

OVERVIEW OF THE CLASS ACTION AND PROPOSED SETTLEMENT

1. What is the Boston Scientific Class Action?

On 22 March 2021 a class action was commenced in the Federal Court of Australia against Boston Scientific Corporation and Boston Scientific Pty Ltd (**Boston Scientific**) by Debra Fowkes (the **Applicant**) in her 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 because they carried a risk of causing certain complications and those complications were not warned against.

Ms Fowkes claims that the implants, which are alleged to have been manufactured and supplied by Boston Scientific, 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). Ms Fowkes also alleges that Boston Scientific was negligent in the design, manufacture and supply of the implants, including by failing to give warnings about the risks associated with the implants and inadequately evaluating the safety of the implants.

Boston Scientific denies these allegations.

On 12 July 2022, the parties to the Boston Scientific Class Action agreed, subject to obtaining the Court's approval, to settle the proceeding (the **Proposed Settlement**). The Proposed Settlement is on a "no admissions" basis. This means that Boston Scientific has agreed to the Proposed Settlement without admission of any liability.

2. Who are Group Members?

You are a Group Member in the Boston Scientific Class Action if you had surgery in Australia to implant one of the following Boston Scientific Transvaginal Mesh Devices on or before 1 June 2022:

- 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 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;
- 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 Polyform Synthetic Mesh implants (**Polyform implants**);
- f) the implant included in the Advantage Transvaginal Mid-Urethral Sling System and the Advantage Blue System (**Advantage Implants**);
- g) the implant included in the Advantage Fit Transvaginal Mid-Urethral Sling System and the Advantage Fit Blue System (**Advantage Fit Implants**);
- h) the implant included in the Obtryx Transobturator Mid-Urethral Halo and Curved Sling System (**Obtryx Implants**);

- i) the implant included in the Obtryx II Transobturator Mid-Urethral Sling System – Halo (**Obtryx II Implants**);
- j) the implant included in the Lynx Suprapubic Mid-Urethral Sling System and the Lynx Blue System (**Lynx Implants**); and
- k) the implant included in the Solyx Single Incision Sling System (**Solyx Implants**)

and the implant was supplied to you by a treating doctor or hospital for the treatment of pelvic organ prolapse or stress urinary incontinence as the case may be.

You do not have to have suffered a complication to be a Group Member in the Boston Scientific Class Action.

You are no longer a Group Member if you opted out of this class action or have entered into a deed of release with Boston Scientific in relation to claims that are the subject of the Boston Scientific Class Action.

If you are unsure whether you are a Group Member, you should contact Shine Lawyers.

3. The Proposed Settlement and Settlement Scheme

Because the Proposed Settlement is subject to the Court's approval, it will not take effect unless and until it is approved by the Federal Court and there is no appeal against the settlement approval or any appeal results in the approval of the Proposed Settlement being confirmed.

The terms of the Settlement Scheme can be viewed at:
www.bostonmeshclassaction.com.au/settlementscheme.pdf.

A general summary of the Proposed Settlement terms follows.

If the Proposed Settlement is approved, the respondents will pay the Settlement Sum of AUD\$105,000,000.00 to settle the Boston Scientific Class Action inclusive of legal costs, expenses, disbursements and interest.

The Settlement Sum will be held and managed by Shine Lawyers as a fund (the **Settlement Fund**) which is to be for the benefit of Registered Group Members. The Settlement Fund will also be used to meet legal costs and to make certain other payments, as described below.

The Applicant will seek orders from the Court so that:

1. a reimbursement payment is made to Ms Fowkes in the amount of \$20,000.00. The Reimbursement Payment will be deducted from the Settlement Fund. The Reimbursement Payment recognises the time spent by Ms Fowkes in prosecuting the Boston Scientific Class Action;
2. the Applicant's legal costs and disbursements in conducting the proceeding, which is estimated to be approximately \$6,106,594.73 will be paid from the Settlement Fund; and
3. The costs of administering the Settlement Scheme, including any tax liabilities of the Settlement Scheme will be paid out of the Settlement Fund.

AJB Stevens Lawyers, solicitors for the Applicants in *Burrows & Ors v Boston Scientific Corporation & Anor* (NSD498/2021) (**Burrows Proceeding**) have advised they will seek to recover their costs in conducting the Burrows Proceeding, estimated to be \$347,517.00, from the Settlement Fund.

Settlement Fund Distributions

The Settlement Sum of \$105,000,000.00 will be held in an interest earning bank account until payments need to be paid. Interest that is earned on the Settlement Sum will increase the amount of funds available to compensate Registered Group Members and to pay administration costs.

The Applicant will seek orders from the Court to approve the Settlement Scheme which establishes the process by which the Settlement Fund is to be distributed.

The Settlement Scheme will be administered by the lawyers at Shine Lawyers who have been responsible for running the Boston Scientific Class Action.

The Settlement Scheme sets out a points-based system for assessing the amount of compensation to which each Registered Group Member is entitled.

The amount of compensation to be paid to each Registered Group Member under the Settlement Scheme will depend on a number of factors such as the complications they have experienced (although it is not necessary to have experienced a complication in order to be eligible for compensation), the type of complication experienced, the duration of any complications, the age of the Registered Group Member and the number and nature of any treatments the Registered Group Member has undertaken. The Settlement Scheme also provides for compensation for certain economic loss, including any care claims and loss of income.

The way in which compensation is to be awarded under the Settlement Scheme is not the same as the way in which damages would be assessed if the Court were determining an individual's claim for compensation. The Settlement Scheme is intended to operate in a time and cost effective manner and to enable compensation assessments to be undertaken in a uniform way (so far as practicable) for all Registered Group Members.

The amount of compensation that a Registered Group Member may obtain under the Settlement Scheme may be adjusted up or down depending upon the value of the Settlement Fund and the number and value of claims made by other Registered Group Members.

Payments will be made to Registered Group Members after liens owing to Medicare and certain other entities (such as private health insurers) are made on behalf of Group Members.

4. Is the settlement an admission by Boston Scientific?

No. The settlement was agreed by the parties on the basis that Boston Scientific does not admit any liability or wrongdoing.

5. Releases

As part of the agreement to settle the Boston Scientific Class Action, the Applicant and all Group Members (excluding Group Members who have opted-out) will release and forever discharge Boston Scientific and any of its related entities from all claims relating to the Applicant's Claim, the Proceeding, or in any way arising out of or in connection with the Claim or Proceeding.

Therefore, if the Proposed Settlement is approved, you will not be able to bring any claim against Boston Scientific or any of its related entities in relation to the Boston Scientific Implants the subject of this class action.

This will mean that if you suffer any complications, or experience worsened complications, from one of the Boston Scientific Implants the subject of this proceeding after the Proposed Settlement is approved, the claims you may otherwise have against Boston Scientific will be released. Additionally, if you have already had your claim assessed under the Settlement Scheme and subsequently suffer any complications, or experience worsened complications, you may not be able to obtain further compensation from the Settlement Fund.

6. Who is eligible to be compensated under the Settlement Scheme?

All Group Members (in accordance with the definition of Group Member above) are eligible to receive compensation under the Proposed Settlement if they satisfy the following Eligibility Criteria:

- (a) the Group Member was implanted with one or more BSC Transvaginal Mesh Devices in Australia; and
- (b) the Group Member has not:
 - opted out of the Boston Scientific Class Action; and/or
 - entered into a deed of release with the respondents or any of their related entities in respect of a Boston Scientific Claim (whether in Australia or elsewhere); and
- (c) the Group Member has submitted a Registration Form by the 'Claim Deadline' as defined under the Scheme (30 days after the last day on which the Settlement Notice is published).

7. How many Group Members are likely to make a claim on the Settlement Fund?

It is not possible to predict precisely how many Group Members will make a claim on the Settlement Fund.

Shine Lawyers' best estimate at the time of preparing this notice, after taking into account the number of Group Members who have registered for the Boston Scientific Class Action and the number who have opted out, is that there may be approximately 2400 Group Members who will make a claim on the Settlement Fund. The value of each of those Group Member's claims will differ.

8. What is the process for making a claim and receiving compensation?

The Settlement Scheme sets out the process for making and assessing claims by Registered Group Members. Broadly, claims will be assessed pursuant to a streamlined, non-adversarial process involving the following steps:

1. Group Members **must register** their claim by submitting a Registration Form by the Claim Deadline. Group Members who have previously registered with Shine Lawyers are automatically deemed to have registered to participate in the Settlement Scheme.
2. The Scheme Administrators will assess and determine the eligibility of Registered Group Members by obtaining implant evidence, and ensuring no opt-out notice has been filed or deed of release has been entered into by that Group Member.
3. The Scheme Administrators will determine eligibility and notify registrants of this determination. If a registrant is dissatisfied with the assessment of their eligibility, they have a right to seek a review which will be conducted by an independent review assessor. The review assessor's determination is final and binding, and no further appeals or reviews will be available.
4. The Scheme Administrators will assess and determine eligible, registered Group Members' claims in accordance with the following procedure:
 - a. by obtaining the following information insofar as it is relevant:
 - i. instructions and information from the Group Member or any other person such as a family member or friend of the Group Member;

- ii. implant evidence, to the extent that those records were not obtained when assessing eligibility;
 - iii. surgical or treatment evidence;
 - iv. medical, clinical or pharmacy records;
 - v. reports of treating medical practitioners;
 - vi. tax returns and other tax, accounting or financial documents, and any employment records or other information from the Group Member's employer/s; or
 - vii. invoices regarding any treatment or other expenses incurred by the Group member; and
- b. arranging for the payment of **liens** for Group Members by investigating the types of health care treatment for which payments were made by third parties, and any other recovery amounts (such as, for example, amounts paid on behalf of the Group Member by Centrelink or the National Disability Insurance Scheme) that may be repayable as a result of the settlement. All Group Members' liens will need to be paid before any Group Members can receive their compensation.
5. The Scheme Administrators will then assign points, in accordance with the Settlement Scheme, based on the totality of the information and resources available to them, consider whether any further compensation is payable in respect of lost income, and then make a determination as to the amount of compensation that the Group Member is assessed as being entitled to receive based on the points allocated pursuant to the Settlement Scheme and the lost income assessed as payable.
 6. The Scheme Administrators will send to the Group Member a Notice of Assessment which provides the Group Member with information about the determination of their entitlement under the Settlement Scheme.
 7. If a Group Member is dissatisfied with the assessment of their compensation entitlements, they have a right to seek a review which will be conducted by an independent review assessor. The review assessor's determination is final and binding, and no further appeals or reviews will be available.
 8. Claims will be either proportionately increased or reduced depending on whether there are surplus settlement funds or whether the total value of all claims is anticipated to be greater than the available settlement funds.
 9. The Scheme Administrators may make payments in several instalments, or at different times in tranches to groups of Group Members as their claims are assessed and finalised.

Boston Scientific will have no active role in assessing and determining the eligibility of a Group Member or the amount of their compensation.

9. How much will Registered Group Members receive under the settlement?

The amount of compensation payable to any one Registered Group Member is not yet known because each person's claim will be assessed according to their personal circumstances and the amount of funds which will ultimately be available and the amount to be paid will only be calculated after allowing for the costs of administering the settlement and adding interest income. A Registered Group Member's individual circumstances will have an impact on the assessment of their compensation under the points system in the Settlement Scheme.

10. Do Group Members need to pay legal fees in order to make a claim?

No.

If the Proposed Settlement is approved, the Applicant's legal costs in conducting the Boston Scientific Class Action will be paid from the Settlement Sum. Registered Group Members do not need to make a contribution to these legal costs.

The Settlement Administrators' costs of administering the Settlement Scheme and processing claims by Registered Group Members will be paid from the Settlement Sum. Again, Registered Group Members do not need to make a contribution to these legal costs, except that Registered Group Members may be requested to pay the costs of a review if the review is unsuccessful.

11. Where can I obtain copies of relevant documents?

Copies of relevant documents, including the Statement of Claim, Originating Application, Defence, Opt Out and Registration Notice, Additional Opt Out Notice and the Settlement Scheme can be obtained by:

- a) Downloading them from: <https://bostonmeshclassaction.com.au/>; or
- b) Contacting Shine Lawyers on 1800 884 139 or emailing prolapsemesh@shine.com.au.

Copies of some of the documents listed above and relevant orders of the Court can also be obtained by contacting:

- a) 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?

If you have further questions or queries, you may seek advice from your lawyer or contact Shine Lawyers as follows:

Email: prolapsemesh@shine.com.au

Tel: 1800 884 139

Post: Shine Lawyers PO Box 12011

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