



FEDERAL COURT OF AUSTRALIA

OPT OUT AND SETTLEMENT NOTICE

Exactech Class Action

Simon Harrold v Exactech Australia Pty Ltd ACN 146 150 754 & Anor
Federal Court Proceedings NSD 1224/2024

The Federal Court of Australia has ordered that this notice be published for the information of persons who might be class members on whose behalf the action is brought and may be affected by this class action.

PLEASE READ THIS NOTICE CAREFULLY, AS IT MAY AFFECT YOUR LEGAL RIGHTS

1. *Why is this Notice important?*

- 1.1. A class action has been commenced in the Federal Court of Australia by Simon Harrold (**the Applicant**) against Exactech Australia Pty Ltd (**Exactech AUS**) and Exactech, Inc. (a US-based corporation, **Exactech US**) (together, **Exactech Respondents**). The class action arises out of the manufacture and supply of hip, knee and shoulder prostheses to members of the public (**the Class Action**). The lawyers running the case on behalf of the Applicant are Gerard Malouf & Partners (**GMP Law**).
- 1.2. The parties to the Class Action have reached a settlement which, if approved by a Judge of the Federal Court of Australia (**the Court**), will resolve the claims of the Applicant and the members of the class on whose behalf the action is brought (**Class Members**).
- 1.3. The Court has ordered that this Notice be published for the information of Class Members. This Notice provides information about the settlement, and about the options available to Class Members to register to participate in the settlement or to opt out of the Class Action.
- 1.4. You are receiving this Notice because you have been identified as a potential Class Member. You should read this Notice carefully.
- 1.5. Any questions you have concerning the matters contained in this Notice should not be directed to the Court. If you have questions arising from this Notice, you should contact



GMP Law using the contact information provided in section 8 below, or seek your own legal advice before the Class Deadline of 10 July 2025.

2. Are you a Class Member?

- 2.1. You are a Class Member if you underwent a total knee, hip, or shoulder joint replacement surgery which included the implantation of an Affected Device (which are listed in **SCHEDULE A** below), in the period from 1 January 2003 to 5 September 2024
- 2.2. If you are unsure whether or not you are a Class Member, you should contact GMP Law.

3. What is a class action?

- 3.1. A class action is a legal proceeding brought by one person (who is the applicant) on their own behalf and on behalf of a class of people who have similar claims against the same respondent.
- 3.2. Class members can cease to be class members by opting out of the class action. An explanation of how class members can opt out is found in section 8 below.
- 3.3. 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:
 - (a) a judgment following a trial; or
 - (b) a settlement of the claim.
- 3.4. In this case the parties have reached a settlement. If the Court approves that settlement the consequences for Class Members who do not opt out are:
 - (a) the Court will make orders in relation to how the compensation sum is to be distributed among Class Members, and the amount that the Applicant's lawyers will be paid.
 - (b) the settlement will extinguish all rights to compensation which a Class Member might have against the respondent in relation to the events the subject of the Class Action and, for Class Members who register, replace those rights with a right to receive a payment from the Settlement Amount.
 - (c) a Class Member who has not opted out will not be able to pursue the same claims and may not be able to pursue similar or related claims against the Exactech Respondents in other legal proceedings.

3.5. If you consider that you have claims against Exactech that are based on your individual circumstances 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 opt out deadline (see sections 6 and 8 below).

3.6. Class Members are **not** individually responsible for the legal costs associated with bringing the class action. In a class action, only the applicant is responsible for the costs. An explanation of how legal costs are payable in a class action can be found in section 5 below.

4. What is this Class Action?

4.1. This Class Action is brought by Simon Harrold, the Applicant, on his own behalf and on behalf of all persons who are class members as defined in the proceeding.

4.2. This Class Action alleges that from 1 January 2003, Exactech supplied consumers (the Class Members) with defective polyethylene inserts used in hip, knee, and shoulder joint replacement devices which caused damage, including personal injuries; anguish, distress and disappointment; and economic losses such as out-of-pocket medical costs and loss of income.

4.3. The Exactech Respondents deny liability for these claims.

5. There are no 'out-of-pocket' costs for you to participate in the Class Action

5.1. You will not become liable for any legal costs simply by remaining a Class Member. 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 GMP Law or other lawyers to do that work for you. A copy of the terms on which GMP Law are acting in the Class Action may be obtained from them using the information shown in section 8 below;
- (b) if any compensation becomes payable to you as a result of the Class Action, the Court may make an order that some of that compensation is used to pay a share of the costs which are incurred by the Applicant in running the Class Action; and
- (c) class actions are often settled out of court, as has occurred in this case. If the proposed settlement is approved, including the proposed Settlement Distribution Scheme, it is intended that you will be able to claim compensation under the Scheme without retaining solicitors.

6. *Settlement of the claims*

- 6.1. The parties entered into settlement negotiations at an early stage of the proceeding.
- 6.2. The decision to explore settlement early was driven by events arising shortly after the proceeding was commenced. On 29 October 2024, Exactech US filed for bankruptcy protection in the United States under Chapter 11 of the US Bankruptcy Code (Case No. 24-12441). US Chapter 11 is an insolvency process governed by US law that provides certain protections to Exactech US, including a worldwide stay of proceedings against Exactech US in the United States of America for the duration of the Chapter 11 Case, and which in due course will release claims against Exactech US that arose before the Chapter 11 filing whether or not a proof of claim is lodged in the Chapter 11 Case. The time for lodging a proof of claim in the Chapter 11 Case has passed.
- 6.3. On 6 February 2025, Model Law recognition orders were made in the Court granting a stay in Australia of any proceedings against Exactech US without the consent of Jesse York as foreign representative of Exactech US, or by leave of the Court.
- 6.4. Further, under a Restructuring Support Agreement between Exactech US and its lenders, there was a risk that Exactech AUS could be placed into voluntary administration if a settlement was not reached by a deadline. If both companies became insolvent, the prospects of any recovery by Class Members would have been limited.
- 6.5. In light of these risks, the parties participated in a mediation which commenced in December 2024, with negotiations continuing through early 2025. As a result of that process, the Class Action was resolved by way of a proposed settlement, which is now subject to approval by a Judge of the Court and the Bankruptcy Court in the United States.
- 6.6. Had the proceeding continued without settlement, Class Members would have faced the risk that Exactech AUS would be unlikely to be able to meet any judgment and the proceeding is stayed against Exactech US. The additional burden of delay, expense, and the uncertainty inherent in complex product liability litigation, such as this Class Action, made settlement the most beneficial course.
- 6.7. Under the proposed settlement:
 - (a) without admission of liability, the Exactech Respondents will pay a total sum of A\$8,700,000 approximately (the **Settlement Sum**);
 - (b) the Settlement Sum will be contributed by Exactech AUS, an external third-party financier and the insurers who provide insurance cover to the Exactech Respondents

(the **Insurers**);

- (c) the contribution to be made by the Insurers may be affected by the rate US dollars are exchanged for Australian dollars, which may have the effect of reducing the Settlement Sum;
- (d) from the Settlement Sum (assuming a total fund of A\$8,700,000), the following deductions will be made:
 - i. A\$100,000 will be paid to the Applicant;
 - ii. an amount, to be approved by the Court, will be deducted on account of past legal costs and disbursements, and for the cost of administration.
- (e) the balance of the Settlement Sum will be available for distribution to Class Members; and
- (f) in return, Class Members will release all claims they have or could have against Exactech US, Exactech AUS, and related parties. The settlement only extinguishes the rights of group members against these parties. It does not affect any right which individual group members may have to bring Court proceedings against other unrelated persons, corporations or organisations for compensation for any injuries caused by being implanted with and Affected Device, although any loss recovered as part of this Class Action cannot be claimed in any other proceeding.
- (g) if more than 276 class members opt out, then the Exactech Respondents and related parties may terminate the settlement.

6.8. The precise amount that each Class Member will receive has not yet been determined and will depend on various factors described in section 7 below.

6.9. Importantly, the amount available to each Class Member is expected to be substantially less than the potential value of their claims in normal circumstances. This is not because the claims lack merit, but because of the commercial realities outlined above, including the insolvency of Exactech US, the solvency concerns of Exactech AUS, and the risks and costs of ongoing litigation.

6.10. The Settlement Sum represents the best available outcome in circumstances where there was a material risk that Class Members would otherwise recover nothing. The added costs, delays and uncertainty of litigation made settlement the most practical option. In that context, the Settlement Sum, now subject to Court approval and subsequently for distribution to Class Members, was considered by the Applicant and his legal

representatives to be a justifiable and prudent outcome in the interests of all Class Members.

6.11. The settlement will only take effect if the Court approves it. The Court will consider whether the settlement as a whole – including any deductions for legal costs and the proposed method for distributing funds – is fair and reasonable.

7. How much compensation will I receive if the settlement is approved?

7.1. GMP Law are developing a methodology for how the Settlement Sum will be distributed between all eligible Class Members who register to participate in the settlement (the **Registered Class Members**). This methodology will be reflected in a Settlement Distribution Scheme, which is also subject to Court approval (the **Scheme**).

7.2. Factors to help calculate the amount of compensation each Registered Class Member may receive may include:

- (a) the number of Registered Class Members who are eligible for compensation and the value of their claim/s;
- (b) whether surgery to remove or replace the Affected Device (revision surgery) has occurred;
- (c) whether you have suffered any personal injury as a result of having been implanted with one of the Affected Devices and/or having revision surgery;
- (d) whether you have experienced disappointment or distress by having been implanted with one of the Affected Devices, but have otherwise not suffered any personal injury.
- (e) whether there is an ongoing need for treatment;
- (f) the nature of ongoing complications (if any);
- (g) the severity and duration of complications;
- (h) age;
- (i) comorbidities (if any)
- (j) any loss of value claims; and
- (k) any amount/s that need to be refunded to third parties, such as Medicare and private health insurers.

7.3. By 30 June 2025 the Scheme will be available on the GMP Law website at <https://www.gerardmaloufpartners.com.au/exactech-class-action/>. Settlement payments to each Registered Class Member will vary depending upon the factors listed above and the methodology outlined in the Scheme, once approved.

7.4. It is not currently possible to provide any indication of how much each Registered Class Member may receive from the Settlement Sum.

8. Participation in the Class Action – what are your options?

8.1. The options available to you are to either remain a Class Member or to opt out. The information outlined in section 6 above is particularly important to consider when making your decision.

Option A: Do nothing and remain a Class Member

8.2. If you wish to remain a Class Member **you do not need to do anything** at this time.

8.3. If the settlement is approved by the Court, you will need to register your participation with GMP Law if you want to receive your share of the Settlement Sum. Only Class Members who register by a deadline (to be fixed by the Scheme) will be eligible to receive a payment from the settlement fund.

8.4. You may contact GMP Law at any time to find out how to register.

Option B: Opt Out

8.5. If you do not wish to remain a Class Member, you **must** complete the 'Opt-Out Notice' contained in **SCHEDULE B** below and send the completed Opt-Out Notice to the New South Wales District Registry of the Federal Court of Australia (Level 17, 184 Phillip Street, SYDNEY NSW 2000) or by email to nswreg@fedcourt.gov.au by no later than 4:00pm on **10 July 2025**, otherwise it will not be effective (**Class Deadline**).

8.6. Each Class Member seeking to opt out should fill out a separate Opt-Out Notice form.

8.7. If you opt out you will **not** be bound by, or entitled to share in the benefit of, the settlement in the Class Action.

8.8. The information outlined in section 6 above is particularly important to consider when making your decision, including the possible external administration of Exactech AU and the solvency position of Exactech US, the prospects of any recovery against Exactech AU are likely limited.

- 8.9. If you wish to bring your own claim against either or both of the Exactech Respondents, you should seek your own independent legal advice about your claim before you decide whether or not to opt out. You may wish to seek advice about any relevant legal limitations to bringing your claim, such as the Chapter 11 Case in respect of Exactech US, prospects of recovery against Exactech AU in the circumstances and about the applicable time limit to bring your claim.

9. The proposed settlement – have your say

Option 1: Support the proposed settlement

- 9.1. If you support the proposed settlement, you **do not** need to take any immediate steps. However, you may express your support to the Court, by:

(a) sending a letter to Gerard Malouf and Partners, Level 5, 109 Pitt Street, Sydney NSW, 2000; or

(b) sending an email to ExactechClaim@gmp.net.au.

This must be received by the Court by **10 July 2025**.

Option 2: Object

- 9.2. If you decide to object to any aspect of the proposed settlement, you **must** complete and return the 'Objection Notice' contained in **SCHEDULE C** below and send the completed Objection Notice to the New South Wales District Registry of the Federal Court of Australia (Level 17, 184 Phillip Street, SYDNEY NSW 2000) or by email to nswreg@fedcourt.gov.au by no later than the Class Deadline, otherwise it will not be effective.
- 9.3. You can also seek to be heard by the Judge at the Court hearing where the settlement will be considered on 22 July 2025. You do not need to be represented or incur any costs in order to object. If you wish to attend the hearing (in person or by video link), you must notify GMP Law by 18 July 2025, so that arrangements can be made.
- 9.4. If you object to the settlement, but it is approved by the Court, you may nevertheless register with GMP Law to share in the proceeds of the settlement. Objecting does not affect your rights to obtain compensation under the settlement scheme.

10. Where can you obtain copies of relevant documents?

- 10.1. Copies of relevant documents, including the Originating Application, the Statement of Claim and the Defence of the Exactech Respondents may be obtained by:

(a) downloading them from [Exactech Class Action – GMP Law](#);



- (b) inspecting them between 9:00am and 5:00pm at one of the offices GMP Law, contact details for which are available from the website at [Exactech Class Action - GMP Law](#) or contacting them on 1800 004 878 or ExactechClaim@gmp.net.au.
- (c) contacting a District Registry of the Court to inspect the file (contact details are available 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.

10.2. Please consider the above matters carefully. If you are unsure about anything, you should contact GMP Law by visiting the website at [Exactech Class Action - GMP Law](#) or contacting them on 1800 004 878 or ExactechClaim@gmp.net.au. In making your decision, please be aware of the relevant deadlines. You should not delay in making your decision.

SCHEDULE A

TABLE OF AFFECTED DEVICES INCLUDED IN THE CLAIM

Row	Summary for ARTG Entry	Class	Registration No.	Registration Date	Deregistration Date	Conditions
1.	Assumed, Novation THA Insert	Assumed III	TBA	Prior to 2003	TBA	TBA
2.	Assumed, Friendly Hip/Cup Insert	Assumed III	TBA	Prior to 2003	TBA	TBA
3.	Assumed, Optetrak TKA Insert	Assumed III	TBA	Prior to 2003	TBA	TBA
4.	Assumed, Prosthesis, internal, joint, hip acetabular Insert	III	168966	1 March 2009, approximately	TBA	TBA
5.	Assumed, a device from the AcuMatch Hip System which used an Insert manufactured with MXPLE	Assumed III	TBA	1 July 2015, approximately	TBA	TBA
6.	Equinox Humeral Liner – Reverse Shoulder Prosthesis Cup	III	264172	24.11.15	TBA	Part 4-5, Div. 2 of the TGA Part 5, Div. 5.2 of the Medical Devices Regulation (or MDR)



7.	Equinoxe Glenoid, Pegged – Prosthesis, Internal, Joint, Shoulder, Glenoid Component	III	264381	25.11.14	24.12.24	Part 4-5, Div. 2 of the TGA
8.	Equinoxe Glenoid, Cage Pegged – Prosthesis, Internal, Joint, Shoulder, Glenoid Component	III	270232	16.02.16	24.12.24	Part 5, Div. 5.2 of the MDR
9.	Optetrak RBK PS, Hi-Flex Tibial Insert – Mobile Bearing Knee	Assumed III	277745	01.07.16	28.06.18	Assumed: Part 4-5, Div. 2 of the TGA
10.	Optetrak Tibial Insert, CC w/ Retaining Screw – Prosthesis, Knee, Internal, Insert Component	III	277743	12.07.16		Part 5, Div. 5.2 of the MDR
11.	Optetrak Tibial Insert, CR Slope – Prosthesis, Knee, Internal, Insert Component	Assumed III	278343	28.07.16	28.06.19	Part 4-5, Div. 2 of the TGA
						Part 5, Div. 5.2 of the



12.	Equinoxe Glenoid, Posterior Augment, 8 Degree, Pegged, Cemented – Prosthesis, Internal, Joint, Shoulder, Glenoid Compartment	III	278648	03.08.16	24.12.24	Part 4-5, Div. 2 of the TGA Part 5, Div. 5.2 of the MDR
13.	Optetrak Patellar Component, 3-Peg, Cemented – Polyethylene Patella Prosthesis	III	279041	11.08.16		Part 4-5, Div. 2 of the TGA Part 5, Div. 5.2 of the MDR
14.	Optetrak Logic Tibial Insert, CRC – Prosthesis, Knee, Internal, Insert Component	III	284907	23.01.17		Part 4-5, Div. 2 of the TGA Part 5, Div. 5.2 of the MDR
15.	Optetrak Tibial Insert, PS – Prosthesis, Knee, Internal, Insert Component	III	285677	14.02.17	28.06.19	Assumed: Part 4-5, Div. 2 of the TGA Part 5, Div. 5.2 of the MDR
16.	Optetrak Tibial Insert, Hi Flex, PS – Prosthesis, Knee, Internal, Insert	Assumed III	286119	14.02.17	28.06.19	Assumed: Part 4-5, Div. 2 of the TGA

Component

17.	Optetrak Logic Tibial Insert, CR – Prosthesis, Knee, Internal, Insert Component	III	285442	09.02.17		Part 5, Div. 5.2 of the MDR
18.	Optetrak Logic, Tibial Insert, PS – Prosthesis, Knee, Internal, Insert Component	III	285502	10.02.17		Part 4-5, Div. 2 of the TGA Part 5, Div. 5.2 of the MDR
19.	Optetrak Logic Tibial Insert PSC – Prosthesis, Knee, Internal, Insert Component	III	285503	10.02.17		Part 4-5, Div. 2 of the TGA Part 5, Div. 5.2 of the MDR
20.	Optetrak Logic RBK Tibial Insert, Posterior Stabilized – Prosthesis, Knee, Internal, Insert Component	III	285911	20.02.17		Part 4-5, Div. 2 of the TGA Part 5, Div. 5.2 of the MDR
21.	Assumed, a device from the Novation Hip System which used an Insert manufactured with	Assumed III	TBA	1 September 2017,	TBA	TBA approximately

	MXPLE (such as the acetabular cup)					
22.	Equinox Glenoid, Cage Pegged, Posterior Augment – Prosthesis, Internal, Joint, Shoulder, Glenoid Component	III	293762	12.09.17	24.12.24	Part 4-5, Div. 2 of the TGA Part 5, Div. 5.2 of the MDR
23.	Prosthesis internal, joint, shoulder, total		159609			
24.	Equinox Reverse Shoulder Constrained Humeral Liner – Reverse shoulder prosthesis cup		279721			
25.	Mobile-bearing total ankle prosthesis		308700			



SCHEDULE B
OPT-OUT NOTICE

IMPORTANT	You should only complete this form if you do <u>NOT</u> want to participate in the Exactech Class Action
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NSD1224 of 2024
Federal Court of Australia
District Registry: New South Wales
Division: General

SIMON HARROLD

Applicant

EXACTECH AUSTRALIA PTY LTD ACN 146 150 754

First Respondent

EXACTECH INCORPORATED

Second Respondent

To: The Registrar
Federal Court of Australia, New South Wales
Level 17
184 Phillip Street
SYDNEY NSW 2000

..... (print name of Class Member), a Class Member in this class action, gives notice under section 33J of the *Federal Court of Australia* 1976, that they are opting out of the class action.

Date:

Signed by:

(Class Member/Lawyer for the Class Member (circle as applicable))	
Class Member Details	
Full Name:	
Email:	
Address:	
Telephone Number:	

Details of persons signing on behalf of Class Member (if applicable):	
Full name:	
Capacity: (e.g. executor)	
Email:	
Address:	
Telephone number:	



SCHEDULE C
OBJECTION NOTICE

IMPORTANT	You should only complete this form if you OBJECT to the Proposed Settlement in the Exactech Class Action
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NSD1224 of 2024
Federal Court of Australia
District Registry: New South Wales
Division: General

SIMON HARROLD

Applicant

EXACTECH AUSTRALIA PTY LTD ACN 146 150 754

First Respondent

EXACTECH INCORPORATED

Second Respondent

To: The Registrar
Federal Court of Australia, New South Wales
Level 17
184 Phillip Street
SYDNEY NSW 2000

(Class Member/Lawyer for the Class Member *(circle as applicable)*)

Class Member Details

Full Name:

Email:

Telephone Number:

I am a Class Member in the abovenamed Proceeding, and I **object** to the proposed settlement of these proceedings because: *(set out reasons for your objection below, or attach additional pages)*:

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Date:

Signed by:

Full name: