

REQUEST FOR TENDERS TO ADMINISTER AND DISTRIBUTE SETTLEMENT FUND

Pelvic Mesh & Tape Class Actions

The parties to the proceedings *Talbot v Ethicon Sàrl & Ors* (NSD 310 of 2021) and *Gill & Ors v Ethicon Sàrl & Ors* (NSD 1590 of 2012) (the **Ethicon Class Actions**) have asked the Federal Court of Australia to approve the proposed settlement of those proceedings.

The Court has ordered that suitably qualified organisations be invited to tender for the role of administering and distributing the settlement fund to group members in accordance with a settlement scheme.

Tenders must be submitted electronically to jjmesh.tender@williamroberts.com.au on or before **5 pm** on **27 January 2023**.

Information for organisations interested in submitting tenders is set out below.

Overview of the Ethicon Class Actions and the proposed settlement

The Ethicon Class Actions concern claims that the applicants and class members suffered loss and harm as a result of pelvic mesh and tape implants manufactured or distributed in Australia by the respondents.

If approved, the proposed settlement will involve the following:

1. the respondents will pay the amount of \$300,000,000.00 for the purpose of a Settlement Fund being established;
2. deductions will be made from the Settlement Fund in amounts to be approved by the Court for, *inter alia*, the applicants' legal costs and disbursements in conducting the Ethicon Class Actions;
3. the balance of the Settlement Fund, less such amounts as are approved by the Court for the costs and disbursements of administering and distributing the fund, will be distributed to group members who have a claim that would otherwise likely give rise to a right to be compensated at law;
4. the eligibility of group members to receive distributions from the Settlement Fund and the amounts of those distributions will be determined in accordance with a settlement scheme (**Settlement Scheme**). The Settlement Scheme will provide for such amounts to be determined based on a number of factors, such as the type of complication(s) experienced, the duration of the complication(s), the age of the group member, and the number and nature of any treatments the group member has undertaken.

Further information about the Ethicon Class Actions is set out in **Annexure A** to this document.

Further information about the group members in the Ethicon Class Actions is set out in **Annexure B** to this document.

The precise number of group members who seek to participate in the settlement is not known, however, it is the applicants' lawyers view that the number of group members eligible to make a claim on the settlement fund may be greater than 6,000 but this is not agreed and is an estimate.

Tender Responses

Responses to this request for tenders may be submitted on one or both of the following two bases.

First, tenders may be submitted on the basis that the tendering party will administer and distribute the Settlement Fund in accordance with the Settlement Scheme currently proposed by the applicants to the Ethicon Class Actions.

A copy of the Settlement Scheme currently proposed by the applicants to the Ethicon Class Actions is **Annexure C** to this document.

Secondly, tenders may be submitted on the basis that the tendering party will administer and distribute the Settlement Fund in accordance with an alternative Settlement Scheme devised by that party and included in its tender.

The following information **must** be provided as part of your tender:

1. the relevant experience of your organisation for the role of administering and distributing the Settlement Fund in the Ethicon Class Actions;
2. the names and relevant experience of the key personnel within your organisation who will be responsible for administering and distributing the Settlement Fund;
3. whether your tender is submitted on the basis that you will administer and distribute the Settlement Fund in accordance with the Settlement Scheme currently proposed by the applicants in the Ethicon Class Actions and/or on the basis that you will administer and distribute the Settlement Fund in accordance with your own alternative Settlement Scheme;
4. if your tender is submitted on the basis that you will administer and distribute the Settlement Fund in accordance with your own alternative Settlement Scheme, (a) a complete copy of that Settlement Scheme and (b) an explanation of the rationale for your eligibility criteria, loss assessment formula, and any dispute resolution process;
5. a timeline identifying both (a) dates by which you anticipate key milestones in the administration and distribution of the Settlement Fund will be completed, and (b) the end date by which you anticipate fully distributing the Settlement Fund to eligible group members;
6. in respect of the costs and disbursements of administering and distributing the Settlement Fund:
 - a. the basis on which such costs and disbursements are to be billed (e.g., whether as a proportion of amounts distributed, on the basis of time spent on administration and distribution tasks, or on some alternative basis or combination of bases);

- b. an itemised estimate of the costs and disbursements for all aspects of the administration and distribution of the Settlement Fund;
 - c. whether you propose that all or any part of your costs and disbursements of administering and distributing the Settlement Fund be capped;
7. how and when you propose to report to group members and the Court on your progress in administering and distributing the Settlement Fund.

Tender Process

Tenders are to be marked “Pelvic Mesh & Tape Class Action – Tender Offer” and, as noted above, must be submitted electronically to jjmesh.tender@williamroberts.com.au on or before **5 pm on 27 January 2023**.

Once tenders have been received, William Roberts Lawyers (which firm is administering the tender process) may, at its absolute discretion, make enquiries of any tendering party for the purpose of better understanding any aspect of that party’s tender.

Selection of the successful tenderer is to be decided by the Federal Court of Australia.

The successful tendering party will be required to submit to orders of the Federal Court of Australia providing for that party to administer and distribute the Settlement Fund in accordance with the Settlement Scheme on the basis of which that party’s tender was submitted.

Further enquiries with respect to the above process should be addressed to William Roberts Lawyers at jjmesh.tender@williamroberts.com.au.

ANNEXURE A

The Gill Proceeding

On 15 October 2012, a class action was commenced in the Federal Court of Australia against Ethicon Sàrl, Ethicon, Inc., and Johnson & Johnson Medical Pty Limited (together Ethicon) by Kathryn Gill, Diane Dawson and Ann Sanders (the Gill Applicants) in their own right and on behalf of women alleging that certain pelvic mesh implants for the treatment of pelvic organ prolapse (**POP**) and stress urinary incontinence (**SUI**) they had implanted in Australia were defective because they had caused them certain complications and those complications were not warned against.

On 21 November 2019, the Federal Court's judgment was delivered. Justice Katzmann found in favour of the Gill Applicants and awarded damages to Ms Gill, Ms Dawson and Ms Sanders. On 6 March 2020, the Federal Court delivered a further judgment relating to common questions and answers relevant to group member claims.

Ethicon appealed the Federal Court's decisions. On 5 March 2021, the Full Federal Court dismissed Ethicon's appeal. Ethicon then applied to the High Court for special leave to appeal the decision of the Full Federal Court. On 5 November 2021, the High Court dismissed Ethicon's application. This concluded the case for Ms Gill, Ms Dawson and Ms Sanders.

The individual claims of group members in the class action were not determined by this outcome.

The Talbot Proceeding

On 7 April 2021, a class action was commenced in the Federal Court of Australia against Ethicon by Lisa Talbot in her own right and on behalf of Australian women raising the same allegations as had been made in the Gill Proceeding for the benefit of women who had suffered a complication after the applicable cut-off date in the Gill Proceeding.

On 24 March 2022, the Federal Court entered orders for the benefit of group members in the Talbot Proceeding who had received an implant on or before 30 June 2020. Those orders included liability findings based on the answers to common questions and answers made in the Gill proceedings. No orders have been made in respect of group members who received an implant after 30 June 2020.

The individual claims of Ms Talbot and of group members in this class action have not been determined.

Although Ethicon acknowledges that the Gill Applicants have each established their claims against it, Ethicon does not admit that any other group member will establish their personal claim that a Pelvic Mesh Implants caused them injury. Nor does Ethicon admit the quantum of any damages or compensation order that any group member asserts they may obtain against

Ethicon in respect of each of their claims. Ethicon denies it is liable to pay damages to any Group Member in the Talbot Proceeding who had a Pelvic Mesh Implant after 30 June 2020.

On 9 September 2022, the parties to the Ethicon Class Actions agreed, subject to obtaining the Court's approval, to settle the proceeding.

ANNEXURE B

The group members in the persons who had surgery performed on them in Australia to implant one or more of the following implants (**Implants**):

1. POP Implants: Gynecare Prolift Pelvic Floor Repair System, Total, Gynecare Prolift Pelvic Floor Repair System, Anterior, Gynecare Prolift Pelvic Floor Repair System, Posterior, Gynecare Prosima Pelvic Floor Repair System, Combined, Gynecare Prosima Pelvic Floor Repair System, Anterior, Gynecare Prosima Pelvic Floor System, Anterior, Gynecare Prosima Pelvic Floor Repair System, Posterior, Gynecare Prolift + M Pelvic Floor Repair System, Total, Gynecare Prolift + M Pelvic Floor Repair System, Anterior, Gynecare Prolift +M Pelvic Floor Repair System, Posterior, and Gynecare Gynemesh PS;
2. SUI Implants: TVT Tension-free Vaginal Tape System, TVT Abbrevio Continence System, TVT Obturator System, TVT Secur System, and TVT Exact System; (together the **Pelvic Mesh Implants**).

The group members were supplied by a treating doctor or hospital for, in the case of the POP Implants, the treatment of pelvic organ prolapse, and in the case of the SUI Implants, the treatment of stress urinary incontinence.

The group members must have suffered a pleaded complication, which may include:

1. chronic inflammatory reaction of the tissues in which the implanted were implanted or the surrounding tissues;
2. chronic inflammatory reaction resulting in the continuous regeneration of scar tissue within and surrounding the implant, causing the implant to contract;
3. chronic pain;
4. damage to entrapment of nerves in the scar tissue surrounding the implant resulting in chronic pain;
5. de novo dyspareunia including sever chronic dyspareunia, worsened dyspareunia and/or apareunia;
6. erosion or extrusion of the implant into the vaginal canal resulting in:
 - a. infection of the tissue surrounding the non-exposed part of the implant which may be difficult to treat resulting in offensive vaginal discharge;
 - b. pain suffered by the group member, her partner or both during sexual

intercourse;

7. erosion or extrusion of the implant into the surrounding organs such as the bladder, urethra, or rectum with the risk of damage to those organs and pain;
8. difficulty voiding or defecating;
9. de novo incontinence and/or urge incontinence;
10. de novo stress urinary incontinence in the case of the POP Implants;
11. recurrence of prolapse;
12. infection;
13. hemorrhage;
14. leg weakness;
15. requiring reoperation or revision surgery associated with complications;
16. psychiatric injury.
 - a. difficulty voiding and in addition, or alternatively, defecating;
 - b. offensive discharge;
 - c. recurrence of a POP;
 - d. de novo or recurring urinary incontinence;
 - e. damage to surrounding organs, nerves, ligaments, tissue and in addition or alternatively, blood vessels;
 - f. hemorrhage;
 - g. infection;
 - h. leg weakness;
 - i. reoperation or revision surgery associated with complications, including those listed above; and in addition, or alternatively
 - j. psychiatric injury.

Opt out has concluded in the Gill and Talbot Proceedings. Individuals who fulfil the above criteria but have opted out are not group members.

ANNEXURE C

SETTLEMENT SCHEME – ETHICON CLASS ACTIONS

[date] 2022

Gill & Ors v Ethicon Sarl & Ors
Federal Court of Australia, Proceeding NSD 1590 of 2012

and

Talbot v Ethicon Sarl & Ors
Federal Court of Australia, Proceeding NSD 310 of 2021

Overview and Summary

- A. On [DATE] 2022, the parties to Federal Court Proceedings NSD 1590 of 2012 (*Gill & Ors v Ethicon Sarl & Ors*) and NSD 310 of 2021 (*Talbot v Ethicon Sarl & Ors*) (the **Proceedings**) executed a Deed of Settlement (the **Deed**).
- B. The Deed sets out the terms of a proposed settlement of the Proceedings subject to Court approval. If the proposed settlement is approved, a **Settlement Fund** will be established.
- C. The Settlement Fund will be managed according to the terms of the Deed and this **Settlement Scheme**. Terms not otherwise defined in this Settlement Scheme are as defined in the Deed.
- D. The Settlement Scheme has the following key elements:

Stage	Clause	Procedure
Registration	Clause 4	Persons who wish to make a claim under this Settlement Scheme, and who are not already deemed to have registered by reason of having completed a Registration Form, must now complete a Registration Form by the Registration Deadline . Persons who have already registered or who register by the Registration Deadline are Registrants .
Claim Records are provided to the Scheme Administrators	Clause 5	Registrants are to provide their Claim Records to the Scheme Administrators. In limited circumstances, the Scheme Administrators may assist Registrants to obtain this material.
Determination of Eligibility by the Scheme Administrators	Clause 6	The Scheme Administrators will determine the eligibility of Registrants to become Participating Group Members who may receive compensation under the Settlement Scheme. The Scheme Administrators will notify Registrants of the outcome of their Eligibility Determination.
Payment of Recovery Amounts	Clause 7	The Scheme Administrators will determine the Recovery Amounts that must be paid to Third Party Payers (such as Medicare) on behalf of Participating Group Members and will make those payments from the Settlement Fund.
Determination of suitability for Fast Track Resolution	Clause 8	The Scheme Administrators will determine the suitability of Participating Group Members for Fast Track Resolution of their claim. The

		Scheme Administrators will notify those Participating Group Members who have been determined to be suitable for Fast Track Resolution.
Fast Track Resolution Payments	Clause 9	Participating Group Members who have been determined to be suitable and elect to take a Fast Track Resolution will receive a Fast Track Resolution Payment within 90 days of notifying the Scheme Administrators of their election.
Claims Assessments	Clause 10	Remaining Participating Group Members will proceed to have their claim assessed under this Settlement Scheme by an independent Assessor . The Scheme Administrators will notify Participating Group Members of the outcome of their claim assessment.
Review rights	Clause 11	A Review may be sought by a Registrant who is dissatisfied with a determination that they are not a Participating Group Member, or by a Participating Group Member who is dissatisfied with a compensation assessment.
Interim Compensation Payments	Clause 12	The Scheme Administrators may begin the process of determining the value of Interim Compensation Payments which will be paid to Participating Group Members in relation to assessed claims.
Final Compensation Payments and Scheme Finalisation	Clause 13	Once assessments (including any reviews) are complete, the Scheme Administrators will make Final Compensation Payments and attend to finalisation of the Settlement Scheme.

1. Definitions and interpretation

In this Settlement Scheme, terms not otherwise defined under the Deed have the following meaning.

Assessed Compensation Amount means the total maximum compensation a Participating Group Member is assessed as being eligible to receive. The amount payable to a Participating Group Member under this Settlement Scheme may ultimately be assessed up or down from the Assessed Compensation Amount by the Scheme Administrators on a pro rata basis in accordance with clause 14.4 having regard to the total Assessed Compensation Amounts payable to all Participating Group Members, the value of the Settlement Fund and the advice of the Scheme Actuary.

Assessor means a member of an Australian State or Territory Bar or a solicitor who is not employed by or a principal of Shine with more than 3 years' experience in personal injury litigation who is appointed by the Scheme Administrators to assess a Participating Group Member's claim.

Claim Records means Complication, Surgical and Treatment Records and Financial Records.

Complication means any of the complications identified in paragraphs 23(d) - (g), 23A, 45(d) – (p) and 46 of the Fifth Further Amended Statement of Claim filed in the Gill Proceeding and paragraphs 10 and 11 of the Amended Statement of Claim filed in the Talbot Proceeding.

Complication, Surgical and Treatment Records:

- (a) means medical records, which may include treating doctor or hospital records supplemented by a letter or report from a treating doctor, of each complication, surgical intervention or non-surgical treatment for which compensation is sought under this Settlement Scheme;
- (b) excludes any medical records or treating doctor letters insofar as they record complications, surgeries or treatments which have occurred after the date on which the settlement is Finally Approved.

For the avoidance of doubt, Complication, Surgical and Treatment Records need not be in a form which would be admissible under the *Evidence Act 1995* (Cth).

Deed means the Settlement Deed dated [date] 2022 and executed by the parties to the Proceedings.

Eligibility Criteria has the meaning given in clause 6.1 of this Settlement Scheme.

Fast Track Resolution and **Fast Track Resolution Payment** have the meaning given in clause 8 of this Settlement Scheme.

Final Compensation Payment means the final amount of compensation which the Scheme Administrators determine is payable to Participating Group Members in accordance with clause 13.1 and is to be paid by the Administrator in accordance with clause 14.3.

Financial Records means any financial records or tax or employment records which record any financial loss a Registrant seeks to include in their claim for compensation under this Settlement Scheme. Financial Records may be supplemented by a letter or report from an accountant in relation to the Registrant's financial records or tax or employment records. For the avoidance of doubt, Financial Records need not be in a form which would be admissible under the *Evidence Act 1995* (Cth).

Gill Proceeding means Federal Court proceeding number NSD 1590 of 2012.

Group Member means a person who is a:

- (a) Group Member as defined in the Sixth Further Amended Statement of Claim filed in the Gill Proceeding; or
- (b) Group Member as defined in the Amended Statement of Claim filed in the Talbot Proceeding,

and, for the avoidance of doubt, does not include any person who was previously a Group Member but has opted out of the Gill Proceeding or Talbot Proceeding as the case may be.

Implant Evidence means the documentation that has been obtained by Shine in answer to the Subpoena Process.

Interim Compensation Payment means any interim payment which the Scheme Administrators determine is payable to Participating Group Members in accordance with clause 12.112.1 and is to be paid by the Administrator in accordance with clause 12.2.

Ethicon Pelvic Mesh Implant means an implant which was supplied under a product name listed in Schedule 1.

Most Extreme Case means a case in which the claimant suffers non-economic loss of the gravest conceivable kind.

Notice of Assessment has the meaning given in clause 10.3.

Notice of Assessment Review has the meaning given in clause 11.5(f).

Notice of Eligibility has the meaning given in clause 6.3.

Notice of Eligibility Review has the meaning given in clause 11.5(f).

Notice of Fast Track Suitability has the meaning given in clause 8.4.

Recovery Amounts has the meaning given in clause 8.1 of the Deed.

Recovery Legislation means:

- (a) the *Health and Other Services (Compensation) Act 1995* (Cth);
- (b) the *Social Security Act 1991* (Cth);

- (c) the *Veteran's Entitlements Act 1986* (Cth);
- (d) the *National Disability Insurance Scheme Act 2013* (Cth); or
- (e) any other enactment or legislative instrument under which the Respondents or the Administrator may be liable to pay a government body an amount arising from or in respect of the payment or distribution of the Settlement Sum or any part thereof.

Registrants means persons who have registered to participate in this Settlement Scheme in accordance with clause 4.

Registration Deadline is the day which is 30 days after the Settlement is Finally Approved.

Registration Form means a registration form substantially in the form approved by the Court pursuant to orders made in the Proceedings on 20 November 2019 and 3 September 2021.

Review Assessor means a member of an Australian State or Territory Bar or a solicitor who is not employed by or a principal of Shine and who has more than 5 years' experience in personal injury litigation, who is appointed by the Scheme Administrators pursuant to clause 11.5.

Scheme Actuary means an actuarial expert appointed by the Scheme Administrators to assist them in determining the appropriate level of compensation to be paid to Participating Group Members from time to time during the administration of the Settlement Scheme.

Scheme Administrators means Rebecca Jancauskas and Janice Saddler (of Shine), jointly and severally, or such other person or persons as may be appointed by the Court to administer this Settlement Scheme.

Settlement Scheme means this Settlement Scheme, including the rights and obligations created by this Scheme. For the avoidance of doubt, the Settlement Scheme may be amended by the Court as it deems fit.

Shine means Shine Lawyers Pty Ltd trading as Shine Lawyers.

Subpoena Process means the process of issuing subpoenas which was undertaken by the Court in the context of the registration process which occurred in the Gill Proceeding and Talbot Proceeding.

Talbot Proceeding means Federal Court proceeding NSD 310 of 2021.

Third Party Payer means a person or entity who has paid a Third Party Payment.

Third Party Payment means any payment made by a third party for the benefit of a Participating Group Member in relation to an Implant which is required to be reimbursed pursuant to Recovery Legislation.

\$ or dollar means the lawful currency of the Commonwealth of Australia.

2. Appointment and functions of Scheme Administrators

2.1 Appointment of Scheme Administrators

- (a) Subject to the Court's approval, Rebecca Jancauskas and Janice Saddler (of Shine) will be jointly and severally appointed as Scheme Administrators to administer and implement the Settlement Scheme fairly and reasonably according to its terms. Ms Jancauskas' and Ms Saddler's duties to the Court will take priority over any duties they may owe to individual Group Members.
- (b) In the performance of their functions as Scheme Administrators Ms Jancauskas and Ms Saddler will have the same immunities from suit as attach to a Referee appointed pursuant to s54A of the *Federal Court of Australia Act 1976* (Cth) by the Court.

2.2 Correction of errors

The Scheme Administrators may at any time correct any error, slip or omission that occurs in the administration or implementation of the Settlement Scheme.

3. Implementation of the Settlement

3.1 Application of the balance of the Settlement Fund

Subject to the provisions of the Deed (including the payment of all Recovery Amounts in accordance with clause 7 of the Deed), the balance of the Settlement Fund (including any interest earned on the Settlement Fund) will be applied and distributed as follows:

- (a) to Participating Group Members in accordance with this Settlement Scheme;
- (b) to the payment of Administration Costs in accordance with clause 17.

4. Registration to participate in the Settlement Scheme

4.1 Persons who have already submitted a Registration Form

Persons who submitted a Registration Form to Shine by [DATE] are deemed to have registered to participate in the Settlement Scheme.

4.2 Persons who have not yet submitted a Registration Form

A person who did not submit a Registration Form to Shine by [DATE] but who wishes to participate in the Settlement Scheme must complete and return to Shine a Registration Form by the Registration Deadline. The Registration Form is available at:

www.jjmeshclassaction.com.au/registrationform.pdf .

4.3 Alternative methods of registration

If a person is not able to complete and return a Registration Form, the Scheme Administrators may assist that person to complete a Registration Form.

4.4 Failure to register by the Registration Deadline

Subject to clause 4.5, if a person fails to complete and return to Shine a Registration Form by the Registration Deadline, they are not entitled to participate in the Settlement Scheme and they forego any right they may have had to receive compensation from the Settlement Fund.

4.5 Discretion to waive late registrations

In their discretion, the Scheme Administrators may accept a late registration (that is, a registration effected after the Registration Deadline), if the person seeking to register has reasonable grounds for late registration, including for the following reasons:

- (a) illness or incapacity; or
- (b) a prolonged absence from their usual place of residence,

except that the Scheme Administrators must not accept a late registration:

- (c) if it is received by Shine more than 12 months after the Registration Deadline.

5. Claim Records

5.1 Notice to provide Claim Records

Within 60 days of Final Settlement Approval, the Scheme Administrators will provide notice to Registrants that they are required to provide their Claim Records to the Scheme Administrators for the purpose of determining the Registrant's entitlements under this Settlement Scheme.

5.2 Time for provision of Claim Records to the Scheme Administrators

Subject to clause 5.3, Registrants must provide the Scheme Administrators with their Claim Records within 90 days of the Scheme Administrators issuing a Registrant with a notice pursuant to clause 5.1.

5.3 Scheme Administrators' discretion in relation to Claim Records

The Scheme Administrators may, in their absolute discretion:

- (a) extend the time by which a Registrant must provide to the Scheme Administrator their Claim Records; and, or
- (b) determine that a Registrant is not reasonably able to obtain their Claim Records, or some of them, in which case the Scheme Administrators may obtain the Claim Records, or some of them, on behalf of the Registrant.

5.4 Costs if the Scheme Administrators obtain a Registrant's Claim Records

If the Scheme Administrators determine, in accordance with clause 5.3(b), to obtain Claim Records, or some of them, on behalf of a Registrant, the Scheme Administrators may:

- (a) require the Registrant to pay a fee of \$500; and
- (b) determine that the fee is to be paid out of any compensation payable to the Registrant under the terms of this Settlement Scheme.

5.5 No obligation to consider material beyond the Claim Records provided to the Scheme Administrators

The Scheme Administrators, Assessors and Review Assessors are not obliged to consider any material in respect of a Registrant's claim under this Settlement Scheme beyond the Claim Records provided to or obtained by the Scheme Administrators in accordance with clauses 5.2 or 5.3.

6. Determinations of Eligibility to be a Participating Group Member under this Settlement Scheme

6.1 Eligibility Criteria

A person becomes a Participating Group Member and is eligible to receive compensation pursuant to this Settlement Scheme if she satisfies the following Eligibility Criteria:

- (a) she is a Group Member by reason that she:
 - i. was implanted with one or more Ethicon Pelvic Mesh Implant in Australia; and
 - ii. experienced one or more Complications by 14 July 2021;
- (b) she is a Registrant; and
- (c) the Scheme Administrators determine that she has a claim for non-economic loss which would be equal to or greater than 15% of a Most Extreme Case if assessed under the *Competition and Consumer Act 2010 (Cth) (CCA)* as at 1 January 2022.

6.2 Process for determining eligibility

The Scheme Administrators will assess and determine whether a Registrant meets the Eligibility Criteria pursuant to clause 6.1 in accordance with the following provisions:

- (a) the Scheme Administrators will utilise such Implant Evidence as has become available to them through the Subpoena Process to confirm that the person has received an Ethicon Pelvic Mesh Implant in Australia;
- (b) the Scheme Administrators will confirm whether the Registrant has filed an opt out notice with the Court;

- (c) the Scheme Administrators will review the Complication, Surgical and Treatment Records obtained in accordance with clause 5.2 or 5.3 to enable them to confirm that the person has suffered at least one Complication by 14 July 2021; and
- (d) the Scheme Administrators will determine whether the Registrant has a non-economic loss claim that would be equal to or greater than 15% of a Most Extreme Case under the CCA utilising the Claim Records obtained in accordance with clause 5.2 or 5.3.

6.3 Eligibility Notices

After a determination is made as to whether a person meets the Eligibility Criteria and is, therefore, a Participating Group Member, the Scheme Administrators will promptly send to the person a Notice of Eligibility in which the Scheme Administrators:

- (a) confirm whether a person is a Participating Group Member; and
- (b) if the person was determined not to meet the Eligibility Criteria, provide:
 - i. a short statement of the basis on which the person has been determined not to meet the Eligibility Criteria; and
 - ii. information in relation to their right to seek a Review under clause 11 of this Settlement Scheme; and
- (c) inform those persons who are Participating Group Members that they may be liable to pay amounts under the Recovery Legislation if any compensation is payable to them under the Settlement Scheme.

7. Payment of Recovery Amounts

7.1 Process for assessment and payment of Recovery Amounts

The Scheme Administrators will:

- (a) identify any and all Recovery Amounts payable in respect of each Participating Group Member's claim, including any necessary statutory clearances (for example under the *Social Security Act 1991 (Cth)* or *National Disability Insurance Scheme Act 2013 (Cth)*) or Notices of Charge (under the *Health and Other Services (Compensation) Act 1995 (Cth)*);
- (b) direct the Administrator to, and the Administrator shall, pay from the Settlement Fund all Recovery Amounts which have been notified to the Respondents within 28 days of notification, provided that the Respondents have not given Notice of any objection to such payment being made; and
- (c) inform the Administrator once they have determined that:
 - (i) all Third Party Payments arising by reason of the Settlement have been ascertained insofar as is reasonably practicable; and

- (ii) all Recovery Amounts have been paid (including, for the avoidance of doubt, by reason of any bulk payment arrangement entered into by the Administrator in relation to a Third Party Payment in accordance with clause 8.4 of the Deed),

in order that the Administrator may then give Notice to the Respondents of the Administrator's Third Party Payment Resolution Determination in accordance with clause 8.5 of the Deed.

8. Fast Track Resolution

8.1 Fast Track Resolution

A "**Fast Track Resolution**" means the full and final resolution of a Participating Group Member's claim for compensation under this Settlement Scheme by way of single, lump sum payment in the amount of \$7,500 (**Fast Track Resolution Payment**).

8.2 Suitability for Fast Track Resolution

If a Participating Group Member has a claim for non-economic loss that would be assessed as being at least 15% but not more than 20% of a Most Extreme Case under the CCA, they are suitable for Fast Track Resolution.

8.3 Determination of suitability for Fast Track Resolution

The Scheme Administrators will determine whether a Participating Group Member is suitable for Fast Track Resolution pursuant to clause 8.2 utilising the Participating Group Member's Claim Records obtained in accordance with clause 5.2 or 5.3

8.4 Notice of Suitability for Fast Track Resolution

If the Scheme Administrators determine a Participating Group Member is suitable for Fast Track Resolution, they will:

- (a) notify the Participating Group Member of their suitability for Fast Track Resolution; and
- (b) seek confirmation from the Participating Group Member, which confirmation must be provided within 90 days, as to whether the Participating Group Member elects to accept a Fast Track Resolution of their claim.

9. Fast Track Resolution Payments

9.1 Fast Track Resolution Payments

The Scheme Administrators will make a Fast Track Resolution Payment to a Participating Group Member within 90 days of the Participating Group Member confirming, in

accordance with clause 8.4(b), that they have elected to accept a Fast Track Resolution of their Claim.

10. Assessment of Participating Group Member Claims

10.1 Assessment of claims

Participating Group Members who:

- (a) are not suitable for; or
- (b) have not elected to accept

a Fast Track Resolution will have their claims assessed and determined by an Assessor in accordance with the provisions and principles which apply to the assessment of damages in Divisions 4, 5 and 6 of Part VIB of the *Competition and Consumer Act 2010* (Cth) as in force at 1 January 2022.

10.2 Process for assessing Participating Group Members' claims

Participating Group Members claims will be assessed as follows:

- (a) The Scheme Administrators will:
 - (i) prepare a claim book containing the Claim Records obtained in accordance with clauses 5.2 or 5.3, which may be in electronic or hardcopy form;
 - (ii) appoint an Assessor to undertake the assessment of the Participating Group Member's claim in accordance with this Settlement Scheme; and
 - (iii) provide the Assessor with a copy of this Settlement Scheme and the Participating Group Member's claim book.
- (b) Upon receipt of the information referred to in clause 10.2(a)(iii) the Assessor will:
 - (i) determine the Participating Group Member's Assessed Compensation Amount in accordance with clause 10.1; and
 - (ii) provide the Scheme Administrators with short form reasons setting out the basis on which the Assessed Compensation Amount was determined.

10.3 Notice of Assessment

After a determination is made as to a Participating Group Member's Assessed Compensation Amount, the Scheme Administrators will promptly send to the Participating Group Member a Notice of Assessment in which the Scheme Administrators will:

- (a) state the Participating Group Member's Assessed Compensation Amount;
- (b) provide the Participating Group Member with a copy of the Assessor's reasons; and

- (c) provide information to the Participating Group Member in relation to their right to seek a Review under clause 11.

11. Reviews

11.1 Right to seek a Review

A person has the right to seek a review of any of the following determinations:

- (a) In the case of a Registrant, a determination under clause 6 that a person is not a Participating Group Member (**Eligibility Review**); and
- (b) in the case of a Participating Group Member, an Assessor's determination of their Assessed Compensation Amount (**Compensation Review**).

11.2 Process for seeking a Review

If a Registrant or a Participating Group Member wishes to seek a Review, they must do so:

- (a) by giving written notice to the Scheme Administrators no later than 28 days after the Scheme Administrators have sent a Notice of Eligibility or Notice of Assessment (as applicable) to the Registrant or Participating Group Member; and
- (b) the notice seeking a review of a Notice of Assessment must state the components of the assessment which the Participating Group Member disputes and the reasons why the Participating Group Member disputes those components of the assessment.

11.3 Failure to seek a Review

If a Registrant or Participating Group Member does not give written notice to the Scheme Administrators within 28 days as required by clause 11.2, the Registrant or Participating Group Member will be deemed to have accepted their Notice of Eligibility or Notice of Assessment (as the case may be).

11.4 Payment of a bond for Reviews

Subject to clause 17.4, where a Registrant or Participating Group Member seeks either an Eligibility Review or a Compensation Review, the Scheme Administrators may, in their absolute discretion:

- (a) require that the Registrant or Participating Group Member pay to the Administrator a bond not exceeding \$2,000 for the cost of the Review;
- (b) if the Registrant or Participating Group Member fails to pay the bond within 28 days of receiving such a request from the Scheme Administrators, treat the Participating Group Member's request for a Review as void and of no effect.

11.5 Process for determination of Reviews

Following receipt of a notice seeking review and upon payment of any bond required in accordance with clause 11.4:

- (a) the Scheme Administrators will engage a Review Assessor;
- (b) the Scheme Administrators will provide the following materials to the Review Assessor:
 - (i) the Registrant's or Participating Group Member's Implant Evidence, Complication, Treatment or Surgical Records;
 - (ii) the Registrant's or Participating Group Member's written notice by which she requested the Review; and
 - (iii) either of the following, depending on the nature of the Review that is sought by a registrant or Participating Group Member:
 - (A) Notice of Eligibility; or
 - (B) Notice of Assessment, including the Assessor's reasons;
- (c) unless the Review Assessor considers it reasonably necessary to do so, the Review Assessor will not consider any new evidence or additional materials that are not already included in the materials referred to in clause 11.5(b);
- (d) the Review Assessor will then:
 - (i) in an Eligibility Review, make a determination as to whether the Scheme Administrators made an error in applying the Eligibility Criteria;
 - (ii) in a Compensation Review, make a determination as to the amount of compensation that the Participating Group Member is assessed as being entitled to receive pursuant to this Settlement Scheme, and in doing so the Review Assessor must only consider the components of the assessment in relation to which the Participating Group Member seeks a Review;
 - (iii) in relation to either type of Review, prepare and provide to the Scheme Administrators a brief statement of reasons for the Review Assessor's determination and, if relevant, include details of the amounts assessed;
- (e) in carrying out a Compensation Review, a Review Assessor may determine that:
 - (i) the Group Member is entitled to more compensation than was initially assessed; or
 - (ii) the Group Member is entitled to less compensation than was initially assessed;
- (f) after receiving a Review Assessor's determination and statement of reasons, the Scheme Administrators will promptly send to the Registrant or Participating Group

Member a Notice of Review Assessment in which the Scheme Administrators provide:

- (i) information to the registrant or Group Member about the determination of their Review and the impact of that determination on the registrant's or Group Member's entitlements (if any) under this Settlement Scheme; and
- (ii) a copy of the Review Assessor's statement of reasons.

11.6 Determinations of Review Assessors are final and binding

- (a) A determination of a Review Assessor is final and binding on the Scheme Administrators and the Registrant or Participating Group Member who sought the Review, and neither the Scheme Administrators nor the Registrant or Participating Group Member is entitled to appeal to the Court or any other court or tribunal in relation to any asserted error of jurisdiction, fact or law arising from the Review Assessor's determination.
- (b) Following a Compensation Review, the Review Assessor's determination will be deemed to be the Participating Group Member's Assessed Compensation Amount for the Participating Group Member under this Settlement Scheme.

11.7 Role of Review Assessors

Review Assessors engaged by the Scheme Administrators:

- (a) will act as independent arbitrators and not as counsel briefed to act for any individual Group Members or the Administrator;
- (b) will have the same immunities from suit as attach to a Referee appointed pursuant to s 54A of the *Federal Court of Australia Act 1976* (Cth) by the Court.

12. Interim Compensation Payments

12.1 Determination of Interim Compensation Payments

Following confirmation of the Administrator's Recovery Amounts Determination in accordance with clause 8.6 of the Deed, the Scheme Administrators may determine Interim Compensation Payments. An Interim Compensation Payment must be:

- (c) determined only after at least 800 Participating Group Members have been notified of their Assessed Compensation Amount (which notifications are to be counted from either the date of commencement of this Settlement Scheme for the first Interim Compensation Payment or otherwise the date of the previous tranche of Interim Compensation Payments); and
- (d) set as a proportion of the Participating Group Members' Assessed Compensation Amounts, which is to be determined by the Scheme Administrators having regard to the advice of the Scheme Actuary, taking into account:

- i. the total value of the Settlement Fund and any projected interest income on the Settlement Fund;
- ii. the total number of Participating Group Members;
- iii. the Scheme Administrators' best estimate of the costs of administering the Settlement Scheme;
- iv. the total number of Participating Group Members for whom assessments have been completed as at the relevant time;
- v. the total number of Participating Group Members who have elected to accept a Fast Track Resolution;
- vi. the aggregate of Assessed Compensation Amounts then known for Participating Group Members; and
- vii. any other matters that the Scheme Actuary considers relevant.

12.2 Payment of Interim Compensation Payment

Upon the Scheme Administrators determining the quantum of an Interim Compensation Payment that is able to be paid in accordance with clause 12.1:

- (a) the Scheme Administrators are promptly to notify the Administrator and Participating Group Members who are to receive an Interim Compensation Payment of their determination; and
- (b) the Administrator is to pay the Interim Compensation Payment in accordance with the Scheme Administrators' determination, with such payments to be made in tranches to all Participating Group Members who have:
 - i. received notification of their Assessed Compensation Amounts more than 28 days prior to the Interim Compensation Payment being made; and
 - ii. either:
 - A. not sought a review pursuant to clause 11.2; or
 - B. received a final and binding determination of a Review Assessor pursuant to clause 11.6.

13. Final Compensation Payments

13.1 Determination of Final Compensation Payment

As soon as reasonably practicable following:

- (a) notification by the Scheme Administrators to Participating Group Members of all Assessed Compensation Amounts; and
- (b) determination by Review Assessors of any Compensation Reviews,

the Scheme Administrators must determine the Final Compensation Payments which are to be paid to Participating Group Members, which are to be:

- i. set as a proportion of the Participating Group Members' notified Assessed Compensation Amounts;
- ii. in a proportion of the Participating Group Members' Assessed Compensation Amounts which is to be determined by the Scheme Administrators having regard to the advice of the Scheme Actuary, taking into account:
 - A. the remainder of the Settlement Fund and any projected interest income on the Settlement Fund up to the time of payment of the Final Compensation Payments;
 - B. the total number of Participating Group Members;
 - C. the Scheme Administrators' best estimate of the final costs of administering the Settlement Scheme; and
 - D. any other matters that the Scheme Actuary considers relevant.

13.2 Payment of Final Compensation Payments

Upon the Scheme Administrators determining the quantum of the Final Compensation Payments that are to be paid in accordance with clause 13.1:

- (a) the Scheme Administrators are promptly to notify the Administrator and Participating Group Members of their determination; and
- (b) the Administrator is to pay the Final Compensation Payments in accordance with the Scheme Administrators' determination in a final tranche to all Participating Group Members.

14. Management of the Settlement Fund and payments to Participating Group Members

14.1 Settlement Fund is held by the Administrator

Upon Final Settlement Approval, subject to the terms of the Deed, this Settlement Scheme and any applicable statutory requirements, the Administrator will hold the money in the Settlement Account in the manner prescribed by the Deed.

14.2 Management of the Settlement Fund

Subject to clause 14.3 below and to the payment of Recovery Amounts from the Settlement Fund, the Administrator will take all reasonable steps to ensure that the Settlement Fund and payments to Participating Group Members are managed in such a way as to maximise the availability of funds to make compensation payments to all Participating Group Members as may be directed from time to time by the Scheme Administrators.

14.3 Payments to Participating Group Members

The Administrator shall:

- (a) make payments to Participating Group Members by way of Interim Compensation Payments as directed by the Scheme Administrators, with a portion of Assessed Compensation Amounts to be withheld pending the assessment of additional Participating Group Members, and those Assessed Compensation Amounts may be adjusted in light of such additional assessments;
- (b) pay Interim Compensation Payments in tranches to Participating Group Members over time; and
- (c) pay the Final Compensation Payments to Participating Group Members as directed by the Scheme Administrators;

and for the purpose of this clause the Administrator, in consultation with the Scheme Administrators, may take advice from the Scheme Actuary to ensure that, insofar as reasonably practicable, the Settlement Fund is distributed equitably amongst Participating Group Members having regard to the total Assessed Compensation Amounts.

14.4 Adjustments to compensation payments

The following adjustments may be made by the Scheme Administrators to the Assessed Compensation Amounts:

- (a) if the aggregate of Assessed Compensation Amounts is (or is anticipated to be) less than the net amount available for distribution to Participating Group Members, the Assessed Compensation Amounts may be proportionately grossed up and if practicable additional payments will be made to Participating Group Members; and
- (b) if the aggregate of Assessed Compensation Amounts is (or is anticipated to be) greater than the net amount available for distribution to Participating Group Members, the Assessed Compensation Amounts will be proportionately reduced.

15. Obligations of Participating Group Members

15.1 Cooperation of Participating Group Members

Each Participating Group Member must cooperate with the Administrator and Scheme Administrators and take all steps that they are required to take pursuant to this Settlement Scheme and/or that are reasonably requested or directed by the Administrator or Scheme Administrators, including:

- (a) providing instructions, information, documents or other materials;
- (b) providing authorities or permissions;
- (c) attending and participating in meetings or telephone conferences with the Scheme Administrators or any other person (such as a Review Assessor);

- (d) promptly informing the Scheme Administrators of any change in their contact details;
- (e) executing documents,

and each Participating Group Member must do so:

- (f) complying to the best of the Participating Group Member's ability with the substance and not merely the form of the requirement, request or direction; and
- (g) by the date or within the timeframe specified in the requirement, request or direction.

15.2 Obligation regarding honesty

In fulfilling the obligation in clause 15.1, each Participating Group Member must act honestly and must take all reasonable steps to ensure that any of their agents or representatives likewise act honestly.

15.3 Disclosure to agencies and other organisations

Participating Group Members acknowledge and agree that any of the Administrator and Scheme Administrators may, if required by statute or contract, disclose their personal information, details of their claim or other documents and materials to an agency or other organisation including Centrelink, Medicare, the National Disability Insurance Agency, a private health insurer, a worker's compensation authority or the Australian Taxation Office.

16. Person under a disability

16.1 Application of this clause

This clause applies if a Participating Group Member is a "person under a legal incapacity" within the meaning of the *Federal Court Rules 2011*.

16.2 Process for claims requiring approval by the Court

The following procedure applies where settlement or compromise of a Participating Group Member's claim requires approval by the Court:

- (a) if any entitlement to compensation is subject to approval by the Court pursuant to rules 7.11 or 9.70 of the *Federal Court Rules 2011*, the Scheme Administrators will at the earliest opportunity join in supporting the Participating Group Member's "litigation representative" or "interested person" to seek appropriate orders for approval of the relevant compensation payment;
- (b) if the Court does not approve the payment to the Participating Group Member, the claim will be referred back to the Scheme Administrators for further assessment and determination, and the Scheme Administrators will again join in seeking appropriate orders for approval at the earliest opportunity after the claim has been reassessed.

17. Costs

17.1 Payment of Administration Costs

Subject to the other provisions of this clause 17, Administration Costs are to be paid:

- (a) on a “solicitor and own client” basis to:
 - i. the Administrator, provided that the Scheme Administrators are Rebecca Jancauskas and Janice Saddler;
 - ii. such other person as the Court approves should alternative Scheme Administrators be appointed,on a “solicitor and own client” basis;
- (b) from the Settlement Fund, including, from any interest earned on the Settlement Fund after it is paid by the Respondents pursuant to clause 2 of the Deed;
- (c) in such amounts as are approved by the Court from time to time during the implementation of this Settlement Scheme;
- (d) in the case of disbursements which individually total no more than \$3,000, on a quarterly basis from the Settlement Sum provided that such disbursements have been reviewed by a costs assessor who certifies that the disbursements have been reasonably incurred; and
- (e) at the following rates or at such other rates as are approved by the Court from time to time:

<u>Role</u>	<u>Hourly rate (excluding GST)</u>
Practice Leader	\$790
Special Counsel	\$750
Senior Associate	\$675
Associate	\$550
Lawyer	\$450
Graduate Lawyer / Trainee Lawyer / Articled Clerk	\$350
Paralegal / Legal Clerk / Law Clerk	\$295

Litigation Technology Consultant

\$250

17.2 Costs of determining Participating Group Members' claims

The Administrator is entitled to charge the following fees for the assessment of Participating Group Members' Claims:

<u>Category of Work</u>	<u>Fees (excluding GST)</u>
Assessment of Eligibility (<i>implant and complication evidence</i>)	\$1,000.00
Assessment of Eligibility (<i>complication evidence</i>)	\$500.00
Assessment of Third Party Payments	\$1,000.00
Fast track	\$750.00
Claim assessment (<i>Assessors fee</i>)	\$2,000.00
Preparation of Claim Book	\$1,250.00
Review costs	\$1,000.00

17.3 Fees charged by Assessors and Review Assessors

The Assessor will be paid fees of \$3,000 for assessing a Participating Group Member's Assessed Compensation Amount but may apply to the Scheme Administrators to seek fees of up to \$4,000 where a Participating Group Member's claim involves either complex questions of fact in relation to causation or complex claims for economic loss.

The Review Assessor will be paid fees of \$1,000 for Eligibility Review and fees of \$2,500 for Compensation Review.

These fees will be Administration Costs.

17.4 Costs of Reviews

The following provisions apply in relation to the costs of a Review:

Eligibility Review

- (a) if a Registrant succeeds in an Eligibility Review:
 - (i) the costs of the Review will be Administration Costs; and

- (ii) any bond paid by the Registrant will be returned to the Registrant;
- (b) if a Registrant fails in an Eligibility Review, the Administrator will apply the bond paid by the Registrant to the payment of the Review costs payable by the Registrant.

Compensation Review

- (c) if a Participating Group Member succeeds in a Compensation Review and the amount assessed by the Review Assessor is greater than 110% of the amount initially assessed by the Assessor, the costs of the Review will be Administration Costs and any bond paid by the Participating Group Member will be returned to the Participating Group Member;
- (d) if a Participating Group Member fails in a Compensation Review or succeeds in circumstances where the amount assessed by the Review Assessor is less than 110% of the amount initially assessed by the Assessor, the bond paid by the Participating Group Member will be applied toward the cost of the Review and any shortfall in costs will be deducted from the compensation payable to the Participating Group Member.

17.5 Costs of lawyers other than the Administrator, Scheme Administrators, Assessors or Review Assessors

Nothing in this Settlement Scheme prevents a Participating Group Member from retaining or seeking advice from a lawyer who is not performing the role of Administrator or Scheme Administrators, except that:

- (a) the Participating Group Member does so at their own cost; and
- (b) the Participating Group Member's lawyer is not entitled to recover any legal costs from the Administrator or Scheme Administrators and any such legal costs must not be treated as Administration Costs unless the Administrator made a written request that the Group Member's lawyer carry out the legal work in question.

18. Supervision by the Court

18.1 Supervision by the Court

The Administration of the Settlement Fund and implementation of the Settlement Scheme are subject to the supervision of the Court.

18.2 Administrator or Scheme Administrators may apply to the Court for directions

Where the Administrator or Scheme Administrators consider that:

- (a) the procedures to be followed in implementing this Settlement Scheme are in doubt or uncertain; or
- (b) it is appropriate for the Court to give directions regarding an issue concerning the implementation or administration of this Settlement Scheme,

the Administrator or Scheme Administrators may approach the Court for directions and the Administrator or Scheme Administrators may seek to be joined to the Proceedings for that purpose.

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SCHEDULE 1 –IMPLANTS

Implant
POP Implants
Gynecare Prolift Pelvic Floor Repair Systems (Anterior, Posterior and Total)
Gynecare Proxima Pelvic Floor Repair Systems (Anterior, Posterior and Combined)
Gynecare Prolift+M Pelvic Floor Repair Systems (Anterior, Posterior and Total)
Gynecare Gynemesh PS Nonabsorbable polypropylene Mesh
SUI Implants
Gynecare TVT
Gynecare TVT Abbrevo
Gynecare TVT Secur
Gynecare TVT Exact
Gynecare TVT Obturator