

IN THE FEDERAL COURT OF AUSTRALIA

Debra Fowkes v Boston Scientific Corporation & Anor
(NSD 244/2021)

Boston Class Action

ADDITIONAL OPT OUT NOTICE

THIS IS AN IMPORTANT NOTICE ISSUED BY ORDER OF THE FEDERAL COURT OF AUSTRALIA

This notice contains important information concerning your right to opt out of this class action, including a deadline for you to exercise this right should you wish to do so. By opting out you will lose any right to any compensation available in this class action, but you will not be prevented from starting your own proceeding to try and get compensation yourself (subject to applicable time limits).

A. WHY IS THIS NOTICE IMPORTANT?

1. A class action (*Debra Fowkes v Boston Scientific Corporation & Anor* (NSD 244/2021) (the **Boston Class Action**) has been commenced in the Federal Court of Australia by Debra Fowkes on behalf of group members who have been implanted with a Boston Scientific pelvic mesh implant against Boston Scientific Corporation and Boston Scientific Pty Ltd (**Boston Scientific**). This class action arises out of allegations that certain pelvic mesh implants had a risk of causing complications in women who were implanted with those devices and that there were not adequate warnings of the risks associated with the use of those devices. The class action is being defended.
2. The class action has recently been amended to expand the group of persons who meet the definition of being members of the class for the purposes of the Boston Class Action. Under the expanded definition, women will now be included in the class if they:
 - have received a Polyform Synthetic Mesh implants (**Polyform Implant**) for the treatment of pelvic organ prolapse up until the date on which an amended statement of claim has been filed in the Boston Class Action; or
 - have received any one or more of the implants identified in paragraph 4 below to treat pelvic organ prolapse or stress urinary incontinence (as the case may be) up until the date on which an amended statement of claim has been filed in Boston Class Action.
3. The Federal Court has ordered that this notice be published for the information of persons who might become members of the class by reason of these amendments and may, therefore, be affected by the Boston Class Action. 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.

B. PERSONS ALREADY GROUP MEMBERS NEED NOT TAKE ANY FURTHER ACTION

4. You were already a group member in the **Boston Class Action** if, **prior to 22 March 2021**, you had surgery in Australia to implant one of the following pelvic mesh implants:
 - a. The implants included in the Pinnacle Pelvic Floor Repair and Pinnacle LITE Floor Repair Anterior-Apical, Posterior and Duet Kit (**Pinnacle Implants**), which were available as Anterior-Apical, Posterior or Duet Implants;
 - b. The implants included in the Uphold Vaginal Support System (**Uphold Implants**) which were made available as Anterior-Apical implants;
 - c. The implants included in the Uphold LITE with Capiro SLIM Vaginal Support System and Pelvic Floor Repair Kit Uphold LITE Vaginal Support System (**Uphold LITE Implants**) which were made available as Anterior-Apical implants;
 - d. The implants included in the Upsilon Y-Mesh Kit and Y-Mesh (**Upsilon Implants**) which were made available as Anterior-Apical implants;
 - e. The implant included in the Advantage Transvaginal Mid-Urethral Sling System and the Advantage Blue System (**Advantage Implants**);
 - f. The implant included in the Advantage Fit Transvaginal Mid-Urethral Sling System and the Advantage Fit Blue System (**Advantage Fit Implants**);
 - g. The implant included in the Obtryx Transobturator Mid-Urethral Halo and Curved Sling System (**Obtryx Implants**);
 - h. The implant included in the Obtryx II Transobturator Mid-Urethral Sling System – Halo (**Obtryx II Implants**);
 - i. The implant included in the Lynx Suprapubic Mid-Urethral Sling System and the Lynx Blue System (**Lynx Implants**);
 - j. The implant included in the Solyx Incision Sling System (**Solyx Implants**).
5. If you were already a group member, and you have not opted out of this proceeding, you remain a group member in this proceeding and need take no other action.

C. ADDITIONAL GROUP MEMBERS

6. You have become an **Additional Group Member** in the **Boston Class Action** if:
 - a. **after 22 March 2021 and up to the date on which the Amended Statement of Claim was filed in the Boston Class Action**:
 - i. you had surgery in Australia to implant one of the following Pelvic Mesh Implants:

1. The implants included in the Pinnacle Pelvic Floor Repair and Pinnacle LITE Floor Repair Anterior-Apical, Posterior and Duet Kit (**Pinnacle Implants**), which were available as Anterior-Apical, Posterior or Duet Implants;
2. The implants included in the Uphold Vaginal Support System (**Uphold Implants**) which were made available as Anterior-Apical implants;
3. The implants included in the Uphold LITE with Capio SLIM Vaginal Support System and Pelvic Floor Repair Kit Uphold LITE Vaginal Support System (**Uphold LITE Implants**) which were made available as Anterior-Apical implants;
4. The implants included in the Upsilon Y-Mesh Kit and Y-Mesh (**Upsilon Implants**) which were made available as Anterior-Apical implants;
5. The implant included in the Advantage Transvaginal Mid-Urethral Sling System and the Advantage Blue System (**Advantage Implants**);
6. The implant included in the Advantage Fit Transvaginal Mid-Urethral Sling System and the Advantage Fit Blue System (**Advantage Fit Implants**);
7. The implant included in the Obtryx Transobturator Mid-Urethral Halo and Curved Sling System (**Obtryx Implants**);
8. The implant included in the Obtryx II Transobturator Mid-Urethral Sling System – Halo (**Obtryx II Implants**);
9. The implant included in the Lynx Suprapubic Mid-Urethral Sling System and the Lynx Blue System (**Lynx Implants**);
10. The implant included in the Solyx Incision Sling System (**Solyx Implants**); and/or

b. you had surgery in Australia to implant a **Polyform Synthetic Mesh Implant**.

7. If you are unsure whether you are a group member in the Boston Class Action, then you should visit Shine Lawyers' website (<https://www.shine.com.au/service/class-actions/prolapse-mesh-class-action>) or telephone 1800 884 139 for further information.
8. If you are an Additional Group Member, you should read this notice carefully.

D. WHAT IS A CLASS ACTION?

9. A class action is a legal action that is brought by one or more persons (the **Applicant(s)**) on their own behalf and also on behalf of a class of people (**group members**), against one or more other persons or entities (the **Respondents**) where the Applicant(s) and the group members have similar claims against the Respondents.
10. Group members in a class action **are not** individually responsible for the legal costs

associated with bringing the class action. In a class action, only the Applicant(s) are responsible for the costs.

11. The Applicant(s) do not need to name each group member, or obtain their consent to bring the action on their behalf. A person who fits the definition of a “group member” will be bound by the result of the class action as if they had started the proceeding themselves, unless they have opted out of the proceeding.
12. A binding result can happen in two ways, being from a *judgment* following a trial, or a *settlement* at any time that is approved by the Court. If there is a judgment or a settlement of a class action, group members *will not* be able to pursue the same claims and *may not* be able to pursue similar or related claims against the Respondents in other legal proceedings.
13. If you have become an Additional Group Member you should note that:
 - a. in a *judgment* following trial, the Court will decide various factual and legal issues in respect of the claims made by the Applicant(s) and group members. Unless those decisions are successfully appealed they bind the Applicant(s), group members (including Additional Group Members) and the Respondents. Importantly, if there are other proceedings between any groupmember and the Respondents, it is likely that neither of them will be permitted to raise arguments in that proceeding which are inconsistent with a factual or legal issue decided in the class action.
 - b. in a *settlement* of a class action, where the settlement provides for compensation to group members it is likely to extinguish *all* rights to compensation which a group member might have against the Respondents which arise in any way out of the events which are the subject-matter of the class action.
14. If you consider that you have claims against one or more of the Respondents which are based on your individual circumstances or otherwise additional to the claims described in this class action, then it is important that you seek independent legal advice about the potential binding effects of the class action **before** the deadline for opting out (see below).

E. WHAT IS THE BOSTON CLASS ACTION ABOUT?

15. The class action has been commenced in the Federal Court of Australia against entities alleged to have designed, manufactured, supplied or marketed certain pelvic mesh implants intended to treat women experiencing prolapse or stress urinary incontinence (**Pelvic Mesh Implants**).

16. The Applicant claims that the Pelvic Mesh Implants were defective and not of a merchantable or acceptable quality under the *Trade Practices Act 1974* (Cth) and the *Competition and Consumer Act 2010* (Cth). The Applicant also alleges that the Respondents were negligent in their design, manufacture and supply of the Pelvic Mesh Implants, including by failing to give warnings about the risks associated with the Pelvic Mesh Implants and inadequately evaluating the safety of the Pelvic Mesh Implants.
17. The class action has been commenced by the Applicant, who was implanted with a Pelvic Mesh Implant that is alleged to have been designed, manufactured, supplied or distributed by one or more of the Respondents.
18. Boston Scientific Corporation and Boston Scientific Pty Ltd are the Respondents to the Boston Class Action.

F. WHAT DOES IT MEAN TO ‘OPT OUT’?

19. The Applicant in a class action does not need to seek the consent of group members to commence a class action on their behalf or to identify a specific group member. However, group members can cease to be group members by opting out of the class action.
20. Opting out of the Boston Class Action will have certain consequences which include that:
 - a. you will preserve any rights that you may have to bring your own separate legal proceedings against the Respondents for the same or similar claims in relation to one or more of the Pelvic Mesh Implants that are the subject of the Boston Class Action;
 - b. you will not be permitted to share in any proposed settlement of or judgment in the Boston Class Action; and
 - c. you will lose the rights that you have as a group member. If you do not understand your rights as a group member, you should seek legal advice.
21. An explanation of how group members are able to opt out is found below in the section headed “*How can you opt out of the class action?*”.

G. WILL YOU BE LIABLE FOR LEGAL COSTS IF YOU REMAIN A GROUP MEMBER?

22. You will **not become liable for any legal costs** simply by remaining a group member for the determination of the common questions. However:
 - a. if the preparation or finalisation of your personal claim requires work to be done in relation to issues that are specific to your claim, you can engage Shine Lawyers in the Boston Class Action or other lawyers, to do that work for you. A copy of the

terms on which Shine Lawyers are acting in the Boston Class Action may be obtained from them on the number shown below;

- b. if any monetary compensation becomes payable to you as a result of any order, judgment or settlement in the Boston Class Action, the Court may make an order that some of that compensation be used to pay a share of the costs which have been incurred by the Applicant in running the class action which are not able to be recovered from the Respondents; and
 - c. class actions are often settled out of court. If this occurs in the Boston Class Action, and you are a group member, you may be able to claim from the settlement amount without retaining a lawyer.
23. If the Boston Class Action is unsuccessful, group members will have no liability to pay any legal costs.

H. WHAT WILL HAPPEN IF YOU CHOOSE TO REMAIN A GROUP MEMBER?

24. Unless you opt out, you will be bound by any settlement or judgment in the Boston Class Action. If the Boston Class Action is successful and you are a group member in that proceeding, you will be entitled to share in the benefit of any order, judgment or settlement in favour of the Applicant and group members, although you may have to satisfy certain conditions before your entitlement arises. If the Boston Class Action is unsuccessful or is not as successful as you might have wished, you will not be able to pursue the same claims and may not be able to pursue related claims against the Respondents to the Boston Class Action.

I. WHAT ADDITIONAL GROUP MEMBERS NEED TO DO

You should read this notice carefully. If there is anything in it that you do not understand, you should seek legal advice.

(a) How can you remain a group member?

25. **If you wish to remain** a group member there is **nothing you need to do** at the present time. The Applicant will continue to bring the proceedings on your behalf up to the point where the Court determines those questions that are common to the claims of the Applicant and the group members. However, you are invited to contact the Applicant's lawyers, (Shine Lawyers) on the number below and register as a group member so that future notices about the class action can be sent to your preferred address and information can be collected which may assist the Court and the parties to understand the amount of compensation, if any, that you maybe entitled to receive.

(b) How can you opt out of the class action?

26. **If you do not wish to remain** a group member in the Boston Class Action you must opt out of the proceeding. If you opt out you will not be bound by or entitled to share in the benefit of any order, judgment or settlement in that proceeding, but you will be at liberty to bring your own claim against the Respondents, provided that you issue Court proceedings within the time limit applicable to your claim. If you wish to bring your own claim against the Respondents, you should seek your own legal advice about your claim and the applicable time limit prior to opting out.
27. **If you wish to opt out** of the Boston Class Action you **must** do so by completing an "**opt out notice**" in the form annexed to this notice. You must return the complete opt out notice to the Registrar of the Federal Court of Australia at the postal address on the form, or electronically via email to pelvicmesh@fedcourt.gov.au (please include in the subject line of the email the words: "*Opt Out Notice NSD244/2021*"). You can also complete the form electronically by visiting Shine Lawyers' website (<https://www.shine.com.au/service/class-actions/prolapse-mesh-class-action>).

IMPORTANT: the opt out notice must reach the Registrar by no later than 4:00pm on 1 July 2022, otherwise it will not be effective.

28. You should submit the opt out notice if you qualify as a group member and you wish to opt out of the Boston Class Action.
29. If you do not meet the criteria set out in the section headed "**ADDITIONAL GROUP MEMBERS**" above, you are not affected by the issues raised in this notice and you do not need to take any step to opt out of the Boston Class Action.
30. Each Additional Group Member seeking to opt out should fill out a separate form.

I. WHERE CAN YOU OBTAIN COPIES OF RELEVANT DOCUMENTS?

31. Copies of relevant documents, including the amended originating application and the amended statement of claim, may be obtained by downloading them from the website of Shine Lawyers (www.shine.com.au/service/class-actions/prolapse-mesh-class-action).
32. Alternatively, you may contact:

Shine Lawyers

Level 13, 160 Ann Street

Brisbane QLD 4000

prolapsemesh@shine.com.au

1800 884 139

**Additional opt out
notice**

Federal Court of Australia
District Registry: New South Wales
Division: General

No. 244 of 2021

Debra Fowkes

Applicant

Boston Scientific Corporation and

Anor

Respondents

To: The Registrar
Federal Court of Australia
New South Wales District Registry
Level 17, Law Courts Building, Queens
SquareSydney NSW 2000
OR BY EMAIL: pelvicmesh@fedcourt.gov.au

..... (print name), a group member in the
Boston Class Action (*Debra Fowkes v Boston Scientific Corporation & Anor* (NSD 244/2021)),
having been implanted with on or about gives notice
(*implant*) (*date*)
under section 33J of the *Federal Court of Australia Act 1976*, that they are opting out of that
representative proceeding.

Date:

.....
Signed by [Name]
[Insert capacity eg group member / Lawyer for the group member]

Filed on behalf of (name & role of party)
Prepared by (name of person/lawyer)
Law firm (if applicable)
Tel Fax
Email
Address for service
(include state and postcode)