settlement Nelson P.O. 20187 – 322 Rideau Street Ottawa Ontario K1N 5Y5

Fax: 1-866-262-0816

Email: info@stjudelCDclaim.ca

You can also download the Claim Form or complete the form online at [Epiq's website address]

or at: https://waddellphillips.ca/class-actions/st-jude-defibrillator-class-action/.

or at: https://www.hshlawyers.com/expertise/mass-tort-litigation/st-jude-defibrillator-pacemaker/

# THE LAWYERS REPRESENTING YOU

# 5. How will Class Counsel be paid?

You will not have to pay any of the fees and expenses of Class Counsel. The Court granted their fee approval request, and Class Counsel's fees and expenses have been deducted from the Settlement Amount, in the total amount of \$X CAD, as approved by the Court.

# **GETTING MORE INFORMATION**

# 6. How do I get more information?

You can obtain more information about this case by contacting Class Counsel or the Claims Administrator using the contact details listed below:

# Claims Administrator:

# **Epiq Class Action Services**

Attention: St. Jude ICD Settlement Nelson P.O. 20187 – 322 Rideau Street Ottawa Ontario K1N 5Y5

Fax: 1-866-262-0816

Email: info@stjudelCDclaim.ca

## Class Counsel:

St. Jude Defibrillator Class Action 36 Toronto St., Suite 1120 Toronto, ON M5C 2C5

Email: reception@waddellphillips.ca

Phone: 647-261-4486 Fax: 416-477-1657

# Referee Guidelines

- 1. The Referee shall be appointed by the Ontario Court to assess the claims of Class Members who assert a claim from the Extraordinary Injury Fund as set out in the Settlement Agreement and Distribution Protocol, and to make a final determination of Eligible Class Members in the event of any dispute in respect of the Claims Administrator's decision with respect to eligibility.
- 2. The Referee shall offer his or her services in both French and English.
- 3. The Referee shall sign and adhere to a confidentiality statement, in a form satisfactory to the Parties, by which she or he agrees to keep confidential any information concerning Class Members or the Defendants. Further, the Referee shall institute and maintain procedures to ensure that the identity of all Class Members and all information regarding any claims and submissions are kept strictly confidential. At the conclusion of the claims administration process, any information obtained by the Referee shall be securely deleted and destroyed.
- 4. The Referee shall report to the Court, Class Counsel and to Defendants' counsel on the total number of claims received, and the decisions made by him or her in respect of each claim from the Extraordinary Injury Fund or eligibility appeal.

# **Extraordinary Injury Fund**

- 5. The Referee shall assess the claims of Patient Class Members and Derivative Class Members who assert a claim for an amount from the Extraordinary Injury Fund, and will make a final determination as to:
  - (A) Whether the Class Member is entitled to an amount from the Extraordinary Injury Fund; and,
  - (B) How much the Class Member is entitled to from the Extraordinary Injury Fund.
- 6. The Extraordinary Injury Fund will provide amounts for:
  - (A) Complications if an Eligible Explant Claimant experienced a complication arising from surgery to explant a Defibrillator including but not limited to, abnormal bleeding, infection, pneumothorax, damage to the heart or to a blood vessel;
  - (B) **Death** if a Patient Class Member's death was caused or contributed to by premature battery depletion where the battery depletion occurred earlier than expected based on the Defibrillator usage and there was no indication that the depletion was related to a cause other than a short circuit that may have been due to the formation of lithium clusters; and

- (C) Out of Pocket Expenses out of pocket expenses that exceed \$100.00 CAD in the aggregate, up to a maximum of \$500.00 CAD, supported by documentary proof, for a Patient Class Member arising from actions taken in response to the receipt of the St. Jude advisory released on October 10, 2016, including but not limited to additional clinic attendances, hospital visits or surgery.
- 7. In the case of 6(B) claims, the Referee shall determine whether the Derivative Class Member has provided sufficient evidence to establish, on the balance of probabilities, that the Patient Class Member's death was caused or contributed to by premature battery depletion where the battery depletion occurred earlier than expected based on the Defibrillator usage and there was no indication that the depletion was related to a cause other than a short circuit that may have been due to the formation of lithium clusters.
- 8. The Referee will make all decisions based upon the standard of the balance of probabilities, based upon the information provided to him by the claimant, which may include but is not limited to:
  - (A) The Class Member's written narrative in support of the claim;
  - (B) Clinical notes and records from the Class Member's physician(s);
  - (C) Hospital records;
  - (D) Death certificate, and proof of identity as a Derivative Class Member; and
  - (E) Receipts for out of pocket expenses.
- 9. The Referee shall assess the quantum of damages to be awarded based upon the scale set out at Appendix 1.
- 10. The determination of the Referee shall be final, with no right of appeal, except if the Referee denies a claimant an amount from the Extraordinary Injury Fund. Only in that circumstance, the claimant will have ten (10) business days from the delivery of the Referee's decision to seek a review of the decision by the case management judge in the Action by filing a written submission with the Court, not to exceed 3 pages in length without leave of the Court. The Court's decision shall be final, with no further right of appeal.

# **Explant Pool Eligibility**

11. The Referee shall make a final determination of whether a Class Member is an Eligible Explant Claimant, including whether the claimant had a Defibrillator replaced due to premature battery depletion where the battery depletion occurred earlier than expected based on the Defibrillator usage and there was no indication that the depletion was related to a cause other than a short circuit that may have been due to the formation of lithium clusters.

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- 12. In making that determination the Referee will apply the standards set out in paragraph #8, above.
- 13. If the Referee determines that the Class Member is not an Eligible Explant Claimant, the Class Member will have ten (10) business days from the delivery of the Referee's decision to seek a review of the decision by the case management judge in the Action by filing a written submission with the Court, not to exceed 3 pages in length without leave of the Court. The Court's decision shall be final, with no further right of appeal.

# Dispute of the Claims Administrator's Decision on Eligibility

- 14. The Referee shall make a final determination of whether a claimant is an Eligible Class Member if the claimant disputes the Claims Administrator's decision with respect to eligibility.
- 15. The Referee shall review any evidence provided by the claimant to demonstrate his or her eligibility, including the claimant's written narrative and any documentation demonstrating that the claimant is an Eligible Class Member.
- 16. The determination of the Referee shall be final, with no right of appeal.

# Appendix 1 to Schedule "F"

# Referee's Guidelines

Nati	ure of the Claim	Quantum of Damages	
1.	Derivative Class Members' claim for wrongful death of Patient Class Member caused or contributed to by premature battery depletion where the battery depletion occurred earlier than expected based on the Defibrillator usage and there was no indication that the depletion was related to a cause other than a short circuit that may have been due to the formation of lithium clusters.	<ul> <li>\$60,000 CAD to the spouse of a deceased Patient Class Member</li> <li>\$45,000 CAD to each minor child of deceased Patient Class Member</li> <li>In the event that there is no spouse or minor children, then \$20,000 CAD to each adult child or parent of the deceased Patient Class Member to a maximum of \$100,000 CAD in the aggregate</li> </ul>	
2.	Complications arising from explant surgery of an Eligible Explant Claimant	<ul> <li>\$12,500 CAD for hospitalization exceeding 3 days</li> <li>\$5,000 CAD for hospitalization from 1 - 3 days</li> <li>\$1,000 CAD for same day treatment in hospital, clinic, or doctor's office, including for prescription of medications to treat complication</li> </ul>	
3.	Out of Pocket Expenses	Out of pocket expenses that exceed \$100.00 CAD in the aggregate, up to a maximum of \$500.00 CAD, supported by documentary proof, for a Patient Class Member arising from actions taken in response to the receipt of the St. Jude advisory released on October 10, 2016, including but not limited to additional clinic attendances, hospital visits or surgery.	

# DISTRIBUTION PROTOCOL

The Claims Administrator will distribute the Net Settlement Fund in the following order to all Eligible Class Members who have completed a valid claim form and submitted it on a timely basis on or before the Claims Deadline.

- 1. \$417,250.00 CAD shall be paid to the Provincial Health Insurers to be allocated between them:
  - a. With respect to \$216,000.00 CAD pro-rata based upon the number of Eligible Explant Claimants resident in each Province or Territory; and
  - b. With respect to the balance pro-rata based upon the number of Patient Class Members whose Defibrillator was implanted any time from and after December 1, 2013, but who is not an Eligible Explant Claimant, resident in each Province or Territory;
- 2. \$500,000 CAD shall be allocated to pay up to \$100 CAD to every Patient Class Member who: (i) had their Defibrillator implanted <u>prior to December 1, 2013</u>; and (ii) is not an Eligible Explant Claimant. The \$500,000 CAD shall be paid to all such Patient Class Members on a pro-rata basis up to \$100 CAD per Patient Class Member. Should any amount remain of the \$500,000 CAD after all such eligible Patient Class Members have been paid, the balance shall be added to the Explant Pool, referenced below;
- 3. \$1,100,000 CAD shall be allocated to pay up to \$500 CAD to every Patient Class Member who (i) had their Defibrillator implanted on or after December 1, 2013; and (iii) is not an Eligible Explant Claimant. The \$1,100,000 CAD shall be paid to all such Patient Class Members on a pro-rate basis up to \$500 CAD per Patient Class Member. Should any amount remain of the \$1,100,000 CAD after all such eligible Patient Class Members have been paid, the balance shall be added to the Explant Pool, referenced below;
- 4. Payments to the Derivative Class Members of deceased Patient Class Members as approved by the Referee in accordance with the Referee Guidelines shall be paid to such Class Members;
- 5. Payments to Eligible Explant Claimants who have experienced complications from explantation surgery in the amounts approved by the Referee in accordance with the Referee Guidelines shall be paid to such Class Members;
- 6. All out of pocket expenses incurred by Class Members in the amounts approved by the Referee in accordance with the Referee Guidelines shall be paid to such Class Members; and,
- 7. After payment of the above amounts, the remaining balance of the Net Settlement Fund (the "Explant Pool") shall be distributed pro rata to those Patient Class Members who either (i) had a Defibrillator replaced due to premature battery depletion where the battery

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depletion occurred earlier than expected based on the Defibrillator usage and there was no indication that the depletion was related to a cause other than a short circuit that may have been due to the formation of lithium clusters, or (ii) had a Defibrillator replaced between October 10, 2016 and August 8, 2017 on an elective basis in response to the St. Jude advisory issued in Canada on October 10, 2016 provided that the electively replaced Defibrillator had been implanted for less than five years at the time of the replacement.

8. If, six months following the conclusion of the distribution of the Net Settlement Fund to all Eligible Claimants, there remain any unallocated amounts, or distributed Settlement Fund cheques have become stale dated without being cashed, then such amounts remaining in the Net Settlement Fund shall be paid cy-près to the Heart and Stroke Foundation of Canada.

# TABLE OF PROVINCIAL HEALTH INSURER STATUES

Health Care Costs Recovery Act, S.B.C. 2008, C. 27
Crown's Right of Recovery Act, S.A. 2009, c.C-35.
The Health Administration Act, R.S.S. 1978, c. H-0.0001
The Health Services Insurance Act, C.C.S.M., c. H35
Health Insurance Act, R.S.O. 1990, c. H.6
Health Insurance Act, R.S.Q., c. A-29
Health Services and Insurance Act, S.N.S. 1989, c. 197
Hospital Services Act, R.S.N.B. 1973, c.H-9
Medical Care and Hospital Insurance Act, S.N.L. 2016, c. M-5.01
Hospital and Diagnostic Services Insurance Act, R.S.P.E.I. 1988,
c. H-8
Health Services Payment Act, R.S.P.E.I. 1988, c. H-2
Hospital Insurance and Health and Social Services Administration
Act, R.S.N.W.T. 1988, c. T-3
Health Care Insurance Plan Act, R.S.Y. 2002, c. 107
Hospital Insurance and Health and Social Services Administration
Act, R.S.N.W.T. (Nu) 1988, c. T-3

Shirley Houle et al
Plaintiff and

St. Jude Medical Inc. et al Defendant

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

# ONTARIO SUPERIOR COURT OF JUSTICE

Proceeding commenced at TORONTO

# ORDER

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