

## OVERVIEW OF THE CLASS ACTION AND PROPOSED SETTLEMENT

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### 1. What is the TFS/IVS Vaginal Mesh Class Action?

On 21 February 2020 a class action was commenced in the Federal Court of Australia against TFS Manufacturing Pty Ltd, IVS Pty Ltd, Covidien Pty Limited and Peter Petros by Lindsey Schofield and Melissa Weedon (the **Applicants**) in their own right and on behalf of Australian women who had been implanted with certain pelvic mesh and sling implants for the treatment of pelvic organ prolapse and stress urinary incontinence. MIPS Insurance Pty Ltd and Chubb Insurance Australia Limited were later joined as respondents to the proceeding. The Respondents to the class action are therefore TFS Manufacturing Pty Ltd (**TFS Manufacturing**), IVS Pty Ltd (**IVS**), Covidien Pty Limited (**Covidien**), MIPS Insurance Pty Ltd (**MIPSI**) and Chubb Insurance Australia Limited (**Chubb**).

The Implants covered by the TFS/IVS Vaginal Mesh Class Action are the Intravaginal Sling Implant inserted with or without the use of an IVS Tunneller (the **IVS Implant**) and the Tissue Fixation System Implant (the **TFS Implant**).

The Applicants' claim against TFS Manufacturing, IVS and Covidien is that the Implants were defective, not fit for a particular or disclosed purpose, not of merchantable quality and not of acceptable quality in contravention of the *Trade Practices Act 1974* (Cth) and the *Competition and Consumer Act 2010* (Cth). The Applicants also allege that TFS Manufacturing, IVS and Covidien were negligent in their design, manufacture, marketing and supply of the Implants, in failing to give certain warnings in connection with the Implants, in their testing of the Implants, and in their post-market surveillance of the Implants.

In the case of Peter Petros (**Petros**), the Applicants claim that he was negligent in using and advising the use of the Implants on his own patients, or in assisting, supervising and advising other surgeons to use the Implants on their patients. It is alleged that Petros was negligent because he knew or ought to have known at all times that the Implants were unsafe and ineffective. The claim against Petros only concerns group members who were his own patients or the patients of other surgeons he assisted, supervised or advised.

The Applicants claim that they and group members suffered loss and harm as a result of the conduct of TFS Manufacturing, IVS, Covidien and Petros in connection with the Implants and that they and group members are therefore entitled to damages.

Chubb is the insurer of TFS Manufacturing and is liable to indemnify TFS Manufacturing for any liability it may have to group members. It has been joined to the proceeding because TFS Manufacturing is being wound up and has no assets from which it could pay compensation to group members.

IVS has not entered an appearance or participated in the proceeding. Its interests were acquired by Covidien in May 2006.

MIPSI is the professional indemnity insurer for Petros and has been joined to the proceeding to determine whether it is liable to indemnify Petros for any liability he may have to some of the group members. Petros is unlikely to have any assets from which he could pay compensation to group members.

The Respondents do not admit the allegations and are defending the class action.

On 15 May 2023, all participating parties to the TFS/IVS Vaginal Mesh 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 the Respondents have agreed to the Proposed Settlement without admission of any liability.

## 2. Who are Group Members?

You are a Group Member in the TFS/IVS Vaginal Mesh Class Action if you had surgery in Australia to implant one of the following:

- a) The Intravaginal Sling Implant inserted with or without the use of an IVS Tunneller (the **IVS Implant**);
- b) The Tissue Fixation System Implant (the **TFS Implant**).

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 TFS/IVS Vaginal Mesh 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 (or agreement of a similar nature) with any of the Respondents in relation to claims that are the subject of the TFS/IVS Vaginal Mesh Class Action.

If you are unsure whether you are a Group Member, you should contact AJB Stevens 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.

By 17 August 2023, the terms of the Settlement Scheme will be accessible on [https://www.ajbstevens.com.au/class\\_actions/ivs-tfs-class-action/](https://www.ajbstevens.com.au/class_actions/ivs-tfs-class-action/) or by contracting AJB Stevens Lawyers.

A general summary of the Proposed Settlement terms follows.

If the Proposed Settlement is approved, the Respondents will pay the Settlement Sum of AUD\$41,450,000 to settle the TFS/IVS Vaginal Mesh Class Action inclusive of legal costs, expenses, disbursements and interest.

The Settlement Sum will be paid as follows:

1. Covidien \$25,000,000,
2. Chubb \$13,000,000,
3. MIPSI \$3,450,000.

The Settlement Sum will be held and managed by AJB Stevens 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 Applicants will seek orders from the Court so that:

1. A payment is made to Ms Schofield in the amount of \$400,000 inclusive of any payments she is required to pay to third parties (apart from Medicare) such as a private health fund or Centrelink (the **Schofield Payment**). The Schofield Payment will be deducted from the Settlement Fund. The Schofield Payment

recognises the time spent by Ms Schofield in prosecuting the TFS/IVS Vaginal Mesh Class Action and the risks she faced in being a lead applicant in the proceeding;

2. A payment is made to Ms Weedon in the amount of \$200,000 inclusive of any payments she is required to pay to third parties (apart from Medicare) such as a private health fund or Centrelink (the **Weedon Payment**). The Weedon Payment will be deducted from the Settlement Fund. The Weedon Payment recognises the time spent by Ms Weedon in prosecuting the TFS/IVS Vaginal Mesh Class Action and the risks she faced in being a lead applicant in the proceeding
3. The Applicants' legal costs and disbursements in conducting the proceeding, which is estimated to be approximately \$7,500,000 will be paid from the Settlement Fund; and
4. The costs of administering the Settlement Scheme, including any tax liabilities of the Settlement Scheme, will be paid out of the Settlement Fund. The costs of administration are estimated to be no more than \$1,800,000.

#### Settlement Fund Distributions

The Settlement Sum of \$41,450,000 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 Applicants 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 AJB Stevens Lawyers who have been responsible for running the TFS/IVS Vaginal Mesh Class Action.

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

The amount that Registered Group Members may receive from the Settlement Fund will depend on many factors, including:

1. The number of Registered Group Members who are eligible for compensation and the value of their claims;
2. Whether they were implanted with a TFS Implant or an IVS Implant;
3. Whether they were also implanted with an implant that is not the subject of the proceeding;
4. Whether they have experienced certain complications;
5. The severity and duration of their complications;
6. Whether they have undergone treatment for their complications and the number and types of treatment undergone;
7. The extent to which treatment has been successful;
8. Their age;
9. Whether they were working at the time they suffered their complications;
10. The date they suffered their complications;
11. The amounts that may need to be paid to third parties like Medicare, a private health fund or Centrelink;
12. Whether they have already received compensation for their complications from parties other than the respondents in this proceeding, such as a from the hospital where the implant was inserted or from a surgeon who carried out the surgery to insert the implant;
13. Whether their claim falls within a period for which Covidien, Chubb or MIPS are liable to pay compensation.

The Settlement Scheme provides for compensation, where appropriate, for non-economic loss, loss of income, the provision of care, and treatment expenses.

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 after a full hearing on the merits. The Settlement Scheme is intended to operate efficiently and cost-effectively so as to facilitate the assessment of eligibility for and the payment of compensation in a uniform way (so far as practicable) for all Registered Group Members.

Payments will be made to Registered Group Members after amounts owing to third parties such as Medicare, private health insurers and Centrelink are made on behalf of all eligible Group Members.

#### **4. Is the settlement an admission by the Respondents?**

No. The settlement was agreed by the parties on the basis that the Respondents do not admit any liability or wrongdoing.

#### **5. Releases**

As part of the agreement to settle the TFS/IVS Vaginal Mesh Class Action, the Applicants and all Group Members (excluding Group Members who have opted out) will release and forever discharge each of the Respondents from all claims relating to the Applicants' Claims, the Proceeding, or in any way arising out of or in connection with the Applicants' Claims or the Proceeding.

Therefore, if the Proposed Settlement is approved, you will not be able to bring any claim against any of the Respondents in relation to the TFS and IVS Implants.

This will mean that if you suffer any complications or experience worsened complications from one of the Implants the subject of this proceeding after the Proposed Settlement is approved, the claims you may otherwise have against any of the Respondents 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 of the TFS Implants or the IVS Implants in Australia; and
- (b) the Group Member has not:
  - opted out of the TFS/IVS Vaginal Mesh Class Action; and/or
  - entered into a deed of release (or agreement of a similar nature) with any of the Respondents in respect of a claim for damages for being implanted with an IVS or a TFS Implant (whether in Australia or elsewhere); and
- (c) the Group Member has submitted a Registration Form by the 'Claim Deadline', which will be defined by the Settlement Scheme as 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.

AJB Stevens Lawyers' best estimate at the time of preparing this notice, after taking into account the number of Group Members who have registered for the TFS/IVS Vaginal Mesh Class Action and the number who have opted out, is that there may be approximately 400 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 AJB Stevens Lawyers or Queensland 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. evidence of being implanted with an IVS Implant or a TFS Implant, 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;
    - vii. invoices regarding any treatment or other expenses incurred by the Group Member;
    - viii. evidence disclosing the amount of any compensation already received for complications suffered as a result of being implanted with an IVS Implant or a TFS Implant; and

- b. arranging for the payment of amounts owing by Group Members to third parties 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. Some payments to third parties may need to be paid before any Group Members can receive their compensation.
5. The Scheme Administrators will then assign or deduct points, in accordance with the Settlement Scheme, based on the totality of the information and resources available to them including information about lost income or the need for care, 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.
  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.

The Respondents 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.

By 17 August 2023, estimates of the average amounts of compensation will be available on [https://www.ajbstevens.com.au/class\\_actions/ivs-tfs-class-action/](https://www.ajbstevens.com.au/class_actions/ivs-tfs-class-action/) or by contracting AJB Stevens Lawyers.

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

No.

If the Proposed Settlement is approved, the Applicants' legal costs in conducting the TFS/IVS Vaginal Mesh 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://www.ajbstevens.com.au/class\\_actions/ivs-tfs-class-action/](https://www.ajbstevens.com.au/class_actions/ivs-tfs-class-action/); or
- b) Contacting AJB Stevens Lawyers on 02 8268 0600 or emailing them at [TFSandIVS@ajbstevens.com.au](mailto:TFSandIVS@ajbstevens.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](http://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>.

#### **12. What if you have further questions?**

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

Email: [TFSandIVS@ajbstevens.com.au](mailto:TFSandIVS@ajbstevens.com.au)

Tel: 02 8268 0600

Post: AJB Stevens Lawyers

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