

ST. JUDE ICD CLASS ACTION SETTLEMENT

READ THIS NOTICE CAREFULLY AS IT MAY AFFECT YOUR LEGAL RIGHTS

www.stjudeicdclaim.ca

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		

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 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 **www.stjudeicdclaim.ca**.

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 is 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 **August 1, 2019** at the Osgoode Hall Court House, 130 Queen Street West, Toronto, at 10:00 a.m.

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 class action ("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.

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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 \$5,000,000.00 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 www.stjudeicdclaim.ca.

The Distribution Protocol anticipates that the Settlement Fund will be paid on the following basis:

- **An amount for each Eligible Explant Claimant¹**, 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 \$100.00 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 \$500.00 CAD to those Patient Class Members** who
 - (i) had their Defibrillator implanted **on or after December 1, 2013**; and
 - (ii) are not an Eligible Explant Claimant;
- **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 \$500.00 CAD, incurred by Class Members** in the amounts approved by the Referee in accordance with guidelines approved by the Court.

¹ "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.

3. What is this class action 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 \$5,000.00 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 Hearing, 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 \$5,000,000.00 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.

YOUR LEGAL RIGHTS AND OPTIONS

<p style="text-align: center;">DO NOTHING Stay in the class action</p>	<p>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.</p> <p>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.</p> <p>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.</p>
<p style="text-align: center;">OBJECT to the Settlement</p>	<p>You can write the Court about why you like or do not like the Settlement.</p> <p>Written objections will be filed with the Court, and must be delivered no later than Monday, July 29, 2019.</p> <p>See question 8 below for additional information.</p>
<p style="text-align: center;">OPT-OUT Exclude yourself from the class action</p>	<p>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 payment or benefits from the Settlement Agreement. This also means that you will not be bound by any potential negative results.</p> <p>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.</p> <p>To Opt Out, you must submit an Opt-Out Form no later than Friday, July 19, 2019.</p> <p>See question 9 below for additional information.</p>

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 \$5,000,000.00 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 at **www.stjudeicdclaim.ca**.

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 **www.stjudeicdclaim.ca**.

Court documents explaining and supporting Class Counsel's request for approval of their fees and disbursements will also be posted at **www.stjudeicdclaim.ca**. 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 \$1,300,000.00 CAD, plus disbursements and taxes.

On **August 1, 2019, at 10 a.m. 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.

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, and must be delivered **no later than Monday, July 29, 2019**.

You may also attend 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 Street, Suite 1120
Toronto ON M5C 2C5
Fax: 416-477-1657
Email : reception@waddellphillips.ca

9. What if I want to exclude myself from the Class?

If you decide that you do not want to participate in the class action, you must exclude yourself - this is referred to as "opting-out". **If you exclude yourself, you will not receive any payment 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 exclude yourself, you must submit an Opt-Out Form to the Claims Administrator **no later than Friday, July 19, 2019** at:

Epiq Class Action Services

Attention: St. Jude ICD Class Action Settlement Claims Administrator
Nelson P.O. Box 20187 – 322 Rideau Street
Ottawa ON K1N 5Y5
Email: info@stjudeicdclaim.ca
Fax: 1-866-262-0816

The Opt-Out Form 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 Form 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 Opt-Out Form set out below.

The Opt-Out Form must be postmarked, if sent by mail, or received, if sent by fax, email or courier, on or before July 19, 2019 at 11:59 p.m. EST. Opt-Out Forms received after this date will not be accepted or valid, and you will 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 get 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.

ADDITIONAL INFORMATION

12. How do I obtain additional information?

You can obtain additional 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 Class Action Settlement Claims Administrator
Nelson P.O. Box 20187 – 322 Rideau Street
Ottawa ON K1N 5Y5
Email: info@stjudeicdclaim.ca
Phone: 1-833-414-8043
Fax: 1-866-262-0816
www.stjudeicdclaim.ca

Class Counsel:

Waddell Phillips Professional Corporation

Attention: St. Jude Defibrillator Class Action
36 Toronto Street, Suite 1120
Toronto ON M5C 2C5
Email: reception@waddellphillips.ca
Phone: 647-261-4486
Fax: 416-477-1657
<https://waddellphillips.ca/class-actions/st-jude-defibrillator-class-action/>

Howie Sacks & Henry LLP

Attention: St. Jude Defibrillator Class Action
20 Queen Street West, Suite 3500
Toronto ON M5H 3R3
Email: pmiller@hshlawyers.com
Phone: 416-361-5990
Fax: 416-361-0083
<https://www.hshlawyers.com/expertise/mass-tort-litigation/st-jude-defibrillator-pacemaker/>

**The Ontario Superior Court of Justice has authorized distribution of this Notice.
Questions about this Notice should NOT be directed to the Court.**

ST. JUDE ICD CLASS ACTION SETTLEMENT

OPT-OUT FORM

www.stjudeicdclaim.ca

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

Opt-Out Forms must be submitted to the Claims Administrator **no later than July 19, 2019.**

You may also submit an Opt-Out Form by email at info@stjudeicdclaim.ca. Mailed Opt-Out Forms must be postmarked by Canada Post **no later than July 19, 2019.**

SECTION A – CLASS MEMBER IDENTIFICATION

You **must** check one (1) of the boxes below:

I am the **Person Implanted** with a Defibrillator (“Patient Class Member”)

OR

I am the **Next-of-Kin of a Deceased Person** who was Implanted with a Defibrillator (“Derivative Class Member”) - *e.g. spouse, child, parent*

Important: If you are a Derivative Class Member you **must** provide the following information:

Full Name of Patient Class Member

Date of Death of Patient Class Member

Was their death related to premature battery depletion with the Defibrillator? Yes / No

Please proceed to page 2.

**ST. JUDE ICD CLASS ACTION SETTLEMENT
OPT-OUT FORM**

SECTION B – CLASS MEMBER NAME AND CONTACT INFORMATION		
<input style="width: 95%; height: 20px;" type="text"/>	<input style="width: 95%; height: 20px;" type="text"/>	
First Name	Last Name	
Complete Street Address		
City	Province	Country
Postal Code		
Telephone Number		
Email		

SECTION C – REQUIRED PATIENT INFORMATION		
Provincial Health Insurance Number of Person Implanted with a Defibrillator		
<input style="width: 95%; height: 20px;" type="text"/>	<input style="width: 95%; height: 20px;" type="text"/>	<input style="width: 95%; height: 20px;" type="text"/>
Make of the Defibrillator	Model of the Defibrillator	Serial Number of the Defibrillator
Date and Location of Implant		
If applicable, Date and Location of when/where the Defibrillator was replaced or removed.		

**ST. JUDE ICD CLASS ACTION SETTLEMENT
OPT-OUT FORM**

SECTION D – REASON FOR OPTING OUT (OPTIONAL)

Please explain your reason(s) for opting-out.

SECTION E – OPT-OUT DECLARATION

I, _____ understand that by opting out, I am confirming that **I do not wish to participate** in the St. Jude ICD 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.

I understand that by opting out, I will not be a part of this class action lawsuit and I will keep any rights that I may have to sue the Defendants myself. I understand that I will not be bound by any of the Court's orders or judgments in this class action lawsuit and will not get any compensation or benefits from this lawsuit or from any settlement.

Signature

Date

Witness Signature

Date

Opt-Out Forms must be received by the Claims Administrator **no later than July 19, 2019.**

Epiq Class Action Services
Attention: St. Jude ICD Class Action Settlement Claims Administrator
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Fax: 1-866-262-0816
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