

**AMERICAN MEDICAL SYSTEMS  
CANADIAN WOMEN’S PELVIC MESH CLASS ACTIONS  
NOTICE OF CERTIFICATION AMENDMENT AND SETTLEMENT  
APPROVAL HEARING**

**PLEASE READ THIS NOTICE CAREFULLY AS IT MAY AFFECT YOUR RIGHTS**

**NOTICE**

This is a notice alerting Class Members to amendments to the class definitions in two Canadian class actions and the proposed settlement of those two Canadian class actions involving mesh devices manufactured by American Medical Systems to treat Stress Urinary Incontinence (“SUI”) and Pelvic Organ Prolapse (“POP”) (“AMS Women’s Pelvic Mesh Devices”).

The class actions seek compensation for injuries that were allegedly related to the AMS Women’s Pelvic Mesh Devices. AMS denies the allegations made in the lawsuits.

The Settlement Agreement provides for the payment of \$20,858,488.48 (Canadian dollars) which will be used to pay claimant compensation, the administration of the settlement, health care expenses incurred by the Provincial Health Insurers and Class Counsel’s legal fees, disbursements and applicable taxes.

If you support the settlement, you do not have to do anything at this time. **It is important however, that you start to collect any medical records related to your mesh implant or complications, if you have not retained counsel to do it for you, or have not already done so yourself.** Participation in the settlement, if court approved, will require proof of implant with an AMS Women’s Pelvic Mesh Device (an AMS SUI Transvaginal Mesh Device, an AMS POP Transvaginal Mesh Device, or an Additional AMS SUI and POP Mesh Device – see page 3 and 4 of this notice for a list of included devices), which may be found in your medical records obtained from your medical provider.

This Notice is to advise you that a proposed settlement has been reached and that a date to have the class definitions amended and the settlement approved by the Court is scheduled for October 4, 2019. The settlement is not yet court approved, and **it is not yet time to file your claim.** If the Settlement Agreement is approved by the Court, a further notice will be distributed that will explain how to make a claim and the deadline for doing so.

**SUMMARY OF  
THE  
SETTLEMENT**

The defendants will pay \$20,858,488.48 to settle the claims of all Class Members, related claims of the Provincial Health Insurers, the costs of

administering the settlement, and Class Counsel legal fees, disbursements and applicable taxes.

Class Members who suffered certain injuries alleged to be associated with their AMS Women's Pelvic Mesh Devices and who satisfy the eligibility criteria may be entitled to compensation that will be based on a points system. Class Counsel is asking the Court to approve a "Compensation Protocol" which sets out the eligibility and points criteria. You can find a copy of the Compensation Protocol at [www.amsmeshclassactions.ca](http://www.amsmeshclassactions.ca). While it is important that you review that document carefully, in brief Class Counsel are proposing that the settlement amount, after fees and other court-approved charges, will be allocated among Class Members who qualify for compensation on the basis of the severity of their injuries. Payments will also be made for the related claims of Provincial Health Insurers. Among other factors, women who have greater injuries, including more revision surgeries, will be allocated more points and will be entitled to greater compensation than those who did not.

Until all claims have been adjudicated it will not be possible to determine the exact value of each point or the total amount of compensation that may be paid to each eligible claimant.

Class Counsel are also seeking Court approval of the disbursements incurred to prosecute the action, up to \$350,000.00, plus fees of up to 30% of the settlement amount, plus applicable taxes.

The Court must approve the settlement and Compensation Protocol. Separately, the Court must approve Class Counsel's fees and disbursements. If you do not agree with the settlement, Compensation Protocol and/or the requested fees and disbursements, you may object. The process for objecting is explained below in the section entitled COURT APPROVAL.

**WHO IS  
INCLUDED? The  
Original Classes**

On May 28, 2015, the Ontario Superior Court of Justice certified two class actions regarding AMS Transvaginal Mesh Devices, one dealing with injuries alleged by women resident in Canada implanted with transvaginal mesh used to treat SUI and one regarding injuries alleged by women resident in Canada implanted with transvaginal mesh used to treat POP.

The AMS SUI Class Action was certified to include:

- a) All persons resident in Canada who have been implanted with an AMS SUI Transvaginal Mesh Device at any time on or before May 28, 2015; and
- 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, (including 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 POP Class Action was certified to include:

- a) All persons resident in Canada who have been implanted with a POP Transvaginal Mesh Device at any time on or before May 28, 2015; and
- 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 & Posterior Prolapse Repair System with IntePro® Lite, Elevate®

Apical & 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).

**WHO IS INCLUDED? The Expanded Class**

As part of the settlement, the Class is being expanded to include:

- 1) women resident in Canada who were implanted with any AMS SUI Transvaginal Mesh Device and/or any AMS POP Transvaginal Mesh Device on or after May 29, 2015;
- 2) women resident in Canada who were implanted with one or more Additional AMS SUI and POP Mesh Devices at any time;

**PARTICIPATION IN THE CLASS ACTION**

and individuals who, by virtue of a personal relationship to one or more of those persons identified above have standing in these actions pursuant to section 61(1) of the *Family Law Act* RSO 1990, c.F.3 or analogous provincial legislation or at common law (“the Expanded Class”).

“Additional AMS SUI and POP Mesh Devices” means each of:

Straight-In Sacral Colpopexy System, InteMesh Silicone-coated sling/silicone-coated surgical mesh with or without InhibiZone, InteXen Porcine Dermal Matrix, IntePro Large pore polypropylene Y mesh and Triangle.

If you are a member of the Expanded Class and want to participate in the class action, you are automatically included and do not need to do anything at this time.

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

**OPTING OUT**

If you were implanted with an AMS SUI Transvaginal Mesh Device or an AMS POP Transvaginal Mesh Device prior to **May 29, 2015**, and did not opt out of the action prior to July 28, 2015 you are a member of this class and may not opt out now, even if you have one of the Additional AMS SUI and POP Mesh Devices.

If you were first implanted with an AMS SUI Transvaginal Mesh Device or an AMS POP Transvaginal Mesh Device on or after **May 29, 2015** or were implanted only with an Additional SUI and POP Mesh Device, however, you may “opt out.”

Opting out means that you will not be entitled to any compensation if the settlement is approved, but you will be able to commence your own lawsuit or continue any lawsuit you already have brought.

Opting Out means that you do not want to be included in the class action. If you opt out, you will not be entitled to any compensation that might otherwise be available to you under the settlement, but you will be able to commence your own lawsuit or continue any lawsuit you may have already filed. In general, only persons who wish to bring an individual action at their own expense have an interest in opting out. **If you want to commence or continue your own lawsuit, you must opt out of this class action.** If you opt out because you wish to commence your own action, there are time limits for doing so (limitation periods). It is important that you abide by all applicable limitation periods and you should consult a lawyer as soon as possible to ensure your rights are protected.

If you are a member of the Expanded Class **and do not wish to be part of the class action(s) or make a claim under the settlement if it is approved, you must “opt out”**.

If you are a member of the Expanded Class and would like to opt out, you must complete an opt out form and send it to Class Counsel **no later than September 11, 2019**. A copy of the opt out form and instructions for completing it are available online at [www.amsmeshclassactions.ca](http://www.amsmeshclassactions.ca) or you may request it from Class Counsel at [amsmeshclassactions@siskinds.com](mailto:amsmeshclassactions@siskinds.com). or by calling Class Counsel at 1-800-461-6166 ext. 2367.

If you are included in one or both of the original Class definitions that were certified in May, 2015, the right to opt out has already passed and you cannot now opt out of the class action. **If you previously opted out, you may not rejoin this action and you are not eligible for compensation under this proposed settlement, if approved.**

## **COURT APPROVAL**

In order for the settlement to become effective, it must be approved by the Ontario Superior Court of Justice. The Court must be satisfied that the settlement is fair, reasonable and in the best interests of the Class Members.

**The Settlement Approval hearing is scheduled to proceed on October 4, 2019 at 10:00AM AT OSGOODE HALL.**

If you wish to object to the Settlement Agreement, the Compensation Protocol or Class Counsel fees and disbursements, you must deliver a written objection to Siskinds LLP by **no later than September 11, 2019** at

amsmeshclassactions@siskinds.com. Individuals who object may make oral submissions to the Court at the approval hearing.

**Do NOT send an objection directly to the Court.** Siskinds LLP will forward all objections received prior to the deadline to the Court.

### **LEGAL FEES**

Class Counsel will seek court approval of legal fees, disbursements and applicable taxes at the Settlement Approval hearing.

Class Counsel conducted this litigation on a “contingency fee” basis, pursuant to a retainer agreement with the representative plaintiffs. As such, Class Counsel is requesting that the Court approve reimbursement for the disbursements incurred, up to \$350,000.00, and a fee of up to 30% of the settlement amount, plus applicable taxes.

You may object to either the fee or disbursement request, or both, if you wish as detailed above.

### **FURTHER INFORMATION**

If you have questions about the Settlement Agreement and/or would like to obtain more information and/or copies of the settlement documents, please visit the settlement website at [www.amsmeshclassactions.ca](http://www.amsmeshclassactions.ca).

You can also contact Class Counsel at any of the firms listed below. There is **no charge** to speak with Class Counsel to discuss the class action. If you wish to retain counsel other than Class Counsel to represent you individually for advice on your claim, assisting you in retrieving medical records and/or preparing your claim, you will be responsible to pay any fees that lawyer might charge.

Class Counsel are:

**Siskinds LLP**  
680 Waterloo St.  
London, ON N6A 3V8  
Elizabeth deBoer  
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**Siskinds, Desmeules sncrl**  
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*This notice was authorized by the Ontario Superior Court of Justice*