

OPT OUT NOTICE
FEDERAL COURT OF AUSTRALIA

Pelvic Mesh & Tape Class Action

Kathryn Gill & Ors v Ethicon Sàrl, Ethicon, Inc. and Johnson & Johnson Medical Pty Limited
NSD 1590 of 2012

1. Why is this notice important?

A class action has been commenced in the Federal Court of Australia by Kathryn Gill (the **First Applicant**), Diane Dawson (the **Second Applicant**) and Ann Sanders (the **Third Applicant**) against Ethicon Sàrl (the **First Respondent**), Ethicon, Inc. (the **Second Respondent**) and Johnson & Johnson Medical Pty Limited (**JJM Australia**) (the **Third Respondent**). The class action arises out of allegations concerning pelvic mesh and tape implants manufactured by Ethicon Sàrl or Ethicon, Inc. and distributed in Australia by JJM Australia. The allegations are explained in more detail in section 5 of this notice.

The Federal Court has ordered that this notice be published for the information of women who were not previously class members in this class action but now, by reason of an amendment to the proceeding, might be members of the class on whose behalf the action is brought and, if so, would be affected by the action. **You should read this notice carefully. Any questions you have concerning the matters contained in the notice should not be directed to the Court.** If there is anything in it that you do not understand, you should seek legal advice.

2. Persons already class members

Before the amendment to the proceeding, you were already a class member if, on or before 15 October 2012:

- you had surgery performed on you in Australia to implant one or more of the following products:
 - Gynecare Gynemesh PS;
 - an implant contained in the Gynecare Prolift Total, Anterior and/or Posterior Pelvic Floor Repair System;
 - an implant contained in the Gynecare Prosima Anterior, Posterior and/or Combined Pelvic Floor Repair System;
 - an implant contained in the Gynecare Prolift +M Total, Anterior and/or Posterior Pelvic Floor Repair System;
 - an implant contained in the TVT Tension-Free Vaginal Tape System;
 - an implant contained in the TVT Abbrevio Continence System;
 - an implant contained in the TVT Obturator System;

- an implant contained in the TVT Secur System;
- an implant contained in the TVT Exact System; and
- you suffered one or more complications as a result of that surgery; and
- you have not previously opted out of this proceeding.

If you were already a class member before the amendment to the proceeding, your rights are not affected by the amendment and you need not take any further action.

3. Persons who have become class members by reason of the amendment to the proceeding

You have become a class member by reason of the amendment of the proceeding if:

- you had surgery performed on you in Australia at any time before 4 July 2017 to implant one or more of the following products:
 - Gynecare Gynemesh PS;
 - an implant contained in the Gynecare Prolift Total, Anterior and/or Posterior Pelvic Floor Repair System;
 - an implant contained in the Gynecare Prosima Anterior, Posterior and/or Combined Pelvic Floor Repair System;
 - an implant contained in the Gynecare Prolift +M Total, Anterior and/or Posterior Pelvic Floor Repair System;
 - an implant contained in the TVT Tension-Free Vaginal Tape System;
 - an implant contained in the TVT Abbrevio Continence System;
 - an implant contained in the TVT Obturator System;
 - an implant contained in the TVT Secur System;
 - an implant contained in the TVT Exact System; and
- you first suffered one or more complications as a result of that surgery in the period **after 15 October 2012 and before 4 July 2017.**

If you may have become a class member by reason of the amendment of the proceeding, you should read this notice carefully. If there is anything in this notice which you do not understand you should seek legal advice.

4. What is a class action?

A class action is an action that is brought by one or more persons (the **Applicants**) on their own behalf and also on behalf of a class of people (**class members**) against one or more other persons (the **Respondents**) where the Applicants and the class members have similar claims against the Respondents.

Class members in a class action **are not** individually responsible for the legal costs associated with bringing the class action. In a class action, only the Applicants are responsible for the costs.

Class members are “bound” by the outcome in the class action, unless they have opted out of the proceeding. A binding result can happen in two ways being either a *judgment* following a trial, or a *settlement* at any time. If there is a judgment or a settlement of a class action class members *will not* be able to pursue the same claims and *may not* be able to pursue similar or related claims against the respondents in other legal proceedings. Class members should note that:

- (a) In a *judgment* following trial, the Court will decide various factual and legal issues in respect of the claims made by the applicants and class members. Unless those decisions are successfully appealed they bind the applicants, class members and the respondents. Importantly, if there are other proceedings between a class member and the respondents, it is likely that they will not be permitted to raise arguments in that proceeding which are inconsistent with a factual or legal issue decided in the class action.
- (b) In a *settlement* of a class action, where the settlement provides for compensation to class members it is likely to extinguish *all* rights to compensation which a class member might have against the respondents which arise in any way out of the events which are the subject-matter of the class action.

If you consider that you have claims against one or more of the respondents which are based in your individual circumstance or otherwise additional to the claims described in the class action, then it is important that you seek independent legal advice about the potential binding effects of the class action **before** the deadline for opting out (see below).

5. What is this class action?

This class action, the Pelvic Mesh and Tape Class Action, is brought by each of Kathryn Gill, Diane Dawson and Ann Sanders on their own behalf and on behalf of all persons who are class members as defined in the proceeding. The term “group members” is used in the documents filed in this proceeding to describe those persons who are class members.

The Applicants’ allegations are set out in the Fifth Further Amended Statement of Claim in Federal Court Proceeding NSD 1590 of 2012. The allegations in this class action relate to mesh and tape implants included in the following surgical systems:

- (A) the Gynecare Prolift Total, Anterior and Posterior Pelvic Floor Repair System;
- (B) the Gynecare Prosima Anterior, Posterior and Combined Pelvic Floor Repair System;
- (C) the Gynecare Prolift +M Total, Anterior and Posterior Pelvic Floor Repair System;
- (D) the TVT Tension-Free Vaginal Tape System;
- (E) the TVT Abbrevio Continence System;
- (F) the TVT Obturator System; and

(G) the TVT Secur System.

(H) the TVT Exact System.

The allegations in the class action also relate to Gynecare Gynemesh PS implants.

Collectively, all of these implants are referred to in this Notice as the **Products**. The Products were manufactured by Ethicon Sàrl or Ethicon, Inc. and distributed in Australia by JJM Australia.

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

The Applicants claim that they and class members suffered loss and harm as a result of the Respondents' conduct in connection with the Products and that they and class members are therefore entitled to damages.

The Respondents to the class action are Ethicon Sàrl, Ethicon, Inc. and JJM Australia. The Respondents deny the allegations and are defending the class action.

6. What is Opt Out?

The Applicants in a class action do not need to seek the consent of class members to commence a class action on their behalf or to identify a specific class member. However, class members can cease to be class members by opting out of the class action. An explanation of how class members are able to opt out is found below in the section headed "How can you opt out of the proceeding?".

7. Are you a class member?

You are a class member if you had surgery performed on you in Australia to implant one or more of the Products listed in this Notice and you have suffered complications as a result **before 4 July 2017**.

If you are unsure whether or not you are a class member, you should contact the Applicants' lawyers, Shine Lawyers (whose contact details are set out below), or seek your own legal advice without delay.

8. Will you be liable for legal costs if you remain a class member?

You will **not become liable for any legal costs** simply by remaining a class member for the determination of common issues. **However:**

- (a) if the preparation or finalisation of your personal claim requires work to be done in relation to issues that are specific to your claim, you can engage the Applicants' lawyers or other lawyers to do that work for you. A copy of the terms on which the Applicants' lawyers are acting in the class action may be obtained from them by contacting them on the details set out below; and

- (b) if any compensation becomes payable to you as a result of any order, judgment or settlement in the class action, the Court may make an order that some of that compensation be used to help pay a share of the costs which are incurred by the Applicants in running the class action but which are not able to be recovered from Ethicon Sàrl, Ethicon, Inc. or JJM Australia; and
- (c) class actions are often settled out of court. If this occurs in the class action, you may be able to claim from the settlement amount without retaining a lawyer.

9. What will happen if you choose to remain a class member?

Unless you opt out, you will be bound by any settlement or judgment of the class action. If the class action is successful you will be entitled to share in the benefit of any order, judgment or settlement in favour of the Applicants and class members, although you may have to satisfy certain conditions before your entitlement arises. If the action is unsuccessful or is not as successful as you might have wished, you will not be able to pursue the same claims and may not be able to pursue related claims against the Respondents in other legal proceedings.

10. What class members need to do

a. How can you remain a class member?

If you wish to remain a class member there is nothing you need do at the present time. The Applicants will continue to bring the proceeding on your behalf up to the point where the Court determines those questions that are common to the claims of the Applicants and the class members. However, you are invited to contact the Applicants' lawyers, Shine Lawyers, on the number below and register as a class member so that future notices about the class action can be sent to your preferred address.

b. How can you opt out of the class action?

If you were already a class member before the amendment to the proceeding, you are no longer able to opt out of the class action.

If you have become a class member by reason of the amendment of the proceedings and you do not wish to remain a class member you must opt out of the class action. If you opt out you will not be bound by or entitled to share in the benefit of any order, judgment or settlement in the class action, but you will be at liberty to bring your own claim against the Respondents provided that you issue Court proceedings within the time limit applicable to your claim. If you wish to bring your own claim against the Respondents, you should seek your own legal advice about your claim and the applicable time limit **before** opting out.

If you wish to opt out of the class action you **must** do so by completing a **"Notice of opting out by a class member"** in the form shown below (Form 21 of the Court's approved forms), then returning it to the Registrar of the Federal Court of Australia at the address on the form. **IMPORTANT: the Notice must reach the Registrar by no later than 4:30pm on 11 May 2018** otherwise it will not be effective.

You should submit the Notice of opting out by a class member if:

- i. you qualify as a class member and you wish to opt out of the class action; or
- ii. you believe that you have been incorrectly identified as a class member, because you do not meet the criteria set out in the section headed “Are you a class member” above.

Each class member seeking to opt out should fill out a separate form.

11. Limitation Period

Limitation periods are set by statute. If a person with an entitlement to a claim does not commence legal proceedings by the time a limitation period expires, they may be barred from making a claim.

The commencement of this class action suspended the limitation periods for all class members who have not opted out. Time starts to run again once a person opts out of the class action. If you opt out of the class action and the statutory time limit on your claim expires, or is found to have already expired because you are no longer covered by the class action, you will be barred from bringing proceedings against Ethicon Sàrl, Ethicon, Inc. or JJM Australia in Court. This will depend on your particular individual circumstances.

Again, if you wish to bring your own claim against Ethicon Sàrl, Ethicon, Inc. or JJM Australia in Court, you should seek your own legal advice about your claim and the applicable time limit **before** opting out.

12. Where can you obtain copies of relevant documents?

Copies of relevant documents, including the application, the Fifth Further Amended Statement of Claim, and the defence to the Fifth Further Amended Statement of Claim, may be obtained by:

- (a) downloading them from www.shine.com.au/service/class-actions/prolapse-mesh-class-action/;
- (b) inspecting them, by appointment, between 9.00am and 5.00pm at an office of Shine Lawyers, details for which are available by calling **13 11 99**;
- (c) by contacting a District Registry of the Federal Court (contact details are available at www.fedcourt.gov.au) and paying the appropriate inspection fee; or
- (d) where appropriate arrangements have been made with the Court, inspecting them on the Federal Court website at <http://www.fedcourt.gov.au/law-and-practice/class-actions/class-actions/documents#nsd1590of2012>.

Please consider the above matters carefully. If there is anything of which you are unsure, you should contact the Applicants’ lawyers, Shine Lawyers, through their website at www.shine.com.au/service/class-actions/prolapse-mesh-class-action/ or by calling **13 11 99** or seek your own legal advice. You should not delay in making your decision.

Opt out notice

No. NSD 1590 of 2012

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

Kathryn Gill and others

Applicants

Ethicon Sàrl and others

Respondents

To: The Registrar
Federal Court of Australia
NSW District Registry
Queens Square
Sydney 2000

Name of group member:,
a group member in this representative proceeding, gives notice under section 33J of the
Federal Court of Australia Act 1976, that
is opting out of the representative proceeding.

Date:

Signed:

Name:

Capacity: [eg group member / lawyer for group member]

Filed on behalf of (name & role of party)

Prepared by (name of person/lawyer)

Law firm (if applicable)

Tel

Fax

Email

Address for service

(include state and postcode)