

ETHICON / JOHNSON & JOHNSON PELVIC MESH CLASS  
ACTION SETTLEMENT ADMINISTRATION

COMPENSATION HANDBOOK

## Purpose of this Handbook

The purpose of this Handbook is to:

1. provide you with information about the compensation assessment process including how compensation will be assessed; and
2. confirm certain obligations imposed on group members under the Scheme (Amended Settlement Scheme approved by the Court on 23 December 2024).

## The Role of the Administrators and the Role of the Court

The Administrators' role is to implement the Scheme, which includes completing group member compensation assessments.

The Administrators have a duty to the Court to implement the Scheme fairly and reasonably according to its terms.

The Court will continue to supervise and monitor the progress of the assessment process.

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## General Information

### How long will the compensation assessment process take and when will I be paid?

We are unable to predict how long it will take to assess all claims.

Timeframes for compensation assessment will depend upon a number of factors, including:

- (a) how many group members are assessed as eligible under the Scheme;
- (b) the complexity of group member claims;
- (c) how quickly the Administrators receive documents and materials requested from third parties, such as medical records; and
- (d) how quickly the Administrators receive further instructions and information from group members.

Many of these factors are outside of our control. We will continue to seek the assistance of the Court to obtain information when it is not forthcoming directly. This is done to quicken the process. The Scheme will remain open until 30 June 2027, and the Administrators will be focused on completing compensation assessments as early as possible prior to that date.

Group members will receive a portion of their assessed compensation amount as a second interim payment and a further portion as a final payment after the Scheme has closed.

The final payment of compensation to group members will be made as soon as reasonably practicable after 30 June 2027. Final compensation payments to group members cannot be made until:

- (a) all group members' claims have been assessed,
- (b) all compensation reviews have been determined by the review assessor, and

- (c) the Administrators have received advice from the Scheme Actuary to ensure that the Settlement Fund is distributed equitably amongst group members having regard to the total Assessed Compensation Amounts.

To date there are almost 5,000 eligible Ethicon group members to consider for compensation assessment. Please note that the Administrators intend to make a second interim payment before the final compensation payment is made. The Administrators estimate that second interim payments will commence in the first quarter of 2026 and will be paid progressively as compensation assessments are completed for group members.

### How much compensation will I be paid?

We cannot presently confirm how much compensation group members will receive.

We do not expect that all group members will recover damages in excess of the \$4,000 interim payment which has already been paid.

We also do not expect that all group members will receive damages in the amounts illustrated in the examples provided in this Handbook.

There are a number of reasons for this.

1. Not all complications that could be attributed to the mesh implants will entitle group members to receive compensation from the Scheme.
2. The Administrators recognise that the mesh implants have had a significant impact on the health and personal lives of many group members for a long period of time, however, not all conditions or every loss or detriment suffered by a group member entitles them to compensation under the Scheme.
3. For example, group members will not be entitled to compensation in excess of

\$4,000 for a pre-existing condition that was the reason their Ethicon implant was inserted (namely stress urinary incontinence or pelvic organ prolapse).

4. In assessing compensation, the Administrators are required to apply the terms of the Scheme, the relevant legislation and applicable case law and must have regard to the available medical records to establish the complications and treatments which have been experienced.

The negotiated settlement was a compromise resolution of the claim for the amount of \$300 million, with that compromise settlement being then approved by the Court. As such, no further compensation will be paid by Ethicon, even if the total of group members' Assessed Compensation Amounts exceeds the settlement sum.

Please note that the settlement sum of \$300 million is NOT the amount of funds available to pay compensation to group members. Whilst interest is being received on the current balance of the fund, costs and other third-party repayments will also be deducted. These third-party payments include Medicare, Centrelink, NDIA and private health funds. Accordingly, the compensation amount payable to group members (also known as the Assessed Compensation Amount) is expected to be scaled down in reliance on advice from the Scheme Actuary.

The compensation paid to an individual group member will be divided fairly by reference to each group member's Assessed Compensation Amount. Group members will receive a portion of their Assessed Compensation Amount as a second interim payment and a further portion as a final payment after the Scheme has closed. Further information about this is in the section entitled "Payments" below.

**VERY IMPORTANT MESSAGE** - Group members should not make any financial or other decisions based upon an expectation that they will recover a particular amount of compensation from this settlement as a result of information provided in this Handbook.

## Assessment of Compensation

The Administrators are required to assess the compensation of eligible group members based on the Scheme.

To be entitled to compensation **in addition to** the \$4,000 interim payment, a group member must have suffered one or more of the following complications and/or treatments:

### *Complications*

- Urinary dysfunction (de novo or exacerbated urinary incontinence, as distinct from a recurrence of incontinence, which does not entitle a group member to additional compensation);
- Erosion, extrusion or protrusion of the mesh into surrounding organs, including the vaginal wall, bladder or urethra;
- Infection;
- Pain of the back, vagina, pelvic, groin, perineum, anus, rectum or thigh;
- Dyspareunia and/or apareunia (pain during intercourse; avoidance of sexual intercourse);
- Bowel dysfunction;
- Damage to surrounding pelvic organs, nerves, ligaments or tissues;
- Significant complications of revision surgery, including increased pain and complications of anaesthesia such as

- stroke or cardiac arrest, haemorrhage or infection; and
- Psychiatric injury.

#### Treatments<sup>1</sup>

- Topical treatment for vaginal area (eg estrogen cream);
- Non-prescription and prescription medication for treatment of pelvic pain or other pain, or for treatment of bladder or bowel problems (commencing at least 90 days after implantation of the pelvic mesh);
- Prescription medical and/or clinical treatment (eg psychiatrist or psychologist) for treatment of a psychological or psychiatric condition;<sup>2</sup>
- Physical therapy of pelvic floor and/or vaginal area;<sup>3</sup>
- Investigative procedures (eg cystoscopy) to investigate the cause of a complication caused by, or in part by, the pelvic mesh;
- Anaesthetic block for treatment of pain in or originating from pelvic area;
- Botox injections into pelvic muscle;
- Revision and/or trimming of pelvic mesh performed using topical or local anaesthesia; and
- Surgical treatment under general anaesthesia or regional anaesthesia to (1) treat a complication more likely than not caused by the pelvic mesh or (2)

investigate whether a group member is experiencing a complication caused by the pelvic mesh.

Please note that an entitlement to compensation **will only** arise where your medical records evidence that:

- your complications were caused by your Ethicon mesh implant; and/or
- your treatment was in respect of complications caused by your Ethicon mesh implant.

While it is possible that future medical science will establish a link between the Ethicon mesh implants and other conditions, symptoms and treatments, those matters are irrelevant, as the Scheme only permits the payment of compensation to group members for the complications and associated treatments identified above.

Every group member's claim is different, and this means that the compensation paid to different group members may vary significantly.

For example, the following factors will cause variation between group members' Assessed Compensation Amounts:

- If the group member has more than one Ethicon implant;
- The group member's age at date of implantation of the Ethicon mesh implant;
- Whether the group member's complication is mild, moderate or severe;
- The length of time over which the group member experienced her complication;

<sup>1</sup> All references to 'pelvic mesh' are to be understood as a reference to one of the Ethicon pelvic mesh devices listed in Annexure B.

<sup>2</sup> To qualify, there must be six or more sessions during a 180 day period by a qualified psychologist

or psychiatrist, commencing at least 90 days after implantation of the mesh device.

<sup>3</sup> To satisfy the criteria the therapy must commence at least 90 days after implantation of the pelvic mesh and involve at least 4 sessions over a 60 day period.

- The number of complications suffered (if more than one);
- The number of qualifying treatments;
- The duration of the qualifying treatment received; and
- The number of qualifying surgeries.

## Methods of Assessment

Group members will have their claims assessed in one of two ways under the Scheme:

- (a) the Points Assessment Method; or
- (b) the Individual Assessment Method in accordance with the *Competition and Consumer Act 2010* (Cth) (the ‘Act’).

The method of assessment should not impact the amount of compensation a group member receives, in that a group member who undergoes an Individual Assessment will not necessarily receive more compensation than if that same group member had undergone a Points Assessment. This is because a Points Assessment is designed to reflect the amount of compensation that would be awarded pursuant to an Individual Assessment but is performed more efficiently than an Individual Assessment which are generally more time consuming.

Individual Assessments are designed to ensure that group members who have experienced more severe complications or who have had more invasive treatments are equitably compensated for their injuries and consequent losses. If the Administrators were to perform an Individual Assessment of every group member’s claim, this process would take considerably longer and the Administrators’ costs and disbursements would be significantly higher thus reducing the compensation available for group members.

## Evidence

The Administrators will request and obtain medical evidence for the purpose of assessing your compensation entitlement.

The Administrators may contact you to obtain further instructions or information about your claim.

The Administrators may obtain and have regard to surgical and treatment evidence, medical, clinical or pharmacy records and reports of treating medical practitioners, depending on each group member’s individual circumstances.

**IMPORTANT INFORMATION** – Do not be concerned if we request information from another group member that is different to the information we have requested from you. Each group member’s claim is different and therefore, it is to be expected that different information will be required from different group members.

## Points Assessment Method

Most group members (approximately 80%) will have their entitlement to compensation assessed using the Points Assessment Method.

Group members’ compensation will be assessed by allocating points for each qualifying complication suffered and any qualifying treatment received.

Compensation calculated based on a Points Assessment Method means that points will be allocated for each qualifying complication and each qualifying treatment, which are added together. The total number of points corresponds to an assessment amount under the Scheme.

**Please note,** *qualifying* complications and *qualifying* treatments are those which are awarded points under the Scheme.

Broadly, the Points Assessment Method assesses compensation based on the following factors:

- Points are allocated for each complication, and multiple points will be awarded if a group member suffers multiple complications;
- More severe complications are allocated higher points;
- Additional points are applied when a group member suffers complications for 3 or more years to reflect the duration of the complications;<sup>4</sup>
- Points are awarded for treatments, including the number and type of surgical and non-surgical treatments undertaken for mesh-related complications, as treatment is generally reflective of a group member's complications;
- Additional points are awarded when a group member receives treatments for 3 or more years to reflect the duration of the treatments;<sup>5</sup>
- The invasiveness and the period of time over which treatments have been required; and
- Points are awarded having regard to a group member's age at the time of implant.

After a determination is made in respect of your compensation entitlement (i.e. your Assessed Compensation Amount), the Administrators will send you a Notice of Assessment which will:

- (a) state your Assessed Compensation Amount;
- (b) provide information about the determination of your entitlement under the Scheme; and

- (c) provide information in relation to your right to seek a review of the determination.

Under the Scheme, the Administrators are appointed to implement the Scheme fairly and reasonably according to its terms and subject to Court supervision.

### **Severity and invasiveness**

The Points Assessment Method attributes a higher number of points to complications that are more severe and to treatments that are more invasive in nature. Group members who meet a certain threshold for points associated with their complications will receive an uplift in their compensation to account for the duration of their complications.

For example, Monica received an Ethicon implant in 2016 and has since experienced several complications. The points she receives for her complications under the points scheme exceed the threshold required to receive an uplift for the duration of her complications. Since Monica has suffered complications for a period of nine years, the points she receives for her complications are multiplied by 1.75, which increases her points.

### **Age**

An uplift is applied to compensation based on the age of the group member at the date of their first Ethicon implant. Group members who receive an implant at a younger age will receive a greater uplift than group members who were older when they received their implant. This is because group members who received their implants earlier in life will typically endure their complications for a greater number of years than those who received them later in life.

For example, Phoebe was 41 when she received her implant. She will receive an extra 5 points, or \$10,000,

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<sup>4</sup> A multiplier will be applied when a group member has suffered complications with a value of 11 points or more and they have suffered complications for more than 3 years.

<sup>5</sup> Additional points will only be awarded if the group member has also undergone non-surgical treatments totalling 11 points or more.

on top of the points she receives for her complications and treatments.

Tania was 66 when she received her implant and she will therefore receive an extra 1.5 points, or \$3,000, on top of the points she receives for her complications and treatments.

### Duration

Additional points are awarded to compensate group members who:

- (a) suffer complications for 3+ years; or
- (b) receive ongoing treatment for mesh complications for 3+ years.

The additional points recognise the length of time over which a group member experiences a mesh-related complication or receive treatment for a mesh-related complication. Time is calculated holistically starting from the first date of a mesh complication/treatment and concluding when either (a) the complications/treatments cease or (b) the compensation assessment is completed (if complications/treatments are ongoing). The duration multiplier creates a point uplift to recognise that ongoing treatment (eg multiple

urodynamic studies) should be awarded additional points for duration of treatment. The duration multiplier is only applied when a group member's complications/treatments total 11 points or more.

### Non-compensable losses

Points Assessments do not compensate group members for economic loss (such as loss of income or loss of earning capacity), out of pocket expenses or domestic assistance and care. Group members who are assessed under the points schedule are unlikely to have loss of earnings claims or care claims because their compensable injuries are less severe. If in the course of undertaking an assessment it is apparent that a group member has these types of claims, it is within the Administrators' discretion to determine that the group member should undergo an Individual Assessment, which compensates for economic loss and domestic care claims.

### *Example Assessments – Points Assessment*

To demonstrate how Points Assessments will operate in practice, we have prepared the following three examples based on fictional case studies.

#### Example 1

Mary is 81 years old. She received a Gynecare TVT-Exact to treat stress urinary incontinence when she was 70. In 2020, Mary experienced a recurrence of her stress urinary incontinence. She has experienced no other complications as a result of her implant.

#### Implant Details

- Gynecare TVT-Exact

#### Points

2

#### Value

\$4,000

#### Complication(s)

- Recurrent stress urinary incontinence

0

\$0

#### Age at Index Surgery

- 68+ years

0

\$0

#### Assessed Compensation Amount:

**\$4,000**

### **Example 2**

Susan is 76 years old. She received a Gynecare Prolift in 2011 when she was 62 to treat a prolapse. Soon after the implant was inserted, Susan began to experience severe pain with sexual intercourse, to the point where she would avoid intimacy with her partner. When she went to the doctor, they discovered that the mesh was protruding into Susan's vagina. The doctor trimmed the protruding mesh in their rooms with the use of local anaesthetic, and prescribed Ovestin cream. Susan has experienced no further complications.

<b>Implant Details</b>	<b>Points</b>	<b>Value</b>
• Gynecare Prolift	2	\$4,000
<b>Complication(s)</b>		
• Moderate erosion (treated in rooms with local anaesthetic)	4	\$8,000
• Severe dyspareunia	6	\$12,000
<b>Non-Surgical Treatment(s)</b>		
• Trimming of the mesh using local anaesthetic	4	\$8,000
• Ovestin cream	0.25	\$500
<b>Age at Index Surgery</b>		
• 61-67 years	1.5	\$3,000
<b>Assessed Compensation Amount:</b>		<b>\$35,500</b>

### **Example 3**

Maggie is 52 years old. In 2004, she received a Gynecare TVT implant to treat stress urinary incontinence when she was 31. In 2009, Maggie received a Gynecare Prosima implant to treat a prolapse. In 2011, Maggie began to experience a moderate level of pain in her groin and her vagina, as well as difficulty voiding. She felt her stream was very slow and she was unable to empty completely.

Maggie went back to her gynaecologist who prescribed Targin for her pain, and requested she do a urodynamics study and a cystoscopy to try and identify the cause of her voiding issues. Maggie underwent the investigative procedures, during which it was discovered that her Gynecare TVT sling had tightened and caused a kink in her urethra and was starting to erode.

It was necessary to remove the Gynecare TVT sling to address Maggie's voiding difficulty and erosion, and in 2013 Maggie had her Gynecare TVT sling removed. This surgery fixed her voiding issues, but she continues to suffer from pelvic pain and has reported her pain to her doctor regularly over that period. She also underwent a further cystoscopy to investigate the pelvic pain in 2013. Maggie has been told that her Gynecare Prosima implant is likely to be the cause of her pelvic pain but was counselled against having it removed as her doctors cannot guarantee that it will fix her pain.

<b>Implant Details</b>	<b>Points</b>	<b>Value</b>
• Gynecare Prosima	2	\$4,000
• Gynecare TVT	2	\$4,000
<i>Implant subtotal</i>	4	<i>\$8,000</i>
<b>Complication(s)</b>		
• Moderate pelvic pain (treated with prescription medication)	4	\$8,000
• Difficulty voiding	3	\$6,000
• Severe erosion	6	\$12,000
• Complications reported for more than 10 years	Double and a half points value (13 x 2.5)	
<i>Complications subtotal</i>	32.5	<i>\$65,000</i>
<b>Non-Surgical Treatment(s)</b>		
• Prescription pain medication (Targin)	3	\$6,000
• Urodynamics to investigate cause of voiding difficulty	1.5	\$3,000
• Cystoscopy (x2) to investigate cause of voiding difficulty	1.5	\$3,000
<b>Surgical Treatment(s)</b>		
• Removal of Gynecare Prosima	12.5	\$25,000
<b>Age at Index Surgery</b>		
• 31-40 years	6	\$12,000
<b>Assessed Compensation Amount:</b>		<b>\$122,000</b>

**Important Information:** the above Assessed Compensation Amounts are very likely to be adjusted to meet the amount available in the Settlement Fund. That is, in the above examples Mary, Susan and Maggie may receive less than each of their Assessed Compensation Amounts depending upon the total amount of all group members' Assessed Compensation Amounts compared to the amount available in the Settlement Fund to be distributed to group members. The percentage (%) adjustment will be the same for each group member.

## Individual Assessment Method

When a group member's level of injury and impairment is anticipated to equate to at least 33% of the 'most extreme case' pursuant to the Act, their compensation will be assessed using the Individual Assessment Method. It is expected that approximately 20% of group members will meet this criteria.

Group members who meet this level of injury and impairment are likely to have:

1. suffered numerous complications and required multiple surgeries to treat erosion or remove their implants;
2. been relatively young at the time they received their Ethicon implant;
3. a considerable economic loss claim by reason of being unable to work because of their mesh-related complications; and/or
4. a significant claim for the care and assistance they have required as a result of their complications.

The Individual Assessment Method considers the impact of the mesh-related injuries on several different aspects of the group member's life. A group member's entitlement to a range of losses will be assessed, including:

- (a) pain and suffering damages, which are referred to as "non-economic loss" or "general damages";
- (b) past and future economic loss such as loss of income or loss of earning capacity;
- (c) past and future domestic assistance and care; and
- (d) out-of-pocket expenses.

The purpose of compensation in Australian law is not to punish or make an example of the wrongdoer, or to enrich the injured person. The amount of compensation awarded to a claimant is

directly proportionate to the severity of the injury and the impact of the injury on their life and ability to work and care for themselves.

This means that compensation will vary considerably from group member to group member.

An overview of the types of losses available in an Individual Assessment are detailed below.

### General damages

General damages are damages awarded for pain and suffering, loss of amenities of life, loss of expectation of life and disfigurement. The following is a non-exhaustive list of considerations relevant to the calculation of general damages:

- the severity and intensity of the complications and the duration over which they are suffered;
- the impact of the mesh-related injuries on the group member's social, recreational, domestic and work activities;
- the impact of the injury on close personal relationships;
- the ability to control the complications with medication;
- the presence of any pre-existing medical conditions;
- loss of physical capacity because of the injury; and
- the type and invasiveness of the treatment required.

To determine a group member's general damages under the Individual Assessment Method, the Administrators will assess the percentage of the "most extreme case" and multiply that percentage against the maximum amount of damages which can be awarded under the Act.

What is the *most extreme case*?

The maximum amount of general damages that can be awarded under the Act is \$396,800. The law states that the most extreme case (i.e. the maximum amount of damages) must only be awarded where the injured person suffers pain and suffering of the “gravest conceivable kind”. This is known as the *most extreme case*. The percentage of a *most extreme case* attributed to a group member’s injury will be determined by the Administrators with regard to their personal circumstances in accordance with legal principles.

Please note that the *most extreme case* is not limited to pelvic mesh complications and the claims made under the Scheme will be considered by reference to other types of significant injuries. An example of an injury representing the *most extreme case* is below.

**Example 1:** Pain and suffering which might be deemed a most extreme case:

Tina, aged 30, was injured in a road accident. She suffered a high spinal cord injury and a brain injury. Tina is now paralysed and relies upon a ventilator to breathe. While Tina is conscious and is aware of her injury, she will never walk, communicate or work again. Tina’s life expectancy has also been reduced and she does not have a prospect of recovery. Tina’s injury is likely to be assessed as a most extreme case and will be awarded the maximum damages.

The Administrators do not anticipate that any group members will be awarded the maximum under the Act (100% of the most extreme case).

Annexure C to this Handbook has two case studies which show examples of group members who would be assessed under the Individual Assessment Method.

### **Out-of-pocket expenses**

A group member is entitled to claim compensation for out-of-pocket expenses incurred by virtue of their mesh-related complications.

Group members whose claims are assessed via Individual Assessments will have their claims for out-of-pocket expenses determined separately. These expenses may include:

- gap fees associated with seeing their treating GP or other specialist;
- travel expenses associated with attending medical appointments or obtaining medication or assistance required as a result of their complications;
- purchasing medication; and
- purchasing aids such as incontinence pads or catheters.

Past out-of-pocket expenses are calculated by reference to documentary evidence of the expenses, such as receipts.

**IMPORTANT INFORMATION** - Please do not send the Administrators evidence of your out-of-pocket expenses. The Administrators will contact group members identified for Individual Assessments and collect all relevant data separately.

Future out-of-pocket expenses relate to the anticipated expenses the group member will incur in the future because of their mesh-related complications.

**IMPORTANT INFORMATION** - No direct payments will be made by the Administrators for your mesh-related treatments. Please do not send invoices for treatment to the Administrators to pay.

### **Economic loss**

Economic loss compensation is intended to put the group member back in the same position they would have been in if their mesh-related injuries had not affected their ability to undertake paid employment. This head of damage takes account of periods during which a group member could not work or had reduced capacity to work as a

result of their mesh-related complications. It also makes an allowance for the loss of superannuation resulting from the reduced capacity to undertake paid employment.

In order to make a claim for economic loss, it is necessary to identify the earning capacity which has actually been lost. The evidence (including tax and employment records) will need to show what the group member would have earned if they had not received the Ethicon implant and compare that to what they did earn. Cash income that is not reflected in a tax return will not be taken into account.

**IMPORTANT INFORMATION** - Do not send us your tax returns or any economic loss related information. If you are identified for an Individual Assessment, we will collect this information from you separately.

#### **Domestic care and assistance**

In certain circumstances, a group member may be compensated for domestic care and assistance (also called “gratuitous care and assistance”). This is care and assistance that is voluntarily provided by a group member’s family, household, or by a friend. The care relates to tasks that the group member previously undertook prior to sustaining the mesh-related complications, but because of mesh-related complications, the group member now requires assistance.

**IMPORTANT INFORMATION** – care and assistance required by a group member due to the natural aging process or a different injury or condition will not be compensated. If awarded compensation for this head of damage, the group member is not required to repay the person whose gratuitous or voluntary services they accepted.

The cost of past and future domestic care provided on a commercial basis may be recoverable if it was or will be a cost reasonably incurred as a result of their complications. The

cost will necessarily be compensated at a lower level than that at which it was incurred, primarily as a consequence of the compromised nature of the settlement.

**IMPORTANT INFORMATION** – it is expected that only a small percentage of group members will receive compensation for domestic care and assistance.

#### **Future loss**

Any future losses, such as loss of earnings or treatment can be recovered but will be discounted to reflect the fact that the loss has not yet been incurred and that the future is uncertain. This discounting process is standard for all personal injury matters and is not unique to the Scheme.

#### **Assessment**

When your claim is ready to be assessed, the Administrators will gather the information and evidence relevant to assessing your compensation. The following steps may occur throughout this period:

- (a) the Administrators may contact you to obtain further instructions or information about your claim;
- (b) with your consent, the Administrators may contact another person (such as a family member or friend) to obtain further information about your claim;
- (c) the Administrators will determine what documents are required to enable the assessment of each claim, these may include:
  - any additional medical records which were not obtained during the eligibility assessment process;
  - tax returns, or other tax, accounting or financial documents;
  - employment records; or

- invoices regarding any treatment or other expenses;

(d) in limited situations, the Administrators may obtain a report from either a treating doctor or from an independent medical practitioner. However, the Scheme is designed to enable the majority of assessments to be undertaken without the need to obtain treating or specialist reports;

(e) once the Administrators have all the information they require, they will determine the amount of compensation you are entitled to receive. The Individual Assessment will be done in accordance with the legal principles for assessing personal injury damages under the Act; and

(f) the Administrators will send you a Notice of Assessment that sets out your compensation entitlement and your rights in relation to seeking a review of the determination.

**IMPORTANT INFORMATION** – Do not be concerned if we request information from another group member that is different to the information we have requested from you. Each group member's claim is different and therefore, it is to be expected that different information will be required from different group members.

## Repayments to Centrelink, Medicare, NDIA and Private Health Insurers

The obligations and process for paying liens is set out in the Scheme.

The Settlement Sum is inclusive of amounts to be repaid to Medicare, Centrelink, National Disability Insurance Agency (NDIA), the Department of Veterans Affairs (DVA) and private health insurers.

**IMPORTANT INFORMATION** – Any repayments to be made on your behalf to government departments and private health insurers will **not** be deducted from your individual compensation amount – rather these liens will be determined and paid from the Settlement Fund.

**IMPORTANT INFORMATION REGARDING MEDICARE AND PRIVATE HEALTH INSURERS** – We have reached agreement with the Commonwealth Government regarding a bulk payment agreement which will govern the repayment of Medicare benefits as a lump sum and which will be deducted from the Settlement Fund. This means that an individual group member's Assessed Compensation Amount will **not** be reduced by reference to the Medicare benefits they have received. The Administrators intend to negotiate similar agreements with private health providers in respect of benefits received by group members from their private health funds.

**IMPORTANT INFORMATION REGARDING CENTRELINK** – Please note that while any repayment to Centrelink will be paid from the Settlement Fund, individuals may still have a preclusion period, during which you will be unable to receive further benefits. The Administrators will liaise with Centrelink to both calculate any repayment amount, which will be deducted from the Settlement Fund and to identify any preclusion period which will be communicated to you.

All group members in receipt of compensation who are in receipt of Centrelink Income Support Payments or a concession card, need to inform Services Australia of the compensation received (including the first interim payment of \$4,000). When notifying Services Australia, please ensure that you advise that you are part of the Ethicon

Pelvic Mesh Settlement Administration. Information is available on Services Australia's website ([www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)) to support group members to understand their obligations, including how to notify of a change in circumstances.

The Administrators will contact group members who undergo an Individual Assessment and are entitled to a claim for economic loss to discuss:

- the potential repayment obligation;
- any potential preclusion period;
- the group member's ability to elect to receive economic loss compensation; and
- the notification process agreed with Centrelink for those group members who wish to receive their claim for economic loss.

### **IMPORTANT INFORMATION**

**REGARDING NDIS** - A similar process applies to the NDIA as to Centrelink. That is, while any repayment to the NDIA will be paid from the Settlement Fund (and not your Individual Assessment amount), the NDIA may make an adjustment to your plan, called a 'compensation reduction amount'.

Please be aware that just because a group member receives Centrelink or NDIA benefits, it does not mean that there will be a repayment amount or a preclusion period/compensation reduction amount. The Administrators are conferring with Centrelink and the NDIA regarding these issues and will communicate any preclusion period (Centrelink) or compensation reduction amount (NDIA) to you.

Further information about how your payments may be affected can be found at:

- Centrelink:  
[https://www.servicesaustralia.gov.au/centrelink-compensation-recovery](http://www.servicesaustralia.gov.au/centrelink-compensation-recovery)

- NDIA:  
<https://www.ndis.gov.au/participants/compensation-and-your-plan/recovery-compensation-reduction-amounts-and-special-circumstances>

You may be asked to assist the Administrators in the process of identifying potential liens, for example, by providing details of your private health insurance arrangements.

### **IMPORTANT INFORMATION**

**REGARDING DVA** – The Administrators are not currently aware of any group members who are in receipt of DVA benefits in respect of mesh-related injuries. If however you are in receipt of DVA benefits, including treatment expenses, for your mesh-related injuries, or conditions related to those injuries, you are obligated to notify the Administrators, and you should do so by contacting us at 07 4158 8772 or via email at:

[enquiries@meshsettlementadmin.com.au](mailto:enquiries@meshsettlementadmin.com.au) and providing details of your DVA entitlements.

### **Tax**

Monies received for compensation or damages relating to personal injuries are generally not taxable as it does not fall under the category of assessable income.

**IMPORTANT INFORMATION** - Please note, we cannot provide you with financial or tax advice and recommend that you speak with your tax adviser about this.

### **Information for Estates**

The Administrators will communicate with the person authorised to represent a group member's estate. To establish the identity of this person and their authority to represent the estate, the Administrators may request copies of the following documents:

- the death certificate;

- any last will or testament; and
- any letters of administration or probate obtained.

In addition, we will require a statutory declaration from the person with the relevant authority of the estate to receive the compensation.

Please note that letters of administration or probate will be required where the amount of compensation to be paid to the estate exceeds \$20,000. Authorised persons will be advised if letters of administration or probate is required once assessments are complete.

## Payments

The Administrators presently intend to make a second interim payment to eligible group members. This is anticipated to occur after the Administrators have assessed:

- (a) a sufficient proportion of group member claims to estimate the totality of group

member compensation which is likely to be awarded under the Scheme; and

- (b) the total amount of money required to be repaid to Centrelink, Medicare, NDIA and the private health insurers.

This is to ensure that there will always be sufficient funds available to pay all group members their (proportional) share of the Settlement Funds. This ensures that all group members will be treated fairly and equally regardless of when their compensation is assessed. The Administrators will rely upon actuarial advice to ensure that the settlement sum is distributed equitably amongst group members and to permit the Administrators to make interim payments whilst maintaining enough funds available to complete the administration including payment of all liens.

## Your obligations under the Scheme

The Scheme imposes obligations on group members in order to ensure an efficient, effective and fair administration of the Settlement. It is important that you comply with these obligations.

As a group member, your obligations under the Scheme are to:

- cooperate with the Administrators and take all steps that you are required to under the Scheme and/or that are reasonably requested by the Administrators;
- act honestly when communicating with the Administrators and ensure that anyone representing or helping you, such as a family member, also acts honestly; and
- comply with all requirements of the Scheme and the requests of the Administrators to the best of your ability and within the timeframe specified by the Administrators.

The actions or steps that the Administrators may require you to take in order to process your claim include:

- providing instructions, information, documents or other materials;
- providing authorities or permissions;
- participating in telephone conferences with the Administrators;
- promptly informing the Administrators of any change in your contact details; and
- signing documents.

### **The consequences of not complying with your obligations**

If you do not comply with your obligations under the Scheme, the Administrators may:

- assess your claim without the benefit of the requested information;
- determine that you are not eligible to participate in the Scheme;
- reduce the amount of compensation that you are entitled to receive;
- determine and make final compensation payments to other group members (notwithstanding that group members have not yet had their claims determined or compensation paid due to their non-compliance); and
- determine that your compensation is nil (\$0).

The Administrators appreciate group members' prompt assistance which is necessary to ensure that the settlement distribution is not unduly delayed. Final compensation payments are unable to be made until all group member claims have been assessed.

## Annexure A – Eligibility Criteria

To be assessed as an eligible group member, you must meet all of the following four criteria:

### 1. Implant Criteria

You were implanted, in Australia, with one or more of the tape and pelvic mesh implants listed below on any date up to and including 14 July 2021 (see complete list in Annexure B):

- Gynecare Prolift Pelvic Floor Repair Systems (Anterior, Posterior and Total);
- Gynecare Prosima Pelvic Floor Repair Systems (Anterior, Posterior and Combined);
- Gynecare Prolift+M Pelvic Floor Repair Systems (Anterior, Posterior and Total);
- Gynecare TVT;
- Gynecare TVT - Abbrevo;
- Gynecare TVT – Secur;
- Gynecare TVT Exact;
- Gynecare TVT - Obturator; and
- Gynemesh PS Nonabsorbable polypropylene Mesh.

(collectively, the **Ethicon Mesh Devices**).

### 2. Complication Criteria

You must have suffered at least one complication prior to 14 July 2021 that is attributable to your Ethicon Pelvic Mesh implant. Evidence of this complication must be identifiable in your medical records.

### 3. Participation Criteria

You must not have previously opted out of the proceedings or reached an individual settlement of your claim with Ethicon and/or Johnson & Johnson.

### 4. Registration Criteria

You must have also registered your interest to participate in this settlement by the Claim Deadline detailed in the Settlement Scheme, or were given permission by the Administrators to register your claim after the Claim Deadline.

## Annexure B – List of Implants

<b>Implant</b>		<b>UPN</b>
<b>POP Implants</b>		
1	Gynemesh PS	JJ790
2	Gynecare Prosima (Anterior, Posterior and Combined)	JJ676, JJ745
3	Gynecare Prolift, (Anterior, Posterior and Total)	JJ476, JJ477, JJ478
4	Gynecare Prolift+M (Anterior, Posterior and Combined)	JJ476, JJ477, JJ478, JJ747, JJ748
<b>SUI Implants</b>		
5	Gynecare TVT	81008141B, 810041BL
6	Gynecare TVT-Exact	TVTRL, JJ070
7	Gynecare TVT-Obturator	810081L, JJ442
8	Gynecare TVT-Abbrevo	MN039, TVTOML
9	Gynecare TVT-Secur	TVTS

## Annexure C – Individual Assessment Case Studies

### Example 1

#### **‘Kelsey’**

Kelsey was born in 1975 and began horse riding at the age of 10. On weekends, she competed in show jumping and won several State championships and two Australian championships. She ceased competing in show jumping when she started her family, however she still enjoyed horse riding weekly. She enjoyed camping and fishing with her family. She regularly swam and jogged.

After the birth of her second child, Kelsey was diagnosed with prolapse. In January 2013 at the age of 36 years old, Kelsey underwent surgery to treat the condition, which included insertion of the Gynecare Prolift mesh implant. Following the surgery, Kelsey experienced severe pain. Around six months later, she could feel something sharp inside her vagina. After investigations, she found out that the mesh implant had eroded and a piece of mesh was piercing her anterior vaginal wall. In September 2013, Kelsey underwent the first of three operations to excise portions of eroded mesh. In June 2014 and August 2018 Kelsey underwent further revision surgeries necessitated by the erosion of her Prolift implant.

Additionally, Kelsey’s medical providers have diagnosed the following complications as a result of her mesh implant:

- recurrent cystocele;
- recurrent rectocele;
- chronic inflammatory reaction to her mesh implant;
- dyspareunia;
- constant pelvic cramp-like pain;
- constant lower back/sacral pain;
- tenderness in the vaginal vault;
- right groin pain;
- faecal incontinence on a weekly or fortnightly basis;
- stress urinary incontinence;
- urge urinary incontinence;
- constant anxiety; and

- panic attacks.

The mesh-related complications have impacted Kelsey's life greatly. For example, as a result of the above complications she:

- needs to digitate to push her prolapse back into place;
- is unable to drive for more than 1-2 hours;
- is unable to sit for more than 30 minutes without experiencing pain;
- is unable to stand for more than 30 minutes without experiencing pain;
- is unable to run;
- is unable to walk more than 2km;
- avoids stairs;
- avoids heavy lifting;
- avoids grocery shopping (she pays for her groceries to be delivered);
- has had to alter her career path to better suit her toileting needs;
- has needed to reduce her working days to three. She spends her days off recovering from the pain and exhaustion she experiences;
- is unable to engage in outdoors activities with her family (eg. camping) and has had to ration time spent engaged in family activities. This has impacted upon her relationship with her young sons;
- is unable to participate in horse riding which has been her passion;
- has difficulty transferring in and out of bed/lounge chairs/motor vehicles;
- has had a significant diminution in the ability to engage in sexual intercourse, which has detrimentally impacted her relationship with her husband and led to the breakdown of her marriage; and
- needs to ingest opioid, non-opioid and neuropathic analgesics, non-steroidal anti-inflammatory drugs (NSAIDs), selective serotonin reuptake inhibitor (SSRI), tranquillisers and dietary supplements daily to control her pain.

## Example 2

### **‘Janet’**

Janet is 42 years old. In 2010, she received an Gynecare TVT implant to treat stress urinary incontinence. Immediately following her surgery, she was unable to void without the assistance of a catheter, and two days later Janet underwent surgery to loosen the tension of the sling.

In December 2012, Janet experienced a recurrence of her stress urinary incontinence. Janet went back to her urogynaecologist, who referred her for urodynamics which confirmed the recurrence of her stress incontinence. As a result of this, Janet’s specialist recommended she undergo another sling procedure and in February 2013 Janet received a Gynecare TVT-Obturator implant to treat her recurrent stress incontinence. In the same procedure, Janet also received a Prosima implant to treat a rectal prolapse.

Within days of the surgery Janet reported severe pelvic pain, which radiated down her thighs. At her six-week follow-up appointment, she was reassured that this pain was a normal part of recovery and was prescribed codeine to manage the pain. The pain did not subside and in June 2013 she began experiencing severe pain with sexual intercourse, burning vaginal discomfort and spotting.

A pelvic exam revealed that the mesh had eroded through the vaginal wall and in July 2013, Janet underwent surgery to excise a portion of the exposed mesh. Janet’s pain persisted, and she began to experience recurrent urinary tract infections and her bladder dysfunction worsened.

In October 2013, Janet underwent a cystoscopy to diagnose the source of her pain and bladder dysfunction. The cystoscopy revealed mesh embedded in the urethra and the bladder wall. In November 2013, Janet underwent further surgery to remove the mesh from the urethra and bladder and repair the damaged tissue. The surgical team excised what they could but Janet experienced significant haemorrhaging, and they were unable to remove all of the mesh.

Following the surgery Janet began experiencing severe nerve pain, which was eventually diagnosed as pudendal neuralgia – a chronic neuropathic condition marked by intense, burning pain in the pelvic region caused by the residual mesh. This made sitting, walking and intercourse excruciating and Janet’s mobility declined rapidly; she became reliant on a wheelchair and oxycodone to manage her pain.

Janet’s mental health also deteriorated, resulting in a diagnosis of major depression and post-traumatic distress disorder (PTSD) due to her ongoing pain and medical trauma. Her intimate relationship with her husband suffered due to worsening dyspareunia (painful intercourse) and loss of physical intimacy. She was forced to leave her career in nursing and began receiving disability benefits.

In May 2013, Janet was referred to a pain specialist who recommended neuromodulation. To manage the nerve pain, Janet underwent a sixth surgery involving the implantation of a sacral nerve stimulator. During this procedure surgeons also attempted targeted removal of mesh tissue suspected to be irritating the pudendal nerve. This surgery yielded only marginal relief and Janet's neuropathic pain persisted, compounded by side effects from chronic opioid use and nerve medications.

In July 2015, Janet developed severe bowel symptoms including faecal incontinence, constipation, bloating and shooting rectal pain. Investigations including a colonoscopy revealed that fragments of the posterior prolapse mesh had eroded and migrated, perforating her colon and causing infection.

Janet was rushed into surgery, where surgeons removed a portion of her colon and, due to the contamination and loss of bowel integrity, performed a permanent colostomy, creating a stoma through which waste exited into an external colostomy bag.

In 2016, Janet travelled to the nearest Pelvic Mesh Clinic for an eighth surgery in a final effort to reclaim some quality of life. Surgeons discovered multiple mesh fragments intertwined with her bladder, urethra, bowel, rectum, pelvic floor muscles and major nerves. Some of the mesh was so deeply embedded that removal posed high risks of permanent nerve damage or loss of organ functions and as such, complete excision was impossible. Janet was warned that any further surgical attempts could result in loss of bladder control entirely.

Janet continues to live with a wide range of severe and permanent complications. She has chronic pelvic pain, which is constant and severe, described as burning, stabbing and radiating into her lower back, inner thighs and perineum. This pain is largely a result of irreversible nerve damage caused by the original mesh erosion and the trauma of repeated surgical interventions. Janet is unable to sit or stand for prolonged periods and relies on a wheelchair for mobility. Despite sacral nerve stimulation and regular nerve blocks, Janet remains dependent on high-dose opioid medications and neuropathic pain treatments.

The nerve damage, scar tissue and physical pain have rendered sexual activity impossible. Janet continues to suffer from profound bladder dysfunction. She experiences ongoing incontinence, incomplete emptying and chronic recurrent urinary tract infections. With the removal of a portion of her colon, she now lives with a permanent colostomy bag. She receives regular psychological counselling and takes multiple medications to manage her PTSD, major depression and anxiety.

Janet is permanently disabled. She is unable to return to her career as a registered nurse and now relies on disability benefits and in-home care. Her energy levels are severely limited, and even routine daily tasks often require assistance.

Socially, Janet has experienced the collapse of her marriage, loss of friendships and deep isolation due to her limited mobility and emotional state. She avoids social gatherings out of fear of incontinence or complications with her colostomy bag.