



FEDERAL COURT OF AUSTRALIA

NOTICE ISSUED PURSUANT TO SUBSECTION 33X(5) OF THE *FEDERAL COURT OF AUSTRALIA ACT 1976* (CTH)

THIS NOTICE IS INTENDED FOR ALL PERSONS WHO ARE GROUP MEMBERS IN THE ASTORA WOMEN'S HEALTH, LLC CLASS ACTION ("ASTORA CLASS ACTION")

PLEASE NOTE:

- 1. This class action was originally brought against American Medical Systems, LLC, which manufactured certain of the implants the subject of the proceeding. Astora Women's Health, LLC has been substituted for American Medical Systems, LLC as the respondent to the proceeding.**
- 2. This notice does not relate to the class actions concerning the Ethicon/Johnson & Johnson implants, the Boston Scientific implants, the TFS implants or the IVS implants.**

PLEASE READ THIS NOTICE CAREFULLY



Why is this notice important, and why am I receiving it now?

1. In 2018 a class action was commenced in the Federal Court of Australia against American Medical Systems, LLC (**AMS**) by Jodie Philipsen and Janice Seymour (the **Applicants**) in their own right and on behalf of Australian women alleging that certain pelvic mesh and sling implants for the treatment of pelvic organ prolapse and stress urinary incontinence were defective and caused complications. In February 2021, Astora Women's Health, LLC (**Astora**) was substituted for AMS. This does not change any of the claims or affect any of your rights.
2. This notice provides important information about an open offer that has now been made to settle this proceeding (ie, the **Astora Class Action**). On 2 September 2021, Astora made an open offer to pay \$27 million to settle the Astora Class Action subject to a number of terms, some of which are described in this notice. This open offer is referred to in this notice as the "**Settlement Offer**". Details of the Settlement Offer, and matters that may be relevant to consideration of the offer, are set out below at paragraphs 66 to 14.
3. The Federal Court has ordered that this notice be published for the information of persons who might be members of the class on whose behalf the action is brought and may be affected by it. You should read this notice carefully. Any questions you have concerning the matters contained in this notice should not be directed to the Court. If there is anything in it that you do not understand, you should seek legal advice.
4. You are receiving this notice now to update you as to the matters set out above and because you may wish to seek legal advice as to your position in light of the Settlement Offer.
5. Information concerning the nature of a class action, the Astora Class Action in particular, and the persons who are Class Members in the Astora Class Action has previously been provided in a notice issued on 20 September 2021 (the **Opt Out and Registration Notice**). A copy of the Opt Out and Registration Notice can be viewed here: <https://www.shine.com.au/service/class-actions/american-medical-systems-mesh-class-action> or may be obtained by contacting Shine Lawyers using the contact details set out at the end of this notice.

Astora's offer to settle the Astora Class Action

6. Astora has denied liability but has made an offer to settle the Astora Class Action for \$27 million on certain terms. If a settlement is not reached, Astora will defend the proceedings.
7. The key terms of the Settlement Offer are as follows:
 - (a) the amount of the cash settlement is \$27 million. This payment is an "all in" amount which means it is a fixed and final amount to cover all claims made in the Astora Class Action and all costs associated with the settlement;



- (b) the settlement covers anyone who was implanted with an AMS transvaginal mesh product made, or partly made of polypropylene mesh (**AMS TVM Product**) in Australia at any time (whether or not they have already allegedly suffered complications or undergone revision surgery or other treatment). All AMS TVM Products ever sold in Australia are to be included. This will require an amendment to the current definition of Class Members referred to in paragraph 14(d) of this notice;
- (c) the Settlement Offer contains certain provisions about whether the parties may “walk away” from the settlement; and
- (d) the cash settlement payment is in exchange for broad class-wide releases and indemnities of Astora. **Acceptance of the Settlement Offer will prevent you from bringing any future claim against Astora or its related entities in relation to the AMS TVM Products.** This will not prevent you from bringing claims against doctors and hospitals that were involved in the prescription, implantation or removal of AMS TVM Products. However, if you do, you may be required to indemnify Astora or other persons released by the settlement in certain circumstances and up to a limited amount.

A “**release**” of Astora will mean that you agree not to claim against Astora or its related entities in relation to your alleged loss, and in return you will be paid an amount from the settlement if the Settlement Offer is accepted by the Applicants.

An “**indemnity**” provided to Astora by you will mean that if any future claim is brought against Astora by a third party against whom you make a claim in relation to your alleged loss, then you may have to pay back to Astora part or all of any settlement amount you receive.

- 8. If you would like to know more about the terms of the Settlement Offer, please refer to the detailed terms that are available on Shine Lawyers’ website (<https://www.shine.com.au/service/class-actions/american-medical-systems-mesh-class-action>).
- 9. The amount of money a Class Member will receive under the terms of the Settlement Offer has not been determined. Based on the information available to them at this time, Shine Lawyers estimates that the likely return to Class Members, assuming all Class Members receive an equal payment out of the Settlement Fund, may be significantly less than a judgment sum that the Applicants may obtain if they are successful in the Astora Class Action.
- 10. However, Astora has provided information indicating that it and its listed indirect parent company Endo International plc (**Endo**) face certain financial challenges and risks. This means that in the event the Settlement Offer is not accepted, there is a substantial risk that Astora will be unable to meet any judgments obtained by Class Members against it.



11. Shine Lawyers also estimates that the likely return to Class Members, assuming all Class Members receive an equal payment out of the Settlement Fund, is likely to be less than judgment sums that have been obtained by Applicants in another proceeding against a different mesh implant manufacturer. However, that manufacturer is in a different financial position to Astora and Endo.
12. The Applicants are considering the Settlement Offer. If the Applicants decide to accept the offer, they will then need to apply to the Court for approval of the proposed settlement. Notice will be given of any application for Court approval of a proposed settlement of the Astora Class Action. A settlement cannot occur without the Court's approval.
13. In considering the Settlement Offer, the Applicants may take into account the views of Class Members to the extent they are able to ascertain those views. If you are a Class Member and you wish to have the Applicants take into account your views about the Settlement Offer, including whether or not you consider the Settlement Offer should be accepted, please contact the Applicants' solicitors, Shine Lawyers, as per the contact details at paragraph 19 below.
14. There are a number of factors which may be relevant to your consideration of whether the Settlement Offer should be accepted. Each Class Member's personal circumstances will be different and may impact upon their consideration of whether the offer is one which is attractive to them. Factors which may be relevant to a Class Member's consideration of the Settlement Offer include:
 - (a) **Astora's and Endo's financial position.** Information provided by Astora indicates that the financial circumstances of Astora and its listed indirect parent company Endo are such that there is a substantial risk of non-recovery from Astora even if the class action is successful. Further information about Astora and Endo's financial circumstances, including an independent finance and accounting expert report provided by Astora, are available from Shine Lawyers (see paragraphs 17 and 19 below).
 - (b) **The total number of Pelvic Mesh Implants distributed in Australia.** Information provided pursuant to orders of the Court indicates that approximately 57,207 Pelvic Mesh Implants (that is, products that are already included in the Astora Class Action) were distributed in Australia. Not all of those Pelvic Mesh Implants may have been used.
 - (c) **The number of Class Members.** Information provided pursuant to orders of the Court as at 11 June 2021 indicates that over 1,200 women with one or more implants had notified the Applicants' solicitors that they have suffered complications. This number may increase.
 - (d) **Expansion in the definition of Class Members.** The Settlement Offer proposes the expansion of the current definition of Class Members. Information provided pursuant to orders of the Court indicates that:



- (i) as noted in (b) above, the number of Pelvic Mesh Implants (that is, products that are already included in the Astora Class Action) distributed in Australia is approximately 57,207; and
- (ii) the number of additional AMS TVM Products distributed in Australia, that would also be included in the class action if the definition of Class Members is expanded, is approximately 646 (an increase of approximately 1.1%).

It is a condition of the Settlement Offer that the Applicants will apply to expand the definition of Class Members if they accept the offer. If the definition of Class Members is not expanded, the settlement will not be available.

- (e) **Proceeds of the settlement.** If the Applicants decide to accept the Settlement Offer from Astora, it is likely they would do so on the basis that the proceeds of the settlement after allowance for legal costs will be shared amongst all persons who are Class Members.
- (f) **Scope of Settlement.** The proposed settlement covers future complications which may arise as well as any current complications a Class Member may have suffered from an AMS TVM Product.

What do Class Members need to do?

15. You should read this notice carefully. If there is anything in it that you do not understand, you should seek legal advice.
16. Class Members who wish to have their views as to the Settlement Offer taken into account by the Applicants may notify their position by contacting the Applicants' solicitors, Shine Lawyers as per the contact details in paragraph 19 by **19 November 2021**.

Where can I obtain copies of relevant documents?

17. Copies of relevant documents, including the Third Further Amended Statement of Claim, Fourth Further Amended Originating Application, Defence, Opt Out and Registration Notice, the terms of the Settlement Offer and documents provided by Astora relating to the financial condition of Astora and Endo, can be obtained by:
 - (a) Downloading them from: <https://www.shine.com.au/service/class-actions/american-medical-systems-mesh-class-action>; or
 - (b) contacting Shine Lawyers on 1800 884 139 or emailing prolapsemesh@shine.com.au.
18. Copies of some of the documents listed above and relevant orders of the Court can also be obtained by
 - (a) contacting a District Registry of the Federal Court (contact details are available at www.fedcourt.gov.au) and paying the appropriate inspection fee; or



(b) inspecting them on the Federal Court website at <https://www.fedcourt.gov.au/law-and-practice/class-actions/class-actions>.

What if you have further questions?

19. If you have further questions or queries, you may contact Shine Lawyers as follows:

Email: prolapsemesh@shine.com.au

Tel: 1800 884 139

Post: Shine Lawyers PO Box 12011

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