

**ONTARIO  
SUPERIOR COURT OF JUSTICE**

THE HONOURABLE JUSTICE ) Thursday, the 3rd day of  
CULLITY ) March, 2005

BETWEEN:

**ERIK ANDERSEN, YVONNE ANDERSEN and SHARON FROST**

Plaintiffs

- and -

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

Defendants

Proceeding under the *Class Proceedings Act*, 1992

**ORDER**

THIS MOTION, made by the plaintiffs, was heard this day at Toronto.

ON READING the case conference memorandum of the plaintiffs dated March 2, 2005 and the affidavit of Yvonne Andersen, sworn on March 2 2005, filed, indicating that the plaintiff Erik Andersen died on January 15 2005, and indicating the consent of Yvonne Andersen to continue these proceedings as executrix of the estate of Erik Andersen, and on hearing submissions of counsel for the plaintiffs and the defendants:

1. **Order to Continue**

1. THIS COURT ORDERS that <sup>subject to any further Order of this Court, see</sup> this proceeding continue and that the title of all proceedings in all documents issued, served and filed after the day of this Order be as follows:

YVONNE ANDERSEN on her own behalf and as Executrix of the Estate of Erik Andersen, and  
SHARON FROST

Plaintiffs

- and -

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

Defendants

2. THIS COURT ORDERS that paragraphs 4 and 5 of the Order dated January 16, 2004 be amended to provide that Yvonne Andersen as Executrix of the Estate of Erik Andersen and Sharon Frost shall be the representative plaintiffs for the Patient Class and Yvonne Andersen on her own behalf shall be the representative plaintiff for the Family Class in this class proceeding.

2. **Notice of Class Certification**

3. THIS COURT ORDERS that the form of the Notice of Class Certification attached hereto as Schedule "A" (the "Notice") be and the same is hereby approved.

4. THIS COURT ORDERS that the identity and addresses of class members be determined as follows:

- (a) the defendants shall provide to class counsel information contained in the defendants' patient tracking database as to the full name, date of birth, last known address, implanting hospital, serial number, model number, and date of implant, of all Canadian residents, other than residents of British Columbia or Quebec, who were implanted with one or more mechanical heart valves or annuloplasty rings coated with Silzone that were designed, manufactured, marketed, distributed or sold by the defendants; and
- (b) the Ontario Health Insurance Plan, the Alberta Ministry of Health and Wellness, and the health insurance plans for each other province and territory of Canada other than British Columbia and Quebec shall provide to class counsel the last

known addresses and, where applicable, the date of death, of the residents of their respective provinces on the list provided pursuant to paragraph 3(a) and class counsel will provide the information so obtained to counsel for the defendants; and

- (c) class counsel shall review their database of contacts with those persons on the list provided pursuant to paragraph 3(a) for last known addresses and provide the information so obtained to counsel for the defendants.

5. THIS COURT ORDERS that the Notice required by section 17 of the *Class Proceedings Act*, 1992 be given to all members of the class in the following ways:

- (a) class counsel shall mail the Notice directly by prepaid first class mail, at the representative plaintiffs' expense, to each member of the patient class at the last known address(es) of the patient, as determined under paragraph 4 above, <sup>and</sup> shall provide defendants' counsel with a list of all patients notified and the last known addresses to which the notification was sent; *free*
- (b) the defendants shall provide a copy of the Notice to all cardiac surgeons who are recorded as implanting surgeons for all patients referred to in paragraph 4(a) in the defendants' patient device tracking database and to all Canadian cardiologists outside of Québec and British Columbia listed on the mailing list compiled by the Canadian Institute for Health Information, Southam Medical Database;
- (c) the defendants shall provide a copy of the Notice to the Canadian College of Family Physicians;
- (d) class counsel and St. Jude Medical, Inc. shall post the Notice on their respective websites.

### 3. Opt-outs

6. THIS COURT ORDERS that class members may opt out of the class by sending the opt out coupon in Schedule "A" to class counsel before September 30, 2005. Class members may not opt out of this proceeding after September 30, 2005.

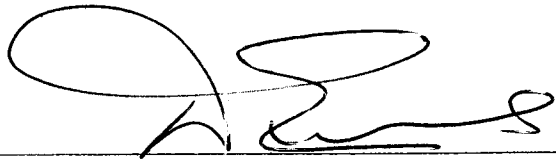
7. THIS COURT ORDERS that class counsel will provide defendants' counsel with copies of all opt-out coupons received by class counsel forthwith upon receipt of same by class counsel.

5. **Litigation Schedule**

8. THIS COURT ORDERS that the parties adhere to the following litigation schedule subject to any further order of the court:

- (a) the plaintiffs shall serve their proposed Fresh as Amended Statement of Claim by March 11 2005;
- (b) the defendants shall serve their Statement of Defence by April 15 2005;
- (c) the plaintiffs shall serve their Reply, if any, by April 25 2005;
- (d) the plaintiffs shall serve their proposal for the use of depositions in related proceedings in the United States by May 31 2005;
- (e) the plaintiffs and the defendants shall serve their affidavits of documents by June 15 2005;
- (f) the plaintiffs and the defendants shall complete any examinations for discovery (subject to the completion of undertakings and any questions witnesses may be required to re-attend to answer) by October 31, 2005;
- (g) the plaintiffs and the defendants shall complete all undertakings, motions arising out of discovery, and further examinations for discovery by January 31 2006;
- (h) the plaintiffs shall serve all expert reports on which they intend to rely by March 31 2006;
- (i) the defendants shall serve all expert reports on which they intend to rely by June 30 2006;
- (j) the plaintiffs shall serve any reply expert reports on which they intend to rely by July 31 2006;

- (k) class counsel will request a trial date commencing on or after October 2, 2006 from the judge responsible for scheduling long trials in Toronto.




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**DAVID EVANS**  
REGISTRAR

ENTERED AT / INSCRIT À TORONTO  
ON / BOOK NO:  
LE / DANS LE REGISTRE NO.:

MAY 20 2005

AS DOCUMENT NO.:  
À TITRE DE DOCUMENT NO.:  
PER / PAR: 

**SCHEDULE "A"**

**NOTICE OF CLASS CERTIFICATION**

**PLEASE READ CAREFULLY. IGNORING THIS NOTICE WILL AFFECT YOUR  
LEGAL RIGHTS.**

Court File No. 00-CV-1 95906CP

**ONTARIO  
SUPERIOR COURT OF JUSTICE**

BETWEEN:

YVONNE ANDERSEN on her own behalf and as Executrix of the Estate of Erik Andersen, and  
SHARON FROST

Plaintiffs

- and -

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

Defendants

**Proceeding under the Class Proceedings Act, 1992**

TO:

Patient Class - Canadian residents, other than residents of British Columbia or Quebec, who were implanted with one or more mechanical heart valves, or annuloplasty rings, coated with Silzone, that were designed, manufactured, marketed, distributed or sold by the defendants, St. Jude Medical, Inc. and St. Jude Medical Canada, Inc.; and,

Family Class - persons who, by reason of their relationships with members of the patient class, would have standing in this action pursuant to section 61(1) of the Family Law Act, R.S.O. 1990, c.F.3 as amended, if that section were otherwise applicable to the claims asserted on their behalf.

Please provide a copy of or show this Notice of Class Certification to members of your family.

The only St. Jude Medical valves and annuloplasty rings at issue in the action are those with the Silzone coating, which would have been implanted between July 1997 and January 2000. This action does not relate to any other heart valves whether manufactured by St. Jude Medical or others. You can obtain information from your physicians or by calling 1-888-276-4170 (a

St. Jude Medical information line) about whether you have a Silzone coated device if you do not know already.

**This notice of class certification is published by Order of the Honourable Justice Cullity of the Ontario Superior Court of Justice.**

### **REPRESENTATIVES OF THE CLASSES**

Yvonne Andersen, as Executrix of the estate of Erik Andersen and Sharon Frost (as representative plaintiffs for the patient class) and Yvonne Andersen (as representative plaintiff for the family class) have commenced an action against St. Jude Medical, Inc. and St. Jude Medical Canada, Inc., on behalf of themselves and of all members of the above classes.

### **NATURE OF THE ACTION**

The representative plaintiffs have commenced a class action as against the defendants for damages, monitoring, interest, costs and punitive damages. The plaintiffs allege negligence in the Silzone valve's pre-market research and development, design, testing, manufacture, release of the device into the marketplace, post market monitoring, recall and warning to regulators, health care professionals and the public. The plaintiffs allege and St. Jude Medical denies that the Silzone coating interferes with normal tissue healing and can cause or contribute to significant health risks including, but not limited to, paravalvular leakage, cardiac dilation and irreversible damage to the heart muscle, infection and endocarditis, thrombosis, thromboembolism and thromboembolic stroke, heart attacks, abnormal cardiac rhythms and death. The plaintiffs assert and St. Jude Medical denies that there is a need for increased medical monitoring even for those patients who have not reported symptoms

The defendants have not yet been required to file a statement of defence, but deny the allegations made by the representative plaintiffs.

In certifying this action as a class proceeding, the Court has made no determination as to the merits of the plaintiffs' claims or the defendants' denials. The plaintiffs will be required to prove their allegations at a trial on the merits in order to obtain the relief which they seek.

The allegations made by the plaintiffs have not been proven in court and should not be considered in any way to be medical advice regarding your specific circumstances. You should consult your physicians if you have any questions regarding your medical condition.

The claims of family members may depend upon whether the laws of Ontario or those of some other jurisdiction - for example, the province where the Silzone device was implanted - are applicable. This legal question will be determined on a case-by-case basis.

### **THE COMMON ISSUES**

The court certifying this action as a class proceeding has directed that the following issues be determined at a common issues trial:

1. Did the defendants breach a duty of care owed to the patient class members by reason of the design, pre-market testing, regulatory compliance, manufacture, sale, marketing, distribution and recall of Silzone coated mechanical heart valves and annuloplasty rings implanted in such members?
2. What effect, if any, does such Silzone coating have on tissue healing?
3. Does the Silzone coating on heart valves or annuloplasty rings materially increase the risk of various medical complications including, but not limited to, paravalvular leakage, thrombosis, thromboembolism, stroke, heart attacks, endocarditis or death?
4. Do Silzone implanted patients need additional or different medical monitoring than that for conventional mechanical heart valve patients?
5. Should the defendants be required to implement a medical monitoring regime, and, if so, of what should that regime comprise and how should it be established?
6. Is the burden of proof of causation or negligence affected by spoliation of evidence by the defendants?
7. Does the defendants' conduct merit an award of punitive damages, and if so, in what amount?

Following a determination of the common issues, further stages of litigation may be required. For example, for those patients who attribute symptoms that they have experienced to the Silzone coating, it will be necessary to have a further individual hearing to determine whether the Silzone coating in fact caused or materially contributed to those symptoms, and to quantify the damages recoverable, if any, by members of the patient class and the family class.

#### **CLASS MEMBERSHIP**

If you fall within the class definitions set out above, you are automatically a class member unless you choose to opt out of the class. While you do not need to do anything further at this stage to participate in this lawsuit you may wish to contact class counsel for further information or to inform them of your desire to participate. Class counsel can be reached at:

#### **Lerners LLP**

Barristers and Solicitors  
130 Adelaide Street West  
Suite 2400, P.O. Box 95  
Toronto, ON M5H 3P5

James M. Newland

Telephone: (416) 601-2640

Fax: (416) 867-2398

Toll Free: (888) 742-1113  
Email: [jnewland@lerners.ca](mailto:jnewland@lerners.ca)  
[www.silzoneclassaction.ca](http://www.silzoneclassaction.ca)

**Cohen Highley LLP**  
Barristers and Solicitors  
One London Place  
255 Queens Avenue,  
11th Floor  
London, ON N6A 5R8

Russell Raikes  
Telephone: (519) 672-9330  
Fax: (519) 672-5960  
Email: [rraikes@cohenhighley.com](mailto:rraikes@cohenhighley.com)  
[www.silzoneclassaction.ca](http://www.silzoneclassaction.ca)

**Heenan Blaikie LLP**  
Barristers and Solicitors  
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Toronto, ON M5J 2J4

Gavin Mackenzie  
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Fax: 1-866-687-9883  
Email: [gmackenzie@heenan.ca](mailto:gmackenzie@heenan.ca)  
[www.silzoneclassaction.ca](http://www.silzoneclassaction.ca)

#### **HOW TO BE EXCLUDED FROM THE CLASS**

If you wish to be excluded from the class, you must fill out the “opt-out-coupon” below and send it to one of the class counsel identified above. The deadline for opting out is September 30 2005. If your written request is not received by class counsel by that date, you will remain a member of the classes.

If a patient opts out of the lawsuit then his or her family members will be deemed to have opted out as well, unless the family member has a separate claim as a patient in which case he or she must make an independent decision concerning whether or not to opt out of the lawsuit. No person may opt out a patient who is a minor or a mental incompetent, without the permission of the Court after notice to the Ontario Public Trustee and Children’s Lawyer as appropriate. If you wish to opt out a minor or mental incompetent patient, please complete the opt out coupon below but indicate that the patient is a minor or mental incompetent.

**ANY JUDGMENT OBTAINED ON THE COMMON ISSUES IN THIS ACTION, WHETHER FAVOURABLE OR NOT, WILL BIND ALL CLASS MEMBERS WHO DO NOT OPT OUT OF THIS ACTION.**

**CLASS COUNSEL AND FINANCIAL CONSEQUENCES**

The representative plaintiffs in this action are represented jointly by James Newland of Lerner LLP, Gavin MacKenzie of Heenan Blaikie LLP, and John Makins and Russell Raikes of Cohen Highley LLP.

The representative plaintiffs have entered into retainer agreements with their solicitors whereby fees and disbursements related to the trial of the common issues will be payable only in the event of success in the class action. Any fees charged by the solicitors for the representative plaintiffs must be approved by the court.

Class members may be entitled to receive financial compensation, or to have their medical monitoring costs paid, to the extent these costs are not covered by a provincial health insurer, if the class action is successful.

The class proceeding will deal with the issues common to the lawsuit. No class member, other than the representative plaintiffs, will be liable for costs with respect to the determination of these common issues. However, once the court has determined the common issues, it may be necessary that individual members of the class participate in individual proceedings to determine issues that are not common to the class in order to establish their claim. While each class member will be bound by the determination on the common issues, each class member will be free to decide whether to participate in an individual proceeding to establish their claim. The decision to pursue an individual claim can be deferred until after the trial of the common issues. If a class member decides to pursue an individual claim, he or she may have to bear the costs of such individual proceedings, and if unsuccessful, could be liable to pay a portion of the defendants' costs incurred with respect to such individual proceedings.

**FURTHER INFORMATION**

For further information, you may contact class counsel or visit the plaintiffs' Silzone heart valve class action website at: [www.silzoneclassaction.ca](http://www.silzoneclassaction.ca). St. Jude Medical also has a website at: [www.sjm.com](http://www.sjm.com). Please do not contact the court or Justice Cullity for information.

**OPT OUT COUPON**

**To: Lerner LLP**  
Barristers and Solicitors  
130 Adelaide Street West  
Suite 2400  
P.O. Box 95  
Toronto, ON M5H 3P5

James M. Newland  
Telephone: (416) 601-2640  
Fax: (416) 867-2398  
Toll Free: (888) 742-1113  
Email: jnewland@lerner.ca

**Attention: Silzone Heart Valve Class Action**

- I wish to opt out of the Andersen v. St. Jude Medical, Inc. Class Action.
- I wish to make application to the Court to opt a minor/mental incompetent (circle one) out of the Andersen v. St. Jude Medical, Inc. Class Action.

\_\_\_\_\_  
Signature

Name: \_\_\_\_\_  
(please print)

Address: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Postal Code: \_\_\_\_\_

Telephone: \_\_\_\_\_

If applicable, the name of minor/mental incompetent:

Name: \_\_\_\_\_  
(please print)

Address: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Postal Code: \_\_\_\_\_

**(Note: To opt out, this coupon must be received by class counsel no later than September 30, 2005.)**

ERIK ANDERSEN ET AL  
Plaintiff and  
ST. JUDE MEDICAL, INC. ET AL  
Defendant

Court File No: 00-CV-195906CP

**ONTARIO  
SUPERIOR COURT OF JUSTICE**

Proceeding commenced at Toronto

**ORDER**

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Gavin MacKenzie LSUC#: 16941B  
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Co-Counsel for the plaintiffs

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