NOTICE OF FILING

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Registrar

Important Information

This Notice has been inserted as the first page of the document which has been accepted for electronic filing. It is now taken to be part of that document for the purposes of the proceeding in the Court and contains important information for all parties to that proceeding. It must be included in the document served on each of those parties.

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Form 17
Rule 8.05(1)(a)

Statement of claim

No. NSD of 2024

Federal Court of Australia

District Registry: New South Wales

Division: General

SIMON HARROLD

Applicant

EXACTECH AUSTRALIA PTY LTD ACN 146 150 754 and another named in schedule 1

Respondents

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A. THE PARTIES

A1. The Group Members and the Applicant

1. This proceeding is commenced as a representative proceeding against Exactech Australia Pty Ltd ACN 146 150 754 (**Exactech Australia**) and Exactech Incorporated (**Exactech US**) (and collectively referred to as the **Respondents**) pursuant to Part IVA of the *Federal Court of Australia Act* 1976 (Cth) (**the FCA Act**) by Simon Harrold (**the Applicant**) on his behalf and on behalf of other persons (the **Group Members**) who:

   a. in Australia, at any time in the period commencing 1 January 2003 and the date of filing of the Originating Application which accompanies this Statement of Claim (**the Filing Date**) inclusive (**the Relevant Period**) were implanted with one or more joint replacement devices for knees (**KJD**) and/or hips (**HJD**) and/or shoulders (anatomic) (**SJD**) (collectively, the **Joint Devices**) which included an orthopaedic impact bearing component (known as a liner or **Insert**) made from 'moderately cross-linked ultra-high molecular weight polyethylene' by Exactech US (the **Affected Devices** or an **Affected Device**, depending upon the context in which the term is used); and

Particulars

A. See the first schedule of this Statement of Claim which identifies the Affected Devices by reference to details recorded with the Australian Register of Therapeutic Goods (**the ARTG**), such as their 'Summary for ARTG Entry' and their registration number (**Schedule 1**).

B. The Relevant Period will be amended following the completion of discovery processes to include joint devices and their Inserts exported to Australia prior to the incorporation of Exactech Australia and made from 'moderately cross-linked ultra-high molecular weight polyethylene' (or **MXPLE**).

   b. are not:

      i. a director or an officer or a close associate of a director or officer (as defined in section 9 of the *Corporations Act 2001* (Cth) (**the Corporations Act**)) of Exactech Australia or Exactech US; or

      ii. a related party (as defined in section 228 of the Corporations Act) of Exactech Australia or Exactech US; or

iii. a related body corporate (as defined in section 50 of the Corporations Act) of the Exactech Australia or Exactech US; or

iv. an associate entity (as defined in section 50AAA of the Corporations Act) of the Exactech Australia or Exactech US; or

v. an Authorised Dealer (a term defined below); or

vi. a person described in section 33E(2) of the FCA Act; or

vii. a Chief Justice, Justice, District Registrar or Deputy District Registrar of the Federal Court of Australia or the High Court of Australia.

2. Such of those Group Members that were implanted with a total knee arthroplasty (**TKA**) with an Affected Device before 1 January 2011 are **Sub-Group A Members**.

3. Such of those Group Members that were implanted with a total hip arthroplasty (**THA**) with an Affected Device before 1 January 2011 are **Sub-Group B Members**.

4. Such of those Group Members that were implanted with an anatomic total shoulder arthroplasty (**TSA**) with an Affected Device before 1 January 2011 are **Sub-Group C Members**.

5. Such of those Group Members that were implanted with a TKA with an Affected Device on or after 1 January 2011 are **Sub-Group D Members**.

6. Such of those Group Members that were implanted with a THA with an Affected Device on or after 1 January 2011 are **Sub-Group E Members**.

7. Such of those Group Members that were implanted with a TSA with an Affected Device on or after 1 January 2011 are **Sub-Group F Members**.

8. As at the date of commencement of this proceeding, seven or more Group Members, which include the Applicant, have claims against the Respondents, as they have suffered injury, loss or damage from:

a. one or more of the same or similar contraventions of the following provisions of the *Competition and Consumer Act 2010* (Cth) (the **CCA**):

i. caused by Exactech US', and/or alternatively, Exactech Australia's failure to supply goods that satisfied the statutory/consumer guarantee as to 'acceptable quality' in contravention of section 54 of the Australian Consumer Law, schedule 2 of the CCA (the **ACL**) as pleaded in section F below;

ii. Caused by Exactech US', and/or alternatively, Exactech Australia's failure to supply goods that satisfied the statutory/consumer guarantee as to 'fitness for

any disclosed purpose' in contravention of section 55 of the ACL as pleaded in section G below;

iii. caused by Exactech Australia's conduct in contravention of one of more of sections 18, 29(1)(a), 29(1)(g) and 33 of the ACL as pleaded in section H below;

iv. caused by Exactech US', and/or alternatively, Exactech Australia's liability for safety defects pursuant to section 138 of the ACL as pleaded in section I below;

b. and/or, one or more of the same or similar contraventions of the following provisions of the *Trade Practices Act 1974* (Cth) (the **TPA**):

i. caused by Exactech US', and/or alternatively, Exactech Australia's failure to supply goods that were of merchantable quality in contravention of section 74D of the TPA as pleaded in section F below;

ii. caused by Exactech US', and/or alternatively Exactech Australia's failure to supply suitable goods in contravention of section 74B of the TPA as pleaded in section G below;

iii. caused by Exactech Australia's conduct in contravention of one of more of sections 52 and 55 of the TPA as pleaded in section H below;

iv. caused by Exactech US', and/or alternatively, Exactech Australia's failure to supply goods without a defect in contravention of sections 75AC and 75AD of the TPA as pleaded in section I below;

c. and/or, the same or similar allegations of their respective negligence as pleaded in section J below.

9. On around 5 May 2017, the Applicant was diagnosed by Dr Ali Gursel, orthopaedic surgeon (the **Treating Surgeon**) with osteoarthritis in the right knee (his **Right Knee Pathology**).

Particulars

A. See letter from the Treating Surgeon to the Applicant's treating general practitioner named Dr Stephen Nicol, practising from the Berkeley Vale Medical Centre and the Long Jetty Medical Centre, dated 5 May 2017.

10. On 8 February 2019, the Applicant consulted the Treating Surgeon for advice and treatment regarding his Right Knee Pathology (the **8 February Consultation**).

11. During the 8 February Consultation, the Treating Surgeon:

a. informed the Applicant he ought to undergo a TKA to his right knee;

b. handed the Applicant a brochure regarding the Optetrak Logic TKA system (the **Optetrak Brochure**); and

c. informed the Applicant that the Optetrak Logic TKA system is safe.

Particulars

A. The Applicant, either no longer possesses a copy of the Optetrak Brochure, or, cannot locate it, in spite of reasonable searches.

B. If the Optetrak Brochure is not discovered by the Applicant beforehand, a copy will be identified through discovery processes.

12. At the conclusion of the 8 February Consultation, the Applicant elected to proceed with the TKA to treat the Right Knee Pathology and signed a document entitled 'Consent to Medical or Surgical Treatment'.

13. In the period between 8 February 2019 to 14 March 2019, the Applicant read the Optetrak Brochure, which included statements that the Optetrak Logic TKA system is, and would be, safe (the **Optetrak Brochure Representations**).

14. Based on the opinion of the Treating Surgeon and the Optetrak Brochure Representations, the Applicant did not resile from his earlier election to proceed with the TKA to his right knee.

15. On 14 March 2019, the Treating Surgeon performed a total knee arthroplasty on the Applicant's right knee (the **Applicant's Index Surgery**).

16. During the Applicant's Index Surgery, the Treating Surgeon implanted an 'Optetrak Logic' or 'Exactech Logic', that included an Affected Device (the **Applicant's Defective Devices**).

Particulars

A. Item/part number: 02-012-49-4009; serial/lot number: 4175433

17. The fees paid by the Applicant to the Treating Surgeon and/or the hospital at which the Applicant's Index Surgery was performed included an outlay for the Applicant's Defective Devices (the **Defective Device Cost**).

Particulars

A. The Applicant will provide particulars of the Defective Device Cost following any discovery processes.

A2. The Respondents

18. In the period commencing from the date of its incorporation until the Filing Date, Exactech Australia:

    a. imported the Affected Devices, as components for the Joint Devices, into Australia;

    b. advertised for sale the Affected Devices, as components for the Joint Devices, throughout Australia;

    c. distributed the Affected Devices to consumers in Australia through a network of third-party dealers/suppliers (each an **Authorised Dealer** and collectively, the **Authorised Dealers**); and

    d. the Authorised Dealers sold the Affected Devices to intermediaries, such as orthopaedic surgeons, and/or other health care professionals and/or other health care providers, and/or hospitals (the **Intermediaries**), who re-supplied those devices to consumers including the Group Members.

19. Since 3 September 2010, Exactech Australia was and remains:

    a. a corporation incorporated in Australia under the Corporations Act;

    b. able to be sued in and by its corporate name and style;

    c. a trading corporation within the meaning of section 41 of the CCA;

    d. a 'person' for the purposes of sections 18, 29 and 33 of the ACL, whereby the said law pursuant to section 131 of the CCA applies as a law of the Commonwealth to the conduct of corporations, and in relation to their contraventions of Chapters 2, 3 and 4;

    e. a 'corporation' for the purposes of sections 52 and 55 of the TPA;

    f. a 'manufacturer' of the Affected Devices supplied in Australia, as defined in section 7 of the ACL and section 74A(3) of the TPA, in that:

        i. since its incorporation and until the Filing Date, it acquired the Affected Devices from Exactech US, which had exported and then provided the Affected Devices to Exactech Australia in Australia;

        ii. at the time of importation of the Affected Devices, Exactech US, being the manufacturer of the goods, did not have a place of business in Australia;

        iii. it was not, but for the operation of section 7 of the ACL and section 74A(3) of the TPA, a manufacturer of the Affected Devices for the purposes of sections 7, 54, 138, 271 and 272 of the ACL and section 74B of the TPA;

    g. a 'supplier' of the Affected Devices supplied and sold in Australia for the purposes of sections 7, 55 and 259(4) of the ACL; and

h. a 'sponsor' of joint devices manufactured by Exactech US and supplied in Australia, including some of the Joint Devices, for the purposes of section 3 of the *Therapeutic Goods Act* 1989 (Cth) (the **TGA**).

Particulars

A. Schedule 1 identifies Affected Devices sponsored by Exactech Australia only.

B. Further particulars identifying any other sponsors will be provided following discovery processes and/or the service of expert evidence.

20. During the Relevant Period, Exactech US:

a. designed and manufactured the Joint Devices and the Affected Devices;

b. packaged the Joint Devices and the Affected Devices; and

c. exported and supplied the Joint Devices and the Affected Devices to its sponsors in Australia, including Exactech Australia (since around its date of incorporation).

21. During the Relevant Period, Exactech US was and remains:

a. a company incorporated under the laws of the United States of America and has its headquarters in the State of Florida;

b. a 'foreign corporation' within the meaning of section 4 of the CCA and section 4 of the TPA;

c. able to be sued in and by its corporate name and style;

d. in the business of designing, manufacturing and packaging joint devices (including the Joint Devices and the Affected Devices) to a number of international markets including Australia;

e. a 'manufacturer' of the Affected Devices supplied and sold in Australia for the purposes of sections 7, 54, 138 and 271 of the ACL and section 74A(3) of the TPA, in that it:

i. holds itself out to the public as the manufacturer of the goods;

ii. causes or permits its name, or a name by which it carries on business, or a brand or mark of Exactech US (namely, 'Exactech') to be applied to goods supplied to Exactech Australia, which are then supplied to consumers by and/or through its Authorised Dealers; and/or

f. a 'supplier' of the Affected Devices supplied and sold in Australia for the purposes of sections 7, 55 and 259(4) of the ACL.

B. THE JOINT DEVICES

B1. What is a Total Knee Arthroplasty?

22. A total knee arthroplasty is a surgical procedure which involves:

    a. the removal of damaged bone and cartilage from the knee joint;

    b. the implantation of a KJD which:

        i. eases pain and restores function to the affected knee joint;

        ii. replaces all or parts of the natural femoral, tibial and patellar articulating surfaces; and

    c. is made from metal and includes an Insert made from a polymer such as MXPLE or 'highly cross-linked ultra-high molecular weight polyethylene' (or **HXPLE**).

23. The primary conditions treated by a total knee arthroplasty are as follows:

    a. pain and/or loss of motion caused by arthritic conditions of the knee joint including osteoarthritis; and

    b. pain and/or loss of motion caused by trauma;

    (the **Knee Pathologies**).

B2. What is a Total Hip Arthroplasty?

24. Total hip arthroplasty is a surgical procedure which involves:

    a. the removal of damaged bone and cartilage from the hip joint;

    b. the implantation of a HJD which:

        i. eases pain and restores function to the affected hip joint;

        ii. replaces either one or both of the natural femoral and/or acetabular articulating surfaces; and

        iii. is made from metal and/or ceramic material and includes an Insert made from a polymer such as HXPLE or MXPLE.

25. The primary conditions treated by a total hip arthroplasty are as follows:

    a. pain and/or loss of motion caused by arthritic conditions of the hip joint including osteoarthritis; and

    b. pain and/or loss of motion caused by traumatic injury and/or post traumatic arthritis

    (the **Hip Pathologies**).

B3. What is Anatomic Total Shoulder Arthroplasty?

26. Anatomic total shoulder arthroplasty is a surgical procedure which involves:

    a. the removal of damaged bone and cartilage from the glenohumeral shoulder joint;

    b. the implantation of a SJD which:

        i. eases pain and restores function to the glenohumeral 'ball and socket' shoulder joint;

        ii. replaces either one or both of the natural humeral and glenoid articulating surfaces;

        iii. involves insertion of a 'ball' component into the humerus, not the glenoid socket;

        iv. is made from metal and/or ceramic material and includes an Insert made from a polymer such as HXPLE or MXPLE.

27. The primary conditions treated by a (anatomic) total shoulder arthroplasty are as follows:

    a. pain and/or loss of motion caused by arthritic conditions of the shoulder joint including osteoarthritis;

    b. pain and/or loss of motion caused by fractures; and

    c. pain and/or loss of motion caused by rotator cuff injuries

    (the **Shoulder Pathologies**).

B4. What is the purpose of an Insert?

28. An Insert:

    a. is used as an orthopaedic impact bearing component positioned between the metal and/ or ceramic components of a joint device;

    b. replaces the natural articulating surface or surfaces of the knee, hip or shoulder joints;

    c. eases pain and restores function for as long as possible to knee, hip or shoulder joints affected respectively by the Knee Pathologies, Hip Pathologies and Shoulder Pathologies; and

    d. safely permits the components of a joint device, used in the treatment of Knee Pathologies, Hip Pathologies and Shoulder Pathologies to articulate smoothly with minimal wear to those components, or the Insert

    (the **Insert Purpose**).

C. THE DEVICE DEFECTS AND THE DEFECT CONSEQUENCES

C1. Production Defect Background

29. Since around 1990, or at least throughout the Relevant Period, Exactech US has manufactured Inserts for the Joint Devices using a process which includes the following steps:

    a. in its resin or powdered state, placing the polymer known as 'ultra-high molecular weight polyethylene' (or **UHMWPE**) into a moulding device in the form of the required Insert; and

    b. exposing the moulding device to around 50 kilogray (kGy) of gamma irradiation to transform the UHMWPE into MXPLE

    (**the Exactech Process**).

30. Since around 2007, it has been the predominant industry standard to manufacture Inserts using a process which includes the following steps to prevent, and/or arrest and/or slow the process of oxidative degradation of an Insert and/or make an Insert more 'wear resistant':

    a. in its resin or powdered state, blending the UHMWPE with alpha tocopherol (or **Vitamin E Dosing**);

    b. in its resin/powdered state, placing the UHMWPE with the Vitamin E Dosing into a moulding device in the form of the required Insert;

    c. exposing the moulding device to around 100 kGy of gamma irradiation to transform the UHMWPE into HXPLE; and

    d. exposing the resulting Insert to post-production thermal processes such as 'annealing' or 'remelting' (or **Post-Production Thermal Processes**)

    (**the Predominant Industry Process**).

C2. The Production Defect

31. Since around 2007, the Affected Devices have been designed and/or manufactured with a defect by reason of the following:

    a. the MXPLE oxidises, *in vitro* and/or *in vivo* at a materially faster rate than Inserts made from HXPLE and/or made pursuant to the Predominant Industry Process because:

        i. the UHMWPE does not receive Vitamin E Dosing; and

        ii. it is not subjected to any of the Post-Production Thermal Processes; and/or

b. the MXPLE degrades, *in vitro* and/or *in vivo,* at a materially faster rate than Inserts made from HXPLE manufactured and treated pursuant to the Predominant Industry Process because of:

i. the matters identified in the foregoing subparagraph; and

ii. its exposure to 50 kGy of gamma irradiation, instead of 100 kGy;

c. by reason of the matters identified in the foregoing subparagraphs (a) and (b), they shed, or possess the propensity to shed, materially greater volumes of particle debris *in vivo* than Inserts made with HXPLE manufactured and treated pursuant to the Predominant Industry Process; and

Particulars

A. On around 24 June 2021, Exactech US published an article entitled 'Frequently Asked Questions' in which it admitted the 'Connexion Liner' manufactured from HXPLE outperformed, in terms of volumetric wear, the 'Connexion Liner' manufactured from MXPLE, see paragraphs [2] and [7].

B. Further particulars of the Production Defect will be provided following completion of discovery processes and the service of expert evidence.

d. they carry an abnormal and/or superadded risk of earlier and/or more frequent revision surgery post index surgery when compared to comparable joint devices using Inserts made with HXPLE manufactured and treated pursuant to the Predominant Industry Process, in the same period

(the **Production Defect**).

Particulars

A. Further particulars of the Affected Devices' abnormal risk of requiring revision surgery will be provided following completion of discovery processes and the service of expert evidence.

C3. The Background to the Packaging Defects

32. In addition, or in the alternative, to the matters pleaded with respect to the Production Defect, in or around the period commencing June 2021 to September 2021, or at some point, or points, thereafter, it was discovered:

a. around 80 per cent of the Inserts contained in the TKAs, including the Affected Devices, manufactured since 2004 were placed in 'out of specification' packaging which exposed, or materially increased the risk of exposing, those Inserts to oxygen;

b. around 88 per cent of the Inserts contained in the TSAs, including the Affected Devices, manufactured since 2004 were placed in 'out of specification' packaging which exposed, or materially increased the risk of exposing, those Inserts to oxygen;

c. most of the Inserts contained in the THAs, including the Affected Devices, manufactured since 2008 were placed in 'out of specification' packaging which exposed, or materially increased the risk of exposing, those Inserts to oxygen; and

d. Exactech US never established any procedures for the acceptance of incoming products from third party suppliers, including the supplier of the 'out of specification' packaging

(the **Defective Packaging System**).

Particulars

A. See paragraph [13] of the Master Personal Injury Complaint (MDL No. 3044 (NGG) (MMH), United States District Court Eastern District of New York (Brooklyn) (or **MPIC**) referencing FDA Form 483, 1038671.

B. On around 5 August 2021, Exactech US replaced the Defective Packaging System with a revised system that placed the Inserts into specification packaging which contained the necessary oxygen barrier.

C4. The Packaging Defects

33. Due to the Defective Packaging System, a substantial percentage of the Affected Devices were exposed to oxygen prior to index surgery and degraded, or started to degrade, *in vitro* and/or thereafter *in vivo* (the **Oxidising Devices** or **Oxidising Device**, depending upon the context in which the term is used)

Particulars

A. See paragraph [32] above.

34. By reason of their exposure to oxygen, the Oxidising Devices shed, or possess the propensity to shed, materially greater volumes of particle debris *in vivo* compared to Inserts made with MXPLE not exposed to oxygen and, to a greater degree, with HXPLE manufactured and treated pursuant to the Standard Industry Process.

35. The population of Oxidising Devices:

a. are distributed throughout the population of the Affected Devices; and

b. are visually indistinguishable from Affected Devices not exposed to oxygen

(the **Distribution of Oxidising Devices**).

36. By reason of the Distribution of the Oxidising Devices, the Affected Devices carry an abnormal and/or superadded risk of earlier and/or more frequent revision surgery post index surgery when compared to the revision rates of comparable joint devices using Inserts made from HXPLE manufactured and treated pursuant to the Predominant Industry Process, in the same period (the **Oxidising Defect**).

Particulars

A. Further particulars of the Affected Devices' abnormal risk of requiring revision surgery will be provided following completion of discovery processes and the service of expert evidence.

C5. The Defects' Consequences

37. The Production Defect and/or the Oxidising Defect:

a. has caused, causes and/or has the propensity to cause a recipient of an Affected Device:

i. an adverse reaction to particle debris (**ARPD**) comprising one or more or all of:

A. chronic inflammation of the periprosthetic tissue;

B. soft tissue necrosis;

C. bone necrosis or osteolysis;

D. formation of pseudotumours;

E. formation of granulomas; and

F. loosening of one or more of the components of the Joint Devices;

ii. osteolysis.

iii. damage to modular components of the Joint Devices;

iv. severe pain;

v. infection;

vi. re-operation;

vii. scarring;

viii. chronic swelling;

ix. loss of movement in affected joint;

x. one or more revision surgeries;

xi. mental harm;

xii. economic loss; and

xiii. non-economic losses;

(each a **Personal Injury Consequence** or collectively, the **Personal Injury Consequences**); and/or

b. has caused, causes and/or has the propensity to cause a recipient of an Affected Device:

i. anguish, distress and disappointment because of the Affected Device's propensity to cause the Personal Injury Consequences; and/or

ii. 'out of pocket' pecuniary loss

(each a **Non-Personal Injury Consequence** or collectively, the **Non-Personal Injury Consequences**).

C6. The Applicant's Facts, Matters and Circumstances

38. Prior to, or around, December 2022, the Applicant started to experience pain and swelling in his right knee.

Particulars

A. See the medical notes of Taabinga Family Practice.

39. On 13 May 2023, the Applicant suffered a pulmonary embolism.

40. On 11 August 2023, the Treating Surgeon sent a letter to the Applicant:

a. giving notice that the Respondents were conducting a recall for all 'knee and ankle' Inserts 'with an 8-year shelf life'; and

b. requesting he attend a consultation to review his right knee, if he had been suffering from any 'swelling, pain or instability'.

41. On 18 October 2023, the Applicant consulted the Treating Surgeon to review his right knee, who observed swelling and 'some clunking in the knee to varus-valgus force' (the **18 October Consultation**).

42. On the same day, following the 18 October Consultation, the Treating Surgeon sent a letter to the Applicant's treating general practitioner that:

a. reported his observations on examination;

b. advised him of his opinion that swelling caused by the Applicant's Defective Devices potentiated a deep vein thrombosis in his right leg and, thereafter, the pulmonary embolus; and

c. confirmed the Applicant's election to proceed with revision surgery to remove the Applicant's Defective Devices and insert another 'Optetrak Logic', or 'Exactech Logic' KJD.

Particulars

A. See the letter from the Treating Surgeon to Dr Audrey Haboosheh of the Taabinga Family Practice of the same date.

43. On 29 November 2023, the Treating Surgeon performed the revision surgery to the Applicant's right knee (the **Total Knee Replacement Revision Surgery**).

44. During the Total Knee Replacement Revision Surgery, the Treating Surgeon observed:

a. the Applicant's right synovial membrane was markedly inflamed requiring radical synovectomy;

b. the Affected Device showed signs of wear and tear, and/or delamination;

c. the presence of osteolysis around the femoral component of the Applicant's Defective Devices; and

d. loosening of the femoral component of the Applicant's Defective Devices.

Particulars

A. See the procedure report dated 29 November 2023.

B. See the ten photographic images taken by the Treating Surgeon of the Affected Device.

C. See the document named 'Knee Form' 'Australian Orthopaedic National Joint Replacement Registry'.

45. The Affected Device, used as a component in the Applicant's Defective Devices, possessed the Production Defect, and/or the Oxidising Defect.

46. Notwithstanding the Total Knee Replacement Revision Surgery, the Applicant continues to experience pain, intermittent swelling and other pathology.

Particulars

A. See Schedule 2 for further particulars.

D. EVALUATION AND WARNINGS

47. Prior to the release, supply, re-supply, distribution, marketing and/or promotion of the Joint Devices, including the Affected Devices, in Australia, Exactech US and/or Exactech Australia did not undertake any or any adequate clinical or any other adequate evaluation,

including post market surveillance, of the risks associated with their use and/or the effectiveness of their use, including:

a. the risk of occurrence of any one of the Personal Injury Consequences;

b. whether use of MXPLE to make Inserts was more effective, or in the alternative, was not materially less effective, than HXPLE;

c. whether the use of MXPLE to make Inserts, excluding Vitamin E Dosing, was more effective, or in the alternative, was not materially less effective, than producing Inserts pursuant to the Predominant Industry Process;

d. whether the use of MXPLE to make inserts, excluding the application of Post-Production Thermal Processes, was more effective, or in the alternative, was not materially less effective, than producing Inserts pursuant to the Predominant Industry Process;

e. whether the use of MXPLE to make inserts, applying only 50 kGy of gamma irradiation, was more effective, or in the alternative, was not materially less effective, than producing Inserts pursuant to the Predominant Industry Process; and

f. whether the use of MXPLE to make inserts, excluding Vitamin E Dosing, and/or excluding the application of the Post-Production Thermal Processes, and/or applying only 50 kGy of gamma irradiation, was more effective, or in the alternative, was not materially less effective, than producing Inserts pursuant to the Predominant Industry Process

(the **Device Evaluation Matters**).

Particulars

A. See paragraphs [13], [232] to [239], [277] to [284] and [287] of the MPIC.

48. At all material times, Exactech US and/or Exactech Australia failed to provide any or any adequate information or warning to the Group Members (directly, or by providing any or any adequate information or warning to the Authorised Dealers and/or the Intermediaries) of the following matters:

a. the Affected Devices, by reason of the Production Defect, have caused, cause and/or possess the propensity to cause, the Personal Injury Consequences;

b. the Affected Devices, by reason of the Oxidising Defect, have caused, cause and/or possess the propensity to cause, the Personal Injury Consequences; and/or

c. the Affected Devices, by reason of the Production Defect and/or Oxidising Defect, have caused, cause and/or possess the propensity to cause, the Personal Injury Consequences; and/or

d. by reason of the Production Defect, the Affected Devices carry an abnormal and/or superadded risk of earlier and/or more frequent revision surgery post index surgery when compared to the revision rates of comparable joint devices using Inserts made from HXPLE manufactured and treated pursuant to the Predominant Industry Process, in the same period;

e. by reason of the Oxidising Defect, the Affected Devices carry an abnormal and/or superadded risk of earlier and/or more frequent revision surgery post index surgery when compared to the revision rates of comparable joint devices using Inserts made from HXPLE manufactured and treated pursuant to the Predominant Industry Process, in the same period;

f. by reason of the Production Defect and/or the Oxidising Defect, the Affected Devices carry an abnormal and/or superadded risk of earlier and/or more frequent revision surgery post index surgery when compared to the revision rates of comparable joint devices using Inserts made from HXPLE manufactured and treated pursuant to the Predominant Industry Process, in the same period;

g. the Device Evaluation Matters

(the **Device Warning Matters**).

E. EXACTECH AUSTRALIA'S REPRESENTATIONS

E1. The Device Representations

49. Since the date of its incorporation, or at some later point thereafter, expressly and/or impliedly, Exactech Australia represented to the Intermediaries that the Affected Devices, as part of the Joint Devices:

a. were, in their design and manufacturing:

i. not defective;

ii. good quality;

iii. reliable;

iv. durable;

v. fit for purpose; and

vi. safe; and

b. provided predictable surgical outcomes

(the **Device Representations**).

Particulars

A. See, Exactech Australia website at: <https://au.exac.com> (the **Exactech Australia Website**).

B. See the Optetrak Brochure Representations.

C. Further particulars will be provided following the completion of discovery processes.

50. The Device Representations were:

a. set out in brochures that were published by Exactech Australia and provided to the Intermediaries for further distribution by them to consumers;

b. made available online at the Exactech Australia Website;

c. made to the public; and

d. made, through the Intermediaries, to the Applicant and the Group Members.

51. Each of the Device Representations was a continuing representation.

52. Exactech Australia failed to correct or qualify any of the Device Representations at any time, or times, since their publication.

53. The Optetrak Brochure Representations were Device Representations.

E2. The Future Device Representations

54. Since the date of its incorporation, or at some later point thereafter, Exactech Australia also represented that the Affected Devices, as part of the Joint Devices:

a. would be:

i. not defective;

ii. good quality;

iii. reliable;

iv. durable;

v. fit for purpose; and

vi. safe; and

b. would provide predictable surgical outcomes

(the **Future Device Representations**).

Particulars

A. See the matters particularised in paragraph [49] above.

B. See the Optetrak Brochure Representations.

55. The Future Device Representations were:

a. set out in brochures that were published by Exactech Australia and provided to the Intermediaries for further distribution by them to consumers;

b. made available online at the Exactech Australia Website;

c. made to the public; and

d. made, through the Intermediaries, to the Applicant and the Group Members.

56. Each of the Future Device Representations was:

a. a representation with respect to future matters within the meaning of section 4 of the ACL and section 51A of the TPA; and

b. a continuing representation.

57. Exactech Australia have failed to correct or qualify any of the Future Defect Representations at any time since their publication.

58. Since at least 2010, and/or at subsequent points in time thereafter following publication, Exactech Australia had no reasonable basis for making the Future Device Representations.

59. The Optetrak Brochure Representations were Future Device Representations.

F. FAILURE TO COMPLY WITH THE CONSUMER GUARANTEE OF ACCEPTABLE QUALITY

LIABILITY FOR THE SUPPLY OF UNMERCHANTABLE GOODS

60. When a Joint Device, including an Affected Device, was supplied to the Applicant or to a Group Member by a 'Supplier', a term described in paragraph [61] below, the Joint Device and the Affected Device were supplied in trade or commerce and other than by way of sale by auction.

61. The Joint Devices, including the Affected Devices, were exported to Australia during the Relevant Period by Exactech US and then supplied to the Applicant and/or the Group Members by or through:

a. a sponsor and/or Exactech Australia; and/or:

b. Authorised Dealers; and/or

c. Intermediaries

(the **Suppliers**).

62. The Joint Devices and the Affected Devices were goods of a kind ordinarily acquired by consumers for personal use or consumption.

63. The Joint Devices and the Affected Devices were not acquired from the Suppliers by the Applicant and the Group Members for the purpose of re-supply.

64. The price paid by the Applicant and the Group Members:

    a. for the Joint Devices and/or the Affected Devices, purchased before 1 July 2021, did not exceed $40,000.00; and

    b. for the Joint Devices and/or the Affected Devices, purchased on and from 1 July 2021, did not exceed $100,000.00.

65. By reason of the matters pleaded in paragraphs [60] to [64] above, in respect of each Affected Device, there was a guarantee of 'acceptable quality' within the meaning of section 54 of the ACL.

66. The purposes for which goods such as the Affected Devices are commonly supplied include the Insert Purpose.

67. By reason of the Production Defect, the Oxidising Defect, the Personal Injury Consequences and the Non-Personal Injury Consequences, the Affected Devices were not:

    a. fit for all purposes for which goods such as the Affected Devices are commonly supplied;

    b. free from defects;

    c. safe; or

    d. durable,

    as a reasonable consumer fully acquainted with the state and condition of the goods, including the Production Defect, the Oxidising Defect, the Personal Injury Consequences and the Non-Personal Injury Consequences, would regard as acceptable having regard to:

    e. the nature of the Affected Devices;

    f. the price of the Affected Devices;

    g. the Device Representations;

    h. the Future Device Representations; and

    i. the Insert Purpose.

68. By reason of the matters pleaded in section C above, individually and/or cumulatively, the Affected Devices were not of 'acceptable quality' within the meaning of section 54 of the ACL (the **Acceptable Quality Contraventions**).

69. The Applicant and each Group Member is an 'affected person' for the purposes of section 271(1) of the ACL, in that each was a consumer who acquired an Affected Device.

70. Additionally, by reason of the same matters pleaded in section C above, individually and/or cumulatively, pursuant to section 74D of the TPA:

    a. the Affected Devices were not of merchantable quality;

    b. the Group Members, or at least one or some of them, have suffered loss and/or damage by reason that the Affected Devices were not of merchantable quality; and

    c. the Respondents, and/or one of them, are liable to pay compensation with respect to those losses and/or damage

    (the **Respondents' Liability for Unmerchantable Goods**).

G. FAILURE TO COMPLY WITH THE CONSUMER GUARANTEE OF FITNESS FOR ANY DISCLOSED PURPOSE

LIABILITY IN RESPECT OF UNSUITABLE GOODS

71. When a Joint Device, including an Affected Device, was supplied to the Applicant or to a Group Member by a Supplier, the Joint Device and the Affected Device were supplied in trade or commerce and other than by way of sale by auction.

72. The Joint Devices and the Affected Devices were goods of a kind ordinarily acquired by consumers for personal use or consumption.

73. The Applicant and/or Group Members made known, expressly or impliedly, the Insert Purpose to:

    a. one or more of the Suppliers, and/or

    b. one or more of the Respondents by or through any one of the Suppliers.

74. By reason of the matters pleaded in paragraphs [71] to [73] above, in respect of each of the Affected Devices, there was a guarantee of 'fitness for any disclosed purpose' within the meaning of section 55 of the ACL.

75. By reason of the Production Defect, the Oxidising Defect, the Personal Injury Consequences and the Non-Personal Injury Consequences, the Affected Devices were not fit for the Insert Purpose.

76. By reason of the matters pleaded in section C above, individually and/or cumulatively, the Affected Devices were not fit for the disclosed purpose within the meaning of section 55 of the ACL (the **Fitness for Purpose Contraventions**).

77. Additionally, by reason of the same matters pleaded in section C above, individually and/or cumulatively, pursuant to section 74B of the TPA:

    a. the Affected Devices were not reasonably fit for the Insert Purpose;

    b. the Group Members, or at least one or some of them, have suffered loss and/or damage by reason that the Affected Devices were not reasonably fit for the Insert Purpose; and

    c. the Respondents, and/or one of them, are liable to pay compensation with respect to those losses and/or damage

    (the **Respondents' Liability for Unsuitable Goods**).

H. MISLEADING AND DECEPTIVE CONDUCT

78. The following conduct was engaged in by Exactech Australia in trade and commerce:

    a. making, and/or failing to correct or qualify the Device Representations; and

    b. making, and/or failing to correct or qualify the Future Device Representations

    (together, **the Misleading Device Conduct**).

79. At the time, or times, that Exactech Australia engaged in the Misleading Device Conduct, and in the period since its incorporation, the Affected Devices:

    a. were not, in their design and/or manufacturing:

        i. not defective;

        ii. good quality;

        iii. reliable;

        iv. durable;

        v. fit for purpose; and

        vi. safe; and

    b. did not provide predictable surgical outcomes.

Particulars

A. See section C above.

80. Further, or alternatively, each instance of the Misleading Device Conduct was:

a. conduct in connection with the supply or possible supply of the Affected Devices and/or in connection with the promotion of the supply or use of the Affected Devices within the meaning of section 29(1) of the ACL;

b. to the extent the relevant conduct was a representation, the making of a representation that the Affected Devices were of a particular standard, quality or composition within the meaning of section 29(1)(a) of the ACL; and/or

c. to the extent the relevant conduct was a representation, the making of a representation that the Affected Devices had performance characteristics, uses or benefits, within the meaning of section 29(1)(g) of the ACL.

81. By reason of the matters pleaded in paragraphs [78] to [79] above:

a. the incidences of the Misleading Device Conduct were, individually and/or cumulatively:

i. conduct that was false; and/or

ii. conduct that was misleading or deceptive, or likely to mislead or deceive,

in contravention of section 18 of the ACL and section 52 of the TPA;

b. to the extent the Misleading Device Conduct was a representation, it was a false or misleading representation in contravention of sections 29(1)(a), and/or 29(1)(g) of the ACL; and/or

c. the incidences of the Misleading Device Conduct were, individually and/or cumulatively, conduct that was liable to mislead the public as to the:

i. nature;

ii. characteristics; and/or

iii. suitability of purpose,

of the Affected Devices in contravention of section 33 of the ACL.

I. LIABILITY FOR A SAFETY DEFECT

82. When a Joint Device, including an Affected Device, was supplied to the Applicant or to a Group Member by a Supplier, the Joint Device and the Affected Device were supplied in trade or commerce.

83. By reason of the Production Defect, the Oxidising Defect and the Personal Injury Consequences, the Affected Devices:

a. possessed a safety defect within the meaning of section 9 and section 138 of the ACL; and/or

b. possessed a defect within the meaning of section 75AC and section 75AD of the TPA; and

c. caused the Applicant and/or the Group Members, or at least one or some of them, to suffer loss and/or damage.

84. By reason of the matters pleaded in the foregoing paragraph, the Respondents, and/or one of them, are liable to pay compensation with respect to those losses and/or damage (the **Respondents' Liability for Safety Defects**).

J. NEGLIGENCE

85. The Respondents owed the Applicant and the Group Members a duty to exercise reasonable care and skill in the design, evaluation, manufacture, packaging and supply of the Affected Devices.

86. At all material times, a reasonable manufacture and/or supplier of the Affected Devices knew or ought to have known that there were not insignificant risks of harm to the Applicant and the Group Members suffering one or more of the Personal Injury Consequences if implanted with a Joint Device which included an Affected Device.

87. A reasonable manufacturer and/or supplier in the position of the Respondents would have taken precautions against the Personal Injury Consequences by:

a. ensuring the Applicant, the Group Members, the Authorised Distributors and/or the Intermediaries were properly informed of the Device Warning Matters;

b. carrying out adequate clinical or other evaluation of the Device Evaluation Matters prior to the release in Australia of the Affected Devices, and their supply, distribution, marketing and/or promotion in Australia;

c. carrying out adequate clinical or other evaluation of the Device Evaluation Matters after the release in Australia of the Affected Devices, and their supply, distribution, marketing and/or promotion in Australia;

d. not marketing or supplying Inserts which have not been manufactured in such a way as to prevent, and/or arrest, and/or slow the process of oxidative degradation, *in vitro* and/ or *in vivo*, such as in accordance with the Predominant Industry Process;

e. not designing and manufacturing the Inserts:

i. with MXPLE, in lieu of HXPLE; and/or

ii. with MXPLE without Vitamin E Dosing; and/or

iii. not applying any Post-Production Thermal Processes;

f. designing and manufacturing the Inserts with HXPLE manufactured and treated pursuant to the Predominant Industry Process;

g. refraining from marketing and/or supplying the Affected Devices until such time as their safety and effectiveness, including their long-term safety and effectiveness, had been established;

h. refraining from marketing and/or supplying the Affected Devices until such time as the Device Evaluation Matters had been adequately evaluated clinically or by other scientific means; and

i. ensuring the Affected Devices were packaged in specification packaging which included an effective oxygen barrier

(the **Device Precautions**).

88. The Respondents, and/or one of them, breached their duty of care to the Applicant and the Group Members by failing to implement any of the Device Precautions (the **Common Law Breach Matters**).

K. CAUSATION

89. The Applicant and/or the Group Members, or at least one or some of them, suffered loss resulting from the occurrence of one or more of the Personal Injury Consequences by reason of:

a. the Acceptable Quality Contraventions and/or the Respondents' Liability for Unmerchantable Goods; and/or

b. the Fitness for Purpose Contraventions, and/or the Respondents' Liability for Unsuitable Goods; and/or

c. the Respondents' Liability for Safety Defects; and/or

d. the Common Law Breach Matters

(the **Personal Injury Damage and Loss**).

90. In addition to, or in the alternative, the Applicant and/or the Group Members, or at least one or some of them, with respect to section 272(1)(a) of the ACL, suffered loss and damage upon paying purchase prices for their Joint Devices and/or their Affected Devices which were greater than their 'true value' at the date of purchase by reason of the Acceptable Quality Contraventions (the **Loss of Value Damages**).

91. In addition to, or in the alternative, the Applicant and/or the Group Members, or at least one or some of them, sustained reasonably foreseeable losses resulting from the occurrence of one or more of the Non-Personal Injury Consequences by reason of:

a. the Acceptable Quality Contraventions pursuant to section 272(1)(b);

b. the Fitness for Purpose Contraventions pursuant to section 259(4); and

c. the Misleading Device Conduct.

92. In addition to, or in the alternative, but for the Misleading Device Conduct:

a. the Suppliers and/or the Authorised Dealers and/or the Intermediaries would not have supplied the Affected Devices to the Applicant and/or the Group Members, or at least one or some of them; and

b. the Applicant and/or the Group Members, or at least one or some of them, would have not suffered:

i. any Loss of Value Damages; and/or

ii. any of the Reasonably Foreseeable Losses.

L. LOSS AND DAMAGE

93. In the premises, the Applicant and the Group Members, or at least one or some of them, have suffered Personal Injury Damage and Loss.

Particulars

A. See the second schedule for particulars regarding the Personal Injury Damage and Loss (**Schedule 2**).

B. Further particulars of loss and damage will be provided after the completion of discovery processes and the service of expert evidence.

94. In the premises, the Applicant and the Group Members, or at least one or some of them, have suffered Loss of Value Damages.

Particulars

A. See the third schedule for particulars regarding Loss of Value Damages particulars (**Schedule 3**).

B. Further particulars of loss and damage will be provided after the completion of discovery processes and the service of expert evidence.

95. In the premises, the Applicant and the Group Members, or at least one or some of them, have suffered Reasonably Foreseeable Losses.

Particulars

A. See the fourth schedule for particulars regarding the Reasonably Foreseeable Pecuniary Losses (**Schedule 4**).

B. Further particulars of loss and damage will be provided after the completion of discovery processes and the service of expert evidence.

M. RELIEF

96. The Applicant claims, in his own right and on behalf of the Group Members, the relief specified in the accompanying Originating Application, namely statutory damages, common law damages (as modified by statute, such as the *Civil Liability Act* (2002) (NSW) and cognate legislation in other States and Territories), interest, costs and such further relief as the Court thinks fit.

Date: 5 September 2024

Signed by David Cossalter
Solicitor for the Applicant

This pleading was prepared by L Judd and M Robinson and settled by DE Graham SC

Certificate of lawyer

I, David Cossalter, certify to the Court that, in relation to the Statement of Claim filed on behalf of the Applicant, the factual and legal material available to me at present provides a proper basis for each allegation in the pleading.

Date: 5 September 2024

Signed by David Cossalter
Lawyer for the Applicant

Schedule 1 – Affected Devices

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	Assumed 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.	Equinoxe 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,	III	264381	25.11.14	TBA	Part 4-5, Div. 2 of the TGA Part 5, Div. 5.2 of the

	Shoulder, Glenoid Component					MDR
8.	Equinoxe Glenoid, Cage Pegged – Prosthesis, Internal, Joint, Shoulder, Glenoid Component	III	270232	16.02.16	TBA	Part 4-5, Div. 2 of the TGA 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, approximately	28.06.19	Assumed: Part 4-5, Div. 2 of the TGA Part 5, Div. 5.2 of the MDR
10.	Optetrak Tibial Insert, CC w/ Retaining Screw – Prosthesis, Knee, Internal, Insert Component	III	277743	12.07.16		Part 4-5, Div. 2 of the TGA Part 5, Div. 5.2 of the MDR
11.	Optetrak Tibial Insert, CR Slope – Prosthesis, Knee, Internal, Insert Component	Assumed III	278343	01.08.16, approximately	28.06.19	Assumed: Part 4-5, Div. 2 of the TGA Part 5, Div. 5.2 of the MDR
12.	Equinoxe Glenoid, Posterior Augment, 8 Degree, Pegged, Cemented – Prosthesis, Internal, Joint, Shoulder, Glenoid Compartment	III	278648	03.08.16		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	01.02.17, approximately	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 Component	Assumed III	286119	01.02.17, approximately	28.06.19	Assumed: Part 4-5, Div. 2 of the TGA Part 5, Div. 5.2 of the MDR
17.	Optetrak Logic Tibial Insert, CR – Prosthesis, Knee, Internal, Insert Component	III	285442	09.02.17		Part 4-5, Div. 2 of the TGA 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	III	285503	10.02.17		Part 4-5, Div.

	Tibial Insert PSC – Prosthesis, Knee, Internal, Insert Component					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 MXPLE (such as the acetabular cup)	Assumed III	TBA	1 September 2017, approximately	TBA	TBA
22.	Equinoxe Glenoid, Cage Pegged, Posterior Augment – Prosthesis, Internal, Joint, Shoulder, Glenoid Component	III	293762	12.09.17		Part 4-5, Div. 2 of the TGA Part 5, Div. 5.2 of the MDR

Schedule 2 - Personal Injury Damage and Loss

The Applicant's Personal Injury Damage and Loss

Injury - Post the Applicant's Index Surgery

1. Pain in the right knee, ranging from moderate to severe
2. Intermittent pain leading to constant pain in the right knee
3. Swelling in the right knee, ranging from moderate to severe
4. Deep vein thrombosis in the right leg
5. Intermittent swelling leading to constant swelling in the right knee
6. Osteolysis in the right knee
7. Synovitis
8. Pseudotumor otherwise known as a 'Baker's Cyst' or 'popliteal cyst'
9. Pulmonary embolism
10. Limited range of movement of the right knee
11. Unable to bear weight on the right leg
12. Depression
13. Stress

[Further particulars to be provided upon service of treating medical evidence and expert medical evidence]

Injury - Post the Total Knee Replacement Revision Surgery

14. Altered gait in the right leg
15. Reduced flexion in the range of movement of the right knee
16. Lower limb weakness
17. Compensatory pain in the left knee
18. Continued intermittent and moderate swelling of the right knee
19. Continued intermittent and moderate pain in the right knees
20. Permanent impairment of the right knee

[Further particulars to be provided upon service of treating medical evidence and expert medical evidence]

Losses - Generally

21. Non-economic loss for permanent impairment of the right knee, pain and suffering and loss of amenities of life

22. Past and future, out of pocket medical treatment and rehabilitation expenses (including any further requirement for revision surgery), to be further particularised upon the service of medical evidence including expert medical evidence

23. Interest on past out of pocket medical treatment and rehabilitation expenses.

24. Past and future, out of pocket medication (including pain relief) expenses, to be further particularised upon the service of medical evidence including expert medical evidence

25. Interest on past out of pocket medication expenses

26. Past and future, loss of earning capacity, to be further particularised upon the service of medical evidence including expert medical evidence and wage/salary information

27. Interest on past economic loss

28. Past and future, need for gratuitous and/or commercial personal attendant care services, to be further particularised upon the service of medical evidence including expert medical evidence and occupational health and safety expert evidence

29. Interest on past commercial attendant care services

30. Past and future, reasonable travel and accommodation expenses

The Group Members' Personal Injury Damages

1. The particulars of their injuries, loss and damage are not yet known and cannot be ascertained unless and until those advising the Applicant take detailed instructions from all Group Members on individual issues relevant to the determination of those individual group member claims.

2. These instructions will be obtained (and particulars of the losses of those group members will be provided) following opt out and the determination of the Applicant's claims and the common issues at any initial trial.

3. The personal injuries of the Group Members are expected to include one or more of those matters identified as the Personal Injury Consequences, together with related losses such as health care expenses, out of pocket treatment expenses, out of pocket travel expenses, economic loss, the need for gratuitous care and/or commercial care and non-economic loss.

Schedule 3 – Loss of Value Damages

The Applicant's Loss of Value Damages

1. The Applicant suffered the following loss and damage:

    a. the reduction in value of the Applicant's Defective Devices calculated by reference to the following factors:

        i. the true value of the Applicants' Defective Devices as a stated percentage of the average retail price for the type of Joint Device and/or Insert at the time of acquisition;

        ii. the average retail price for the particular Joint Device and/or Insert;

        iii. the adoption of an appropriate comparator being the lower of the Defective Device Cost and the average retail price for that type of Joint Device and/or Insert at that time; and

        iv. the difference between the true value of the Applicants' Defective Devices, as calculated in step (i) and the applicable comparator in that particular case as determined in step (iii).

The Group Members' Loss of Value Damages

2. The Group Members, or at least one or some of them, suffered the following loss and damage:

    a. the reduction in value of their Joint Devices and/or Affected Devices calculated by reference to the following factors:

        i. the true value of the Joint Devices and/or the Affected Devices as a stated percentage of the average retail price for those types of devices at the time of acquisition;

        ii. the average retail price for the particular devices;

        iii. the adoption of an appropriate comparator being the lower of the price that was in fact paid for the Joint Devices and/or the Affected Devices and the average retail price for those particular devices at that time; and

        iv. the difference between the true value of the Joint Devices and/or the Affected Devices, as calculated in step (i) and the applicable comparator in that particular case as determined in step (iii).

3. Further particulars of the Group Members' loss and damage are not yet known and cannot be ascertained unless and until those advising the Applicant take detailed instructions

from all Group Members on individual issues relevant to the determination of those individual group member claims.

4. These instructions will be obtained (and particulars of the losses of those group members will be provided) following opt out and the determination of the Applicant's claims and the common issues at any initial trial.

Schedule 4 - Reasonably Foreseeable Losses

The Applicant's Reasonably Foreseeable Losses

Past

1. Out of pocket medical treatment and rehabilitation expenses incurred after the Applicant's Index Surgery with respect to the emergence of pathology caused by the Applicant's Defective Devices
2. Out of pocket medication expenses incurred after the Applicant's Index Surgery with respect to the emergence of pathology caused by the Applicant's Defective Devices
3. Out of pocket transport expenses incurred after the Applicant's Index Surgery in relation to obtaining medical treatment or rehabilitation regarding the emergence of pathology caused by the Applicant's Defective Devices
4. Out of pocket transport expenses incurred after the Applicant's Index Surgery in relation to obtaining medication expenses regarding the emergence of pathology caused by the Applicant's Defective Devices
5. Past loss of earning capacity
6. Pay of any excess GST in acquiring the Applicant's Defective Devices at a price which did not account for the reduction in value of the KJD
7. Disappointment because the Applicant's Defective Devices suffers from the Production Defect and/or the Oxidising Defect whereas other Inserts do not suffer from these defects.
8. Distress because there is a reasonable prospect the Applicant will need to either:
    a. undergo a third revision arthroplasty procedure to his right knee in approximately 15 to 20 years, when he is aged between 72 and 77 years which may cause him significant disability, which may not have been required had the Applicant's Defective Device not possessed the Production Defect and/or the Oxidising Defect; and/or
    b. undergo a third revision arthroplasty procedure to his right knee which may prematurely cause him significant disability, which may not have occurred until the later stages of the Applicant's life had the Applicant's Defective Device not failed prematurely.

[Further particulars to be provided upon service of expert medical and occupational therapy evidence]

Future

9. Out of pocket medical treatment and rehabilitation expenses to be incurred as a consequence of any future revision surgery

10. Out of pocket medication expenses to be incurred as a consequence of any future revision surgery

11. Out of pocket transport expenses to be incurred as a consequence of any future revision surgery, such as obtaining medical care or medication

12. Future loss of earning capacity

[Further particulars to be provided upon service of expert medical and occupational therapy evidence]

The Group Members' Reasonably Foreseeable Losses

1. Particulars of the Group Members' loss and damage are not yet known and cannot be ascertained unless and until those advising the Applicant take detailed instructions from all Group Members on individual issues relevant to the determination of those individual group member claims.

2. These instructions will be obtained (and particulars of the losses of those group members will be provided) following opt out and the determination of the Applicant's claims and the common issues at any initial trial.

3. The Reasonably Foreseeable Losses of the Group Members are expected to include one or more of the following matters:

    a. additional out of pocket expense to have their Joint Device, and its Affected Device, reviewed by their treating general practitioner and/or treating orthopaedic surgeon to ensure its continued safe operation (over and above the usual amounts that would be incurred by person with a joint device not composed with an Affected Device); and/or

    b. additional financing costs to pay the purchase prices for their Joint Devices and/or Affected Devices which were greater than their 'true value'; and/or

    c. additional GST imposts as a consequence of paying the purchase prices for their Joint Devices and/or Affected Devices which were greater than their 'true value'; and/or

    d. non-personal injury damages resulting from the occurrence of one or more and/or the Non-Personal Injury Consequences, such as:

        i. distress and/or anguish because the relevant Affected Device may cause the Group Member to suffer from any one or more of the Personal Injury Consequences;

ii. distress and/or anguish because the relevant Affected Device may require premature revision surgery; and

iii. disappointment because the Affected Device suffers from the Production Defect and/or the Oxidising Defect whereas other Inserts do not suffer from these defects.