

**ONTARIO
SUPERIOR COURT OF JUSTICE**

THE HONOURABLE
MR. JUSTICE P. PERELL

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THURSDAY, THE 28TH
DAY OF MAY, 2015

B E T W E E N:

SHARON HARPER and GERALD HARPER

Plaintiffs

- and -

AMERICAN MEDICAL SYSTEMS, AMERICAN MEDICAL SYSTEMS
CANADA INC. and ENDO PHARMACEUTICALS

Defendants

ORDER

THIS MOTION brought by the representative plaintiffs for an order that this action be certified pursuant to the *Class Proceedings Act, 1992*, S.O. 1992, c.6 was heard on May 28, 2015 at Toronto, Ontario.

ON READING the following materials filed on this motion, on hearing the submissions of the parties and on consent of the parties:

1. **THIS COURT ORDERS** that the within action is certified as a class proceeding, subject to the provisions of this order.
2. **THIS COURT ORDERS** that the Class is described as:

(a) All persons resident in Canada who were or are implanted with an AMS SUI Transvaginal Mesh Device at any time on or before May 28, 2015 (the “Patients’ Class”); and

(b) All persons resident in Canada who by virtue of a personal relationship to one or more such persons described in (a) above, have standing in this action pursuant to section 6(1) of the *Family Law Act*, RSO 1990, c. F. 3 or analogous provincial legislation or at common law (the “Family Class”).

(c) Where “AMS SUI Transvaginal Mesh Device” means each of SPARC® (including, but not limited to, SPARC® Sling System), BioArc® (including, but not limited to, BioArc® TO Sling Kit, BioArc® TO System with InteXen® LP, BioArc® SP Sling Kit and BioArc® SP System with InteXen® LP), Monarc® (including, but not limited to, Monarc® Subfascial Hammock, Monarc® C Subfascial Hammock and Monarc® + Subfascial Hammock), MiniArc® (including, but not limited to, MiniArc® Single-Incision Sling System, MiniArc® Precise™ Single-Incision Sling System, and MiniArc® Pro™ Single-Incision Sling System), In-Fast® (including, but not limited to, In-Fast® Bone Screw System, In-Fast Ultra® Bone Screw System, In-Fast® Sling System, In-Fast Ultra® Sling System and In-Fast® with Influence-TRG Gelseal) and RetroArc™ (including, but not limited to, RetroArc™ Retropubic Sling System).

3. **THIS COURT ORDERS** that the disputed common issues for the Class, to be resolved on the merits through litigation, are:

(a) Did the defendants or any of them breach the standard of care with respect to the design, development, testing, licensing, labelling, marketing, instructions for use,

distribution and/or sale of their AMS SUI Transvaginal Mesh Devices? If so, when and how?

(b) Is AMS SUI Transvaginal Mesh associated with a materially increased risk of complications as compared to traditional and/or other medical management and/or surgical management options? If so, what are those complications?

(c) Is AMS SUI Transvaginal Mesh defective or unfit for the purpose for which it was intended as designed, developed, tested, licensed, labelled, marketed, instructed for use, distributed, sold and/or otherwise placed into the stream of commerce in Canada by the defendants or any of them?

(d) If one or more of common issues (a)-(c) are answered affirmatively, did the defendants, or any of them, breach a duty to warn?

4. **THIS COURT ORDERS** that Sharon Harper is the representative for the Patients' Class and APPOINTS her as the representative plaintiff for the Patients' Class.

5. **THIS COURT ORDERS** that Gerald Harper is the representative for the Family Class and APPOINTS him as the representative plaintiff for the Family Class.

6. **THIS COURT ORDERS** that the claim asserted as against the Defendants on behalf of the Class is in negligence.

7. **THIS COURT ORDERS** that the relief sought by the Class is as set out in the Statement of Claim.

8. **THIS COURT ORDERS** that the litigation plan is hereby approved in the form attached hereto as Schedule "A".

9. **THIS COURT ORDERS** that the form and manner of notice, as well as the timing of and procedure for opting out of this class proceeding shall be addressed by this Court by way of a separate order.

10. **THIS COURT ORDERS** that there will be no costs of the certification motion.

Date: May 28, 2015

Perell, T.

The Honourable Justice Perell

SCHEDULE "A"

Court File No.: CV-15-527760-00CP

ONTARIO
SUPERIOR COURT OF JUSTICE

B E T W E E N:

SHARON HARPER and GERALD HARPER

Plaintiffs

- and -

AMERICAN MEDICAL SYSTEMS CANADA INC., AMERICAN MEDICAL SYSTEMS
INC., and ENDO PHARMACEUTICALS

Defendants

Proceeding under the *Class Proceedings Act, 1992*

PLAINTIFFS' LITIGATION PLAN

ARTICLE ONE DEFINITIONS	3
ARTICLE TWO REPORTING TO AND COMMUNICATING WITH CLASS MEMBERS.....	4
ARTICLE THREE LITIGATION SCHEDULE PRIOR TO THE COMMON ISSUES TRIAL.....	4
Notice of Certification	4
Opt-Out Procedure	8
Pleadings	9
Document Exchange and Management	9
Examinations for Discovery	9
Expert Reports	10
Motions	10
Mediation	10
Clarification of the Common Issues	11
Pre-Trial Conference.....	11
ARTICLE FOUR TRIAL OF THE COMMON ISSUES	11
ARTICLE FIVE LITIGATION STEPS FOLLOWING THE COMMON ISSUES TRIAL.....	11
ARTICLE SIX RESOLUTION OF INDIVIDUAL ISSUES FOLLOWING THE COMMON ISSUES TRIAL.....	12
ARTICLE SEVEN AMENDMENT OF THIS PLAN.....	12

**ARTICLE ONE
DEFINITIONS**

1.1 In this Plan,

- (1) **“Class”** means the class defined by the Court in the Certification Notice;
- (2) **“Class Action”** means Ontario Superior Court of Justice Action Court File No. CV-15-527760-00CP;
- (3) **“Class Counsel”** means Siskinds LLP and Rochon Genova LLP;
- (4) **“Court”** means the Ontario Superior Court of Justice;
- (5) **“CPA”** means the *Class Proceedings Act, 1992*, SO 1992, c 6;
- (6) **“Notice of Certification”** shall be the form of notice approved by the Court on the motion contemplated in paragraph 3.2(1);
- (7) **“Notice Plan”** shall be the form of Notice approved by the Court as outlined in paragraph 3.2(2);
- (8) **“Notice of Resolution”** shall have the meaning attributed to it in paragraph 5.2;
- (9) **“Parties”** means the Defendants and the Plaintiffs;
- (10) **“Rules”** means the *Rules of Civil Procedure* RRO 1990, Reg 194; and
- (11) **“AMS SUI Transvaginal Mesh”** means surgical mesh that is implanted through the vagina used for urogynecologic procedures for the treatment of stress urinary incontinence.

ARTICLE TWO
REPORTING TO AND COMMUNICATING WITH CLASS MEMBERS

- 2.1 Class Counsel will regularly report to the Class through their respective firm websites and as otherwise provided in this Litigation Plan. The websites shall include an electronic form that persons can complete in order to receive additional information about the Class Action.
- 2.2 Each Class Counsel firm will designate a person to answer communications from putative class members concerning the Class Action. Class Counsel are able to communicate with French-speaking class members.

ARTICLE THREE
LITIGATION SCHEDULE PRIOR TO THE COMMON ISSUES TRIAL

- 3.1 If the action is certified, the Parties shall attend a case management conference to set a schedule for the remaining steps in the Class Action, which are described below.

Notice of Certification

- 3.2 The Plaintiffs will ask the Court to:
- (1) Settle the form and content of the Notice of Certification (the “Notice of Certification”); and
 - (2) Settle the means by which the Notice of Certification will be disseminated to class members (the “Notice Plan”).
- 3.3 The Plaintiffs propose that the Notice Plan will provide, among other things that:
- (1) The Notice of Certification will be sent by email or direct mail by Class Counsel to any person who has inquired about the Class Action or who has registered to

receive updates on Class Counsel's respective websites. Where the person is located in Quebec (or otherwise specifically requests), the Notice of Certification will be sent in English and French;

- (2) The Notice of Certification will be posted by Class Counsel, in English and French, on their respective websites;
- (3) The Notice of Certification, together with a request that the Notice of Certification be forwarded to all hospital personnel who may treat patients who were or are implanted with AMS SUI Transvaginal Mesh, will be disseminated by Class Counsel, with a cover letter approved by the Defendants, to all hospitals in Canada that purchased AMS SUI Transvaginal Mesh according to AMS's records;
- (4) The Notice of Certification will also be posted by the Defendants, in English and French, on americanmedicalsistemas.com;
- (5) The Notice of Certification will be published by the Defendants once in the following newspapers, in either English or French, as is appropriate for each newspaper, subject to each having reasonable publication deadlines and costs:
 - (i) The Globe and Mail, national edition;
 - (ii) National Post, national edition;
 - (iii) Courier (Kelowna, BC);
 - (iv) Times Colonist;

- (v) The Edmonton Journal;
- (vi) The Leader-Post;
- (vii) Winnipeg Free Press;
- (viii) The Spectator (Hamilton, ON);
- (ix) Ottawa Citizen;
- (x) Waterloo Region Record;
- (xi) The Windsor Star;
- (xii) La Presse (Montréal, QC);
- (xiii) Times-Transcript;
- (xiv) The Chronicle-Herald;
- (xv) The Guardian (Charlottetown, PEI);
- (xvi) The Province;
- (xvii) The Calgary Sun;
- (xviii) Lethbridge Herald;
- (xix) Red Deer Advocate;
- (xx) The StarPhoenix (Saskatoon, SK);
- (xxi) The London Free Press;

- (xxii) The Sault Star;
 - (xxiii) Toronto Star;
 - (xxiv) The Gazette (Montreal, QC);
 - (xxv) Le Journal de Québec;
 - (xxvi) New Brunswick Telegraph Journal;
 - (xxvii) The Telegram (St. John's, NL);
 - (xxviii) Le nouvelliste;
 - (xxix) L'écho de Shawinigan;
 - (xxx) L'écho de Trois-Rivières;
 - (xxxi) Le quotidien;
 - (xxxii) Le réveil; and
 - (xxxiii) Le point du Lac St-Jean;
- (6) A national press release, approved by the Defendants, will be issued in English and French through Canada Newswire; and
- (7) The Notice of Certification will be provided by Class Counsel to any person who requests it.

Opt-Out Procedure

3.4 The Notice of Certification shall advise putative class members of their right to opt-out of the Class Action.

3.5 The following opt-out procedure is proposed:

- (1) A person may opt-out of the Class Action by sending a written election to opt-out to Class Counsel at an address to be specified in the Notice of Certification. The written election must be signed by the putative class member and contain a statement to the effect that the putative class member wants to be excluded from the Class Action;
- (2) Written elections to opt-out must be postmarked no later than sixty (60) days after the Notice of Certification is first published;
- (3) No person may opt out a minor or a person who is mentally incapable without leave of the Court after notice to the Children's Lawyer and/or the Public Guardian and Trustee, as appropriate;
- (4) If a Class Member under part (a) of the class definition opts out of the Class Action, all derivative Class Members under part (b) of the class definition will be deemed to have also opted out; and
- (5) During the opt-out period, Class Counsel will provide the Defendants with weekly updates on the opt-outs as they are received. Within thirty (30) days of the opt-out deadline, Class Counsel will provide a report to the Defendants and the Court listing the names of all persons who timely requested to opt out of the Class Action.

Pleadings

- 3.6 The Defendants shall provide Statements of Defence no later than thirty (30) days following a request from Class Counsel for delivery of same.

Document Exchange and Management

- 3.7 Within sixty (60) days of either Parties' request, the Parties shall attend a "meet and confer" in order to develop a discovery plan in accordance with Rule 29.1 of the *Rules*. In developing the discovery plan, the Parties shall consult the Sedona Canada Principles Addressing Electronic Discovery.
- 3.8 In accordance with Rule 30 of the *Rules* and the discovery plan, the Parties shall provide documentary discovery.
- 3.9 The Plaintiffs will ask the Court to order the Defendants to produce documents relating to liability that were produced in any U.S. action regarding the same subject matter as this litigation, whether or not they are covered by a U.S. protective order. The Defendants will oppose such relief.
- 3.10 Class Counsel are able to handle the intake and organization of the documents that will likely be produced by the Defendants and will use data management systems and specialized software to organize, code and manage the documents.

Examinations for Discovery

- 3.11 The Parties shall conduct examinations for discovery in accordance with Rule 31 of the *Rules*.
- 3.12 The Plaintiffs will seek to examine for discovery at least one representative from each of the Defendants but cannot, until the production of documents has been completed,

estimate the time required for each examination. The Defendants will oppose multiple examinations.

3.13 The Plaintiffs may ask the Court for an Order allowing them to examine multiple representatives of one or more Defendant and/or for an Order allowing more than seven (7) hours of examination if the Parties cannot otherwise agree. The Defendants will oppose such relief.

3.14 The Parties may elect to conduct examination for discovery by written questions in accordance with Rule 35 of the *Rules*.

3.15 The Parties may agree to conduct some or all examinations for discovery by way of video conferencing.

Expert Reports

3.16 All expert reports will be exchanged in accordance with the directions of the case management judge with respect to scheduling, following completion of examinations for discovery, unless the Parties agree or the Court orders otherwise.

Motions

3.17 Although no motions other than those indicated in this Plan are currently anticipated by the Plaintiffs, additional motions may be required and will be scheduled as the case progresses in conference with the Defendants and the case management judge. For example, the examinations for discovery may result in the need for motions relating to undertakings and refusals.

Mediation

3.18 The Plaintiffs will participate in mediation if the Defendants are prepared to do so.

Clarification of the Common Issues

- 3.19 Following certification, examinations for discovery and the exchange of expert opinions and before the trial of the common issues, the Plaintiffs or the Defendants may ask the Court for an Order to clarify and/or redefine the common issues, if required.

Pre-Trial Conference

- 3.20 If it is deemed necessary by the Court, the parties will attend a pre-trial conference in advance of a trial on the common issues.

ARTICLE FOUR TRIAL OF THE COMMON ISSUES

- 4.1 The common issues trial will determine the common issues as certified by the Court.
- 4.2 The common issues trial will proceed pursuant to the *Rules*.

ARTICLE FIVE LITIGATION STEPS FOLLOWING THE COMMON ISSUES TRIAL

- 5.1 Following the common issues trial, assuming success in favour of the Plaintiffs, the Parties shall attend a case management conference to set a schedule and confirm the process to be followed in bringing the Class Action to a final resolution, including a resolution of any individual issues.
- 5.2 Class Counsel will prepare a notice, the form and content of which is to be approved by the Court, informing class members of the resolution of the common issues trial, the amount and allocation of damages and the individual claims process, including the claims deadline (the "Notice of Resolution"). The Plaintiffs may request that the Notice of Resolution be published in the same manner as the Notice of Certification.

**ARTICLE SIX
RESOLUTION OF INDIVIDUAL ISSUES FOLLOWING THE COMMON
ISSUES TRIAL**

- 6.1 Once the common issues have been determined it may be necessary to resolve certain remaining issues, such individual issues may involve causation or limitation periods. The amount and distribution of damages may also need to be determined on an individual basis.
- 6.2 Following resolution of the common issues, the Parties shall meet and confer to discuss a method for resolving any individual issues. If the Parties are unable to agree, the Parties shall seek direction from the Court.

**ARTICLE SEVEN
AMENDMENT OF THIS PLAN**

- 7.1 Once approved, this litigation plan may be amended from time to time by directions given at case conferences or by further order of the Court.

**ONTARIO
SUPERIOR COURT OF JUSTICE**

Proceeding commenced at London, ON
Transferred to Toronto, ON

Proceeding under the *Class Proceedings Act, 1992*

**ORDER
(NOTICE OF CERTIFICATION)**

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