

AMERICAN MEDICAL SYSTEMS TRANSVAGINAL MESH SUI AND POP CLASS ACTIONS LONG-FORM NOTICE OF CERTIFICATION

This is a notice alerting Class Members to the certification of two class actions regarding certain medical devices sometimes referred to as “transvaginal mesh,” “TVM,” “slings” or “hammocks” manufactured by American Medical Systems Canada Inc., American Medical Systems Inc., and Endo Pharmaceuticals Inc. (“AMS”). Various of these devices are used to treat Stress Urinary Incontinence (“SUI”) or Pelvic Organ Prolapse (“POP”). There is an AMS SUI Class Action and an AMS POP Class Action. If you were implanted with an AMS TVM mesh, you should read all of this notice carefully.

This notice is about AMS transvaginal mesh only. The AMS SUI Class Action and AMS POP Class Action do not include claims against various other manufacturers of TVM mesh devices, including Johnson & Johnson, Boston Scientific, CR Bard, Coloplast Corp., Covidien, and Cook Medical Inc.

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

Class Definition

There are two class actions regarding AMS transvaginal mesh, one regarding alleged injuries by women implanted with AMS mesh devices used to treat Stress Urinary Incontinence (“SUI”) and one regarding alleged injuries by women implanted with AMS mesh devices used to treat Pelvic Organ Prolapse (“POP”).

The “Class Definition” for the AMS SUI Class Action is:

- (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.
- (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.

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).

(the “**AMS SUI Class Action**” the members of which are “**SUI Class Members**”)

The “Class Definition” for the AMS POP Class Action is:

(a) All persons resident in Canada who were or are implanted with an AMS POP Transvaginal Mesh Device at any time on or before May 28, 2015.

(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.

Where “AMS POP Transvaginal Mesh Device” means each of Apogee® (including, but not limited to, Apogee® Vault Suspension System, Apogee® System with Cape, Apogee® System with Bio-Cape, Apogee® Enhanced, Apogee® System with IntePro®, Apogee® System with IntePro® Lite, and Apogee® System with InteXen® LP), Elevate® (including, but not limited to, Elevate® Apical and Posterior Prolapse Repair System with IntePro® Lite, Elevate® Apical and Posterior Prolapse Repair System with InteXen® LP, Elevate® Anterior & Apical Prolapse Repair System with IntePro® Lite, Elevate® Anterior & Apical Prolapse Repair System with InteXen® LP, Elevate® PC Apical & Posterior Prolapse Repair System, and Elevate® PC Anterior & Apical Prolapse Repair System), and Perigee® (including, but not limited to, Perigee® System, Perigee® System with IntePro®, Perigee® System with Biologic InteGraft, Perigee® Enhanced, Perigee® System with IntePro® Lite, Perigee® Plus, Perigee® Plus with IntePro® Lite and Perigee® System with InteXen® LP).

(the “**AMS POP Class Action**” the members of which are “**POP Class Members**”)

In this notice, the AMS SUI Transvaginal Mesh Devices and AMS POP Transvaginal Mesh Devices are referred to, together, as the “AMS Transvaginal Mesh Devices,” and the SUI Class Members and the POP Class Members are referred to, together, as the “Class Members”.

**Class Action
Lawsuits
And Claims
Alleged**

The AMS Transvaginal Mesh Devices, are medical devices that are implanted through the vagina to treat SUI or POP. Class action lawsuits have been initiated in Canada alleging that AMS marketed and sold the Transvaginal Mesh Devices without properly warning of alleged increased risks of injuries, conditions and complications including:

mesh erosion, mesh contraction, mesh hardening or shrinking, extrusion of the mesh, vaginal erosion, urethral erosion, infection, fistula, inflammation, vaginal scarring, vaginal pain, organ perforation, pain with intercourse, blood loss, neuropathic and other acute and chronic nerve damage and pain, neuromuscular problems, pelvic floor damage, granuloma formation, urinary and fecal incontinence, prolapse of organs and psychological damage.

The AMS SUI Class Action and AMS POP Class Action seek, among other things, damages for personal injuries allegedly relating to the AMS Transvaginal Mesh Devices as well as consequential damages allegedly suffered by family members of women who have been implanted with an AMS Transvaginal Mesh Device.

Certification

On May 28, 2015, the actions were certified as the AMS SUI Class Action and AMS POP Class Action by order of the Ontario Superior Court of Justice.

The common disputed issues to be resolved on the merits through litigation include:

- whether or not AMS SUI or AMS POP transvaginal mesh create an increased risk of the injuries, conditions and complications described above compared to other available alternatives for correcting SUI and POP (as the case

may be); and

- whether the defendant properly warned of the alleged risks.

For a complete list of the certified common issues, see the Certification Orders available at amsmeshclassactions.ca or from Class Counsel.

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

THIS NOTICE DOES NOT MEAN THAT THE COURT HAS DECIDED ON 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.

Participation in the Class Actions

SUI Class Members and POP Class Members who want to participate in the class action relevant to them 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 either or both of the class actions is successful, Class Members may be entitled to share in the amount of any award or settlement recovered. In addition, there may 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, 1-800-461-6166 x2409.

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(s) applicable to her will be bound by the terms of any judgment or settlement and will not be allowed to pursue an independent action against AMS.

Opting Out

If you are a Class Member and **do not** want to be a part of the class action relevant to you, you must “opt out” of it. Opting out means that **you will not be entitled to any compensation that may become available as part of the AMS SUI Class Action and/or the AMS POP 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 July 28, 2015 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.amsmeshclassactions.ca 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, 1-800-461-6166 x2409.

What Happens Next

The AMS SUI Class Action and AMS POP Class Action will proceed to trial. If either action is not successful, that result will bind all members of that Class. If either action is successful, or settles before trial, Class Members may be entitled to compensation in the manner in which the Court orders and will be bound by that result. 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 either 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**

For information on the AMS SUI Class Action and AMS POP Class Action:

- www.amsmeshclassactions.ca
- For assistance in English: (800) 461-6166 x2367 or (866) 881-2292
- For assistance in French: (800) 461-6166 x2409.

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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This notice was authorized by the Ontario Superior Court of Justice