

BOSTON SCIENTIFIC TRANSVAGINAL MESH CLASS ACTION LONG-FORM NOTICE OF CERTIFICATION

This is a notice alerting Class Members to the certification of a class action regarding certain medical devices sometimes referred to as “transvaginal mesh,” “TVM,” “slings” or “hammocks” manufactured by Boston Scientific Ltd. and Boston Scientific Corporation (“BSC”) as listed below. These devices are used to treat Stress Urinary Incontinence (“SUI”) or Pelvic Organ Prolapse (“POP”). If you were implanted with a BSC transvaginal mesh product, you should read all of this notice carefully.

This notice is about BSC transvaginal mesh products only. The BSC Class Action does not include claims against various other manufacturers of transvaginal mesh devices, including Johnson & Johnson, Covidien, American Medical Systems, and Cook Medical Inc.

If you do not know what transvaginal mesh you were implanted with, you should retrieve your medical records, which will typically note what brand of mesh was used. If you need help retrieving your records, Class Counsel can assist. See below under “Class Counsel” for more information.

Class Action Lawsuits And Claims Alleged

Class action lawsuits have been commenced in Canada alleging that BSC did not properly warn of alleged complications, including: erosion, extrusion, mesh contraction, hardening and/or shrinking, scarring, pain including dyspareunia, organ perforation, pelvic floor damage, incontinence, and psychological damage.

The BSC Class Action seeks, among other things, damages for personal injuries allegedly relating to the BSC transvaginal mesh products as well as consequential damages allegedly suffered by family members of women who have been implanted with a BSC transvaginal mesh products.

Certification

On February 17, 2017, the action was certified as a class action by Order of the Ontario Superior Court of Justice.

The claims against BSC **have not been resolved, and the defendants deny any fault or liability.**

THIS NOTICE DOES *NOT* MEAN THAT THE COURT HAS DECIDED ON LIABILITY OR THE LIKELIHOOD OF RECOVERY ON THE PART OF ANY CLASS MEMBER, OR AS TO THE MERITS OF THE CLAIMS OR DEFENCES ASSERTED BY EITHER SIDE. THE ALLEGATIONS MADE BY THE PLAINTIFFS HAVE NOT BEEN PROVEN IN COURT, AND THE COURT HAS NOT MADE ANY CONCLUSIONS. THIS NOTICE SHOULD NOT BE CONSIDERED IN ANY WAY TO BE MEDICAL ADVICE.

**Class
Definition**

The "Class Definition" for the BSC Class Action is:

- a) all persons resident in Canada who have been implanted with the transvaginal mesh products listed below at any time on or before the date of the certification order, and which products were designed, developed, tested, manufactured, licensed, assembled, labeled, marketed, instructed for use, distributed and/or sold or otherwise placed into the stream of commerce by the Defendants:
 - (i) Advantage System, including Advantage Fit System;
 - (ii) Obtryx Transobturator Mid-Urethral Sling and Obtryx II;
 - (iii) Lynx Suprapubic Mid-Urethral Sling System;
 - (iv) Solyx Single Incision Sling (SIS) System;
 - (v) Pinnacle Pelvic Floor Repair Kit, anterior/apical and posterior configuration; and
 - (vi) Uphold Vaginal Support System.
- b) all persons resident in Canada who by virtue of a personal relationship to one or more of such persons described in (a) above, have standing in this action pursuant to section 61(1) of the *Family Law Act*, RSO 1990, c F 3 or analogous provincial legislation or at common law.

**Common
Issues**

By court Order, the class proceeding will determine the following "Common Issues". This means that these issues will be determined as part of the common issues trial on behalf of the Class:

- a) Does embrittlement and degradation of HGX-030-01 make it unfit for use in the female pelvis for the treatment of POP or SUI?
- b) If the answer to (a) is "yes," then is use of HGX-030-01 in the Defendants' transvaginal mesh products a design defect?
- c) If the answer to (b) is "yes," then did the Defendants breach the standard of care with respect to the design, development and/or testing of their transvaginal mesh products?
- d) Does embrittlement and degradation of HGX-030-01 after it is implanted in the female pelvis for the treatment of POP and SUI cause complications including erosion, extrusion, mesh contraction, hardening and/or shrinking, scarring, pain including dyspareunia, organ perforation, pelvic floor damage, incontinence, and psychological damage?
- e) Did the Defendants' failure to disclose in their DFU that HGX-030-01 degrades constitute a breach of their duty to warn?
- f) If the answer to (e) is "yes," when did the breach of duty occur?
- g) Did the Defendants' failure to disclose in their DFU that degradation of HGX-030-01 causes complications including erosion, extrusion, mesh contraction, hardening and/or shrinking, scarring, pain including dyspareunia, organ perforation, pelvic floor damage, incontinence, and psychological damage constitute a breach of their duty to warn?
- h) If the answer to (g) is "yes," when did the breach of duty occur?
- i) Did the Defendants' failure to disclose in their DFU that the removal of their transvaginal mesh to remediate complications might not be possible and if possible could require multiple surgeries constitute a breach of the duty to warn?
- j) If the answer to (i) is "yes," when did the breach of duty occur?
- k) If the answer(s) of any of questions (c), (e), (g), or (i) is "yes" would the Defendants' breach of duty justify an award of exemplary or punitive damages?

**Participation
in the Class
Actions**

BSC Class Members who want to participate in the class action are **automatically included** and do not need to do anything at this time. The *Class Proceedings Act* provides that no class member, other than the representative plaintiffs, will incur liability for legal costs if a class action is dismissed. If the class action is successful, Class Members may be entitled to share in the amount of any award or settlement recovered. In addition, there will be a process by which Class Members will be required to prove their individual damages and injuries. For this reason, you should preserve any records, including medical records, you have regarding mesh. For English-language assistance contact Class Counsel at 1-800-461-6166 x2367 or, for assistance in French, 1-418-694-2009. Email inquiries may be directed to BSCmesh@siskinds.com.

IF YOU DO NOTHING AND REMAIN A CLASS MEMBER, YOU ARE NOT REQUIRED TO PAY LEGAL COSTS OR OTHER EXPENSES

Each Class Member who does not opt out of the class action will be bound by the terms of any judgment or settlement and will not be allowed to pursue an independent action against BSC.

Opting Out

If you are a Class Member and **do not** want to be a part of the class action you must “opt out”. Opting out means that **you will not be entitled to any compensation that may become available as part of the BSC Class Action** but you will be able to commence your own lawsuit or continue any lawsuit you already have brought. If you want to commence or continue your own lawsuit, **you must opt out**. If you do opt out, you **must** abide by all applicable limitation periods and should consult a lawyer. In general, only persons who wish to bring an individual action at their own expense have an interest in opting out.

If you would like to opt out, you must do so no later than September 6, 2017 by completing the opt-out form and sending it to Class Counsel. You can get a copy of the opt-out form and accompanying instructions by retrieving it online at www.siskinds.com/transvaginal-mesh/ or by requesting it from Class Counsel. For English-language assistance contact Class Counsel at 1-800-461-6166 x2367 or, for assistance in French, 1-418-694-2009. Email inquiries may be directed to BSCmesh@siskinds.com.

**What
Happens
Next**

The BSC Class Action will proceed to a common issues trial. If the action is not successful, that result will bind all members of that Class. If the action is successful, or settles before trial, Class Members will be bound by that result and may be entitled to compensation in the manner in which the Court orders if they prove individual damages. No Class Member will have to pay for any expenses or legal costs. The retainer agreements between the representative plaintiffs and Class Counsel provide that Class Counsel will pay for all disbursements and indemnify the Class Members for any adverse cost awards. However, if the action is successful at trial or is settled, Class Counsel will be entitled to a contingency fee in an amount approved by the Court. The retainers provide that class counsel will be paid by a 30% contingency fee, plus applicable taxes and disbursements, subject to Court approval. No private or public funding has been sought.

Class Members will receive notice of any major steps in the litigation, including settlement. If the action is settled, you will have an opportunity to “object” to the settlement and the amount of Class Counsel’s fees if you do not think they are appropriate.

**Class
Counsel**

There is **no charge** to speak with Class Counsel to discuss the class action, to have your questions answered, or to retrieve a copy of the opt-out form, or related documents.

Class Counsel are:

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For information on the BSC Class Action:

- www.siskinds.com/transvaginal-mesh/
- BSCmesh@siskinds.com.
- For assistance in English: (800) 461-6166 x2367
- For assistance in French: (418) 694-2009.

This notice was authorized by the Ontario Superior Court of Justice