NOTICE OF FILING

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Details of Filing

Document Lodged:	Statement of Claim - Form 17 - Rule 8.06(1)(a)
File Number:	NSD244/2021
File Title:	DEBRA FOWKES v BOSTON SCIENTIFIC CORPORATION & ANOR
Registry:	NEW SOUTH WALES REGISTRY - FEDERAL COURT OF AUSTRALIA

Dated: 7/06/2022 10:42:26 AM AEST Registrar

Important Information

As required by the Court's Rules, 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)

Amended Statement of claim

Amended on 7 June 2022, filed pursuant to an order of the Court made on 1 June 2022

No. of 20

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

Debra Fowkes
Applicant

Boston Scientific Corporation
First Respondent

Boston Scientific Pty Limited
Second Respondent

PART A: THE PARTIES

(i) Group Members

1. The Applicant brings this proceeding as a representative proceeding pursuant to Part IVA of the *Federal Court of Australia Act 1976* (Cth):

   (a) in her own right; and

   (b) on behalf of persons (**Group Members**), being persons who, at any time up to and including the date on which leave is granted to file and serve this Amended Statement of Claim:

      (i) had surgery performed on them in Australia to implant one or more of the following transvaginal mesh devices (**Implants**):

Filed on behalf of (name & role of party) Debra Fowkes (Applicant)
Prepared by (name of person/lawyer) Rebecca Jancauskas, Shine Lawyers
Law firm (if applicable) Shine Lawyers
Tel (07) 3006 6051 Fax (07) 3229 1999
Email rjancauskas@shine.com.au
Address for service (include state and postcode) Level 13, 160 Ann Street, Brisbane QLD 4000

(A) implants intended to treat pelvic organ prolapse (collectively, **POP Implants**), being:

(i) the implants included in the Pinnacle Pelvic Floor Repair and Pinnacle LITE Floor Repair Anterior-Apical, Posterior and Duet Kit (**Pinnacle Implants**), which were available as Anterior-Apical, Posterior or Duet implants;

(ii) the implants included in the Uphold Vaginal Support System (**Uphold Implants**) which were made available as Anterior-Apical implants;

(iii) the implants included in the Uphold LITE with Capio SLIM Vaginal Support System and Pelvic Floor Repair Kit Uphold LITE Vaginal Support System (**Uphold LITE Implants**) which were made available as Anterior-Apical implants; and

(iv) the implants included in the Upsylon Y-Mesh Kit and Y-Mesh (**Upsylon Implants**) which were made available as Anterior-Apical implants; and

(v) the Polyform Synthetic Mesh implants (**Polyform Implants**).

(B) implants intended to treat stress urinary incontinence (collectively, **SUI Implants**), being:

(i) the implant included in the Advantage Transvaginal Mid-Urethral Sling System and the Advantage Blue System (**Advantage Implants**);

(ii) the implant included in the Advantage Fit Transvaginal Mid-Urethral Sling System and the Advantage Fit Blue System (**Advantage Fit Implants**);

(iii) the implant included in the Obtryx Transobturator Mid-Urethral Halo and Curved Sling System (**Obtryx Implants**);

(iv) the implant included in the Obtryx II Transobturator Mid-Urethral Sling System – Halo (**Obtryx II Implants**);

(v) the implant included in the Lynx Suprapubic Mid-Urethral Sling System and the Lynx Blue System (**Lynx Implants**); and

(vi) the implant included in the Solyx Single Incision ~~Mid-Urethral~~ Sling System (**Solyx Implants**); and

(ii) were supplied with one or more of the Implants by their treating hospital or doctor for the treatment of pelvic organ prolapse or stress urinary incontinence as the case may be.

(ii) The Applicant

2. The Applicant (**Mrs Fowkes**) is a Group Member by reason of the matters pleaded at paragraphs 40 to 59 below.

(iii) The Respondents

3. At all material times, the First Respondent, Boston Scientific Corporation (**Boston Scientific**):

(a) was and is a company incorporated under the laws of the United States of America;

(b) was and is a foreign corporation within the meaning of section 4 of the *Trade Practices Act 1974* (Cth) (**the TPA**) and section 4 of the *Competition and Consumer Act 2010* (Cth) (**the CCA**);

(c) did not have a place of business in Australia;

(d) carried on business within Australia by:

(i) supplying the Implants to a related body corporate, being the Second Respondent, Boston Scientific Pty Ltd (**Boston Australia**), for distribution to hospitals and doctors in Australia for re-supply to patients during the periods of time identified in the schedule annexed to this statement of claim and marked "**A**"; and

(ii) marketing and promoting the Implants in Australia, including by causing the distribution of physician brochures to hospitals and doctors, marketing the Implants at medical symposiums held in Australia for the medical profession, sponsoring medical symposiums and workshops held in Australia and distributing patient brochures;

Particulars

(A) Boston Scientific distributed physician brochures to hospitals and doctors, including:

(i) a product brochure for the Uphold Implants titled "*Uphold Vaginal Support System*";

(ii) a product brochure for the Upsylon Implants titled "*Upsylon Y-Mesh and Colpassist Vaginal Positioning Device*";

(iii) a product brochure for the Advantage Implants and Advantage Fit Implants titled "*Advantage Fit and Advantage Transvaginal Mid-urethral Sling Systems*";

(iv) a product brochure for the Obtryx II Implants titled "*Obtryx II Transvaginal Mid-urethral Sling Systems*"; and

(v) a technique brochure for the Obtryx Sling System titled "*Technique Spotlight Transobturator Mid-Urethral Sling*" (2006).

(B) Boston Scientific marketed and promoted the Implants at medical symposiums, including:

(i) a 2005 event, Australian Gynaecological Endoscopy Society Ltd (AGES) – XV Annual Scientific Meeting - Art & Science;

(ii) a 2005 event, Australian Gynaecological Endoscopy Society Ltd (AGES) – Pelvic Floor Symposium & Workshop VI 2005 - New Solutions;

(iii) a 2006 event, Australian Gynaecological Endoscopy Society Ltd (AGES) – XVI Annual Scientific Meeting – Managing Common Gynaecological Challenges;

(iv) a 2007 event, Australian Gynaecological Endoscopy Society Ltd (AGES) – XVII Annual Scientific Meeting – Risk Management in Gynaecology and Endoscopic Surgery;

(v) a 2007 event, Australian Gynaecological Endoscopy Society Ltd (AGES) - Pelvic Floor Symposium & Workshop VIII – Pelvic Floor Surgery in Perspective;

(vi) a 2008 event, Australian Gynaecological Endoscopy Society Ltd (AGES) - Pelvic Floor Symposium & Workshop IX – Cleveland Clinic Downunder;

(vii) a 2009 event, Australian Gynaecological Endoscopy Society Ltd (AGES) – Pelvic Floor Symposium & Workshop X 2009, The Horizon;

(viii) a 2010 event, Australian Gynaecological Endoscopy Society Ltd (AGES) – XX Annual Scientific Meeting – Gynaecological Endoscopy: Has it Come of Age?;

(ix) a 2011 event, Australian Gynaecological Endoscopy Society Ltd (AGES) – XXI Annual Scientific Meeting – Disaster Recovery & Risk Management;

(x) a 2011 event, Urological Society of Australia and New Zealand (Victorian Section) – Annual Scientific Meeting;

(xi) a 2012 event, Australian Gynaecological Endoscopy Society Ltd (AGES), XXII Annual Scientific Meeting 2012 – Minimally Invasive Gynaecology: Idealism, Scepticism & Reality;

(xii) a 2013 event, Australian Gynaecological Endoscopy Society Ltd (AGES) – XXIII Annual Scientific Meeting – The Pelvis in Pain, Endometriosis and Beyond;

(xiii) a 2014 event, Australian Gynaecological Endoscopy Society Ltd (AGES) – XXIV Annual Scientific Meeting – Tomorrow's Theatre Today: Robotics, Instrumentation, Vision;

(xiv) a 2014 event, 23rd National Conference on Incontinence (Joint Meeting of the Continence Foundation of Australia, International Children's Continence Society and the UroGynaecological Society of Australasia;

(xv) a 2015 event, The International Society for Gynaecologic Endoscopy ISGE 24th Annual Congress with Australian Gynaecological Endoscopy & Surgery (AGES) – XXV Annual Scientific Meeting – Controversies and Challenged in Minimally Invasive Surgery;

(xvi) a 2016 event, Australian Gynaecological Endoscopy Society Ltd (AGES) – XXVI Annual Scientific Meeting - The Modern Woman;

(xvii) a 2017 event, Australian Gynaecological Endoscopy Society Ltd (AGES) – XXVII Annual Scientific Meeting – Surgery in O&G: Building it Up, Breaking it Down;

(xviii) a 2018 event, Australian Gynaecological Endoscopy Society Ltd (AGES) – XXVIII Annual Scientific Meeting - Evolution Towards Excellence; and

(xix) a 2018 event, Australian Gynaecological Endoscopy Society Ltd (AGES) – Pelvic Floor Symposium & Workshop XIX – More than Gynaecology? The Pelvic Floor MDT (Multi-Disciplinary Team).

(C) Boston Scientific sponsored symposiums and workshops, including:

(i) a 2006 event, Australian Gynaecological Endoscopy Society Ltd (AGES) - Pelvic Floor Symposium & Workshop VII – Anatomy & Function of the Female Pelvic Floor;

(ii) a 2010 event, Australian Gynaecological Endoscopy Society Ltd (AGES) – Pelvic Floor Symposium & Workshop XI 2010, Optimising Surgical Outcomes;

(iii) a 2011 event, Australian Gynaecological Endoscopy Society Ltd (AGES) – Pelvic Floor Symposium & Workshop XII 2011 – Obstetric Trauma to Pelvic Floor Repair, Surgical Essentials;

(iv) a 2012 event, Australian Gynaecological Endoscopy Society Ltd (AGES) – Pelvic Floor Symposium & Workshop XIII 2013 – Vaginal and Pelvic Surgery: The Art & The Controversies;

(v) a 2013 event, Australian Gynaecological Endoscopy Society Ltd (AGES) – Pelvic Floor Symposium & Workshop XIV 2013 – The Pelvic Floor, From Every Angle;

(vi) a 2014 event, Australian Gynaecological Endoscopy Society Ltd (AGES) – Pelvic Floor Symposium & Workshop XV – Pelvic Floor Surgery – Going Native;

(vii) a 2016 event, Australian Gynaecological Endoscopy Society Ltd (AGES) – Pelvic Floor Symposium & Workshop XVII – the Art of Reconstruction; and

(viii) a 2017 event, Australian Gynaecological Endoscopy Society Ltd (AGES) – Pelvic Floor Symposium & Workshop XVIII – Challenging Times.

(D) Boston Scientific distributed patient brochures, including:

(i) a patient brochure titled "*What you should know about your diagnosis of incontinence (Advantage Sling System)"* (2004);

(ii) a patient brochure titled "*Obtryx Sling System, A minimally Invasive Approach to Treating stress Urinary Incontinence*" (2005);

(iii) a patient brochure titled "*Pelvic Organ Prolapse, Your Guide to Pelvic Floor Reconstruction, Upsylon Y-Mesh"* (2013); and

(iv) a patient brochure titled "*A Patient Guide to Understanding Stress Urinary Incontinence"* (May 2017).

Further particulars may be provided following discovery and the issue of subpoenas.

(e) was the manufacturer of each of the Implants.

Particulars

(i) Boston Scientific produced or assembled the Implants, including within the meaning of section 74A(1) of the TPA and section 7(1)(a) of the CCA.

(ii) Boston Scientific held itself out to the public as the manufacturer of the Implants, including within the meaning of section 74A(3)(a) of the TPA and section 7(1)(b) of the CCA.

(iii) Boston Scientific caused or permitted its name to be applied to each of the Implants within the meaning of section 74A(3)(b) of the TPA and section 7(1)(c) and CCA.

4. At all material times, the Second Respondent, Boston Australia:

(a) was and is a company incorporated in Australia;

(b) was and is a trading corporation within the meaning of section 4 of the TPA and section 4 of the CCA;

(c) was not the manufacturer of the Implants;

(d) imported the Implants into Australia;

(e) acquired the POP Implants and SUI Implants from Boston Scientific for re-supply in trade or commerce to treating hospitals and in addition, or alternatively, to treating doctors;

(f) marketed, promoted and supplied the Implants in Australia; and

(g) by reason of the matters referred to at paragraphs 3(e), 4(c) and 4(d) is deemed to be the manufacturer of the Implants above by operation of section 74A(4) of the TPA and section 7(e) of Schedule 2 of the CCA.

PART B: THE CONDITIONS OF POP AND SUI

5. Pelvic organ prolapse (**POP**):

(a) is an anatomical change in which there is downward displacement of a pelvic organ;

(b) can present as:

(i) uterine prolapse, in which the uterus descends;

(ii) cervical prolapse, involving the descent of the cervix (the neck of the uterus); or

(iii) vaginal prolapse, involving the descent of one or more of the compartments of the vagina;

(c) is not a life threatening condition; and

(d) may be treated surgically or non-surgically at the election of the patient.

6. POP may result in one or more of the following symptoms:

(a) problems with bowel movement;

(b) problems with voiding;

(c) problems during sexual intercourse;

(d) vaginal bulge; and

(e) feelings of pelvic and in addition, or alternatively, vaginal fullness, heaviness, discomfort and/or pain.

7. Stress urinary incontinence (**SUI**):

(a) can occur when pelvic support structures to the bladder and urethra are damaged, weakened or otherwise compromised;

(b) involves urine involuntarily leaking from the urethra during moments of increased abdominal pressure such as with physical activity, coughing, sneezing or laughing; and

(c) may be treated surgically or non-surgically at the election of the patient.

PART C: THE IMPLANTS, THEIR RISKS AND COMPLICATIONS

(i) The Implants

8. The Implants are surgical implants that are:

(a) made, at least partly, from polypropylene;

(b) implanted transvaginally, abdominally or laparoscopically;

(c) brought into contact with the vagina and, in the case of the SUI Implants, the urethra during implantation;

(d) intended to, and do, elicit a chronic inflammatory reaction of the tissues and, or alternatively, the surrounding tissues, in which they are implanted; and

(e) catalysts for the continuous regeneration of scar tissue within and surrounding the Implant for so long as it remains in the body, which can cause the Implant (separately or in conjunction with surrounding tissue) to contract.

9. The price of the Implants acquired by each of the Group Members did not exceed forty thousand dollars ($40,000) per Implant.

10. Group Members were supplied with the Implants, by their treating hospital or treating doctor, on the advice of their treating doctor.

11. The POP Implants were designed and manufactured to:

(a) be used during pelvic surgery for the safe and effective treatment of POP;

(b) restore pelvic anatomy and pelvic function safely and effectively; and

(c) alleviate the symptoms of POP

(**the POP Purpose**)

12. The SUI Implants were designed and manufactured to:

(a) be implanted in women for the safe and effective surgical treatment of SUI;

(b) provide urethral support safely and effectively in patients; and

(c) alleviate safely and effectively involuntary urine leakage caused by SUI

(the **SUI Purpose**).

(ii) The Implant Risks and Complications

13. By reason of one or more of the matters pleaded at paragraph 8, or otherwise, the Implants had a risk of causing the following complications (**Implant Complications**):

(a) pain, which may be chronic and, or alternatively, severe and may be refractory to treatment;

(b) entrapment of nerves in the scar tissue surrounding the Implant resulting in pain which may be chronic and, or, severe and may not remain localised and may be refractory to treatment;

(c) de novo dyspareunia which may be severe, worsened dyspareunia and in addition, or alternatively, apareunia;

(d) erosion or extrusion of the Implant into the vaginal canal resulting in:

(i) infection of the tissue surrounding the non-exposed part of the Implant which may be difficult to treat effectively and may result in offensive vaginal discharge;

(ii) pain including during sexual intercourse;

(e) erosion or extrusion of the Implant into surrounding organs such as the bladder, urethra or rectum with the risk of damage to those organs, infection and, or alternatively, pain;

(f) difficulty voiding or defecating;

(g) de novo urge incontinence and/or urge incontinence;

(h) de novo stress urinary incontinence in the case of the POP Implants; and

(i) psychiatric injury as a consequence of the development of one or more of the complications referred to at paragraphs (a) to (h) above.

14. The risk that a patient may suffer an Implant Complication is a lifelong risk.

15. The likelihood of occurrence of Implant Complications cannot be accurately predicted for a patient, although certain patients may be particularly susceptible (**Particularly Susceptible Patients**) to Implant Complications, including if they:

    (a) suffer an autoimmune condition or connective tissue disorder;

    (b) have used or are using immuno-suppressant medication;

    (c) are of advanced age;

    (d) are obese;

    (e) suffer uncontrolled diabetes; and, or,

    (f) are anaemic.

16. Further:

    (a) treatment of the Implant Complications may require one or more surgical procedures for the purpose of removing the Implants or those parts of the Implants that are reasonably capable of being removed;

    (b) despite the risk that treatment may be required as described in subparagraph (a), the Implants are difficult or impossible safely to remove from patients suffering from one or more of the Implant Complications;

    (c) by reason of the matters identified at subparagraphs (a) and (b) and otherwise, treatment of the Implant Complications may be difficult or impossible and carries with it the risk of new or aggravated complications; and

    (d) patients may suffer psychiatric injury as a consequence of the matters referred to at subparagraphs (a) to (c) above

    (**the Implant Treatment and Removal Complications**).

PART D: AVAILABILITY OF ALTERNATIVE TREATMENTS

17. At all material times:

    (a) reconstructive surgery for the treatment for POP could be undertaken without the use of POP Implants (**Native Tissue Repair**);

(b) Native Tissue Repair was as effective in treating POP, or in the alternative was not materially less effective in treating POP, as reconstructive surgery for the treatment for POP undertaken using POP Implants;

(c) Native Tissue Repair did not have the risks of, and in addition, or alternatively, was not susceptible to causing:

(i) the Implant Complications; and, or alternatively

(ii) the Implant Treatment and Removal Complications;

(d) Native Tissue Repair was an accepted method of reconstructive surgery for the treatment for POP;

(e) in addition, or alternatively, Native Tissue Repair was safer or, in the alternative, was not materially less safe in treating POP, as reconstructive surgery for the treatment of POP undertaken using POP Implants.

18. At all material times:

(a) there were alternative treatments available for the treatment of SUI (**Alternative SUI Treatments**) which could be undertaken without the use of SUI Implants;

Particulars

Alternative SUI Treatments included:

(i) bulking agents;

(ii) open colposuspension (Burch procedure);

(iii) laparoscopic colposuspension;

(iv) fascial (or native tissue or autologous) sling repair; and

(v) non-surgical treatments including but not limited to pelvic floor exercises.

(b) the Alternative SUI Treatments were accepted methods of treating SUI;

(c) the Alternative SUI Treatments were as effective in treating SUI, or alternatively were not materially less effective in treating SUI as surgery for the treatment of SUI undertaken using SUI Implants;

(d) the Alternative SUI Treatments did not have the risks of causing, and were not susceptible to cause:

(i) some or all of the Implant Complications; or

(ii) the Implant Treatment and Removal Complications; and

(e) in addition, or alternatively, the Alternative SUI Treatments were as safe in treating SUI, or, in the alternative, were not materially less safe in treating SUI, as surgery for the treatment of SUI undertaken using SUI Implants.

PART E: FAILURE TO EVALUATE OR WARN

19. Prior to the supply, distribution, marketing or promotion in Australia of the Implants, Boston Scientific did not undertake any, or any adequate, clinical or other evaluation of the risks, including long-term risks, and effectiveness, including the long-term effectiveness, associated with the use of the Implants, including:

(a) the risk of occurrence of the Implant Complications;

(b) the risk of occurrence of the Implant Treatment and Removal Complications;

(c) as to the comparative safety and effectiveness of:

(i) the treatment of POP using the POP Implants as compared to Native Tissue Repair;

(ii) the treatment of SUI using the SUI Implants as compared to the Alternative SUI Treatments;

(the **Implant Evaluation Matters**).

20. At all material times, Boston Scientific and, or alternatively, Boston Australia failed to give sufficient information or warning to Group Members (directly or by providing sufficient information or warning to their treating hospitals and/or treating doctors) of:

(a) the risk or susceptibility of the Implants to cause one or more of the Implant Complications;

(b) the heightened risks for Particularly Susceptible Patients associated with the use of the Implants;

(c) the Implant Treatment and Removal Complications; and in addition, or alternatively,

(d) the Implant Evaluation Matters.

(the **Implant Warning Matters**).

PART F: CLAIMS UNDER THE TPA AND CCA

21. The Implants are goods within the meaning of sections 4 and 74A(2)(a) of the TPA, and sections 2 and 271 of Schedule 2 of the CCA.

22. By reason of the matters pleaded at paragraphs 9 and 11 or 12, the Implants were supplied to each of the Group Members as consumers within the meaning of section 4B of the TPA and section 3 of Schedule 2 of the CCA.

The Implants are defective and have a safety defect

23. Having regard to all of the relevant circumstances, which include that:

(a) the Implants were intended to treat conditions, being POP or SUI, which are not life-threatening;

(b) alternative treatments, in the form of Native Tissue Repair in the case of POP or Alternative SUI Treatments in the case of SUI, were available;

(c) prior to the release in Australia of the Implants, or the supply, distribution, marketing or promotion in Australia of the Implants, Boston Scientific did not undertake any, or any adequate, clinical or other evaluation of the Implant Evaluation Matters;

(d) a patient who receives an Implant is at risk that she may suffer one or more of the Implant Complications;

(e) the risk of developing one or more Implant Complications is a lifelong risk;

(f) it is not possible to predict whether a patient will suffer an Implant Complication;

(g) a patient who suffers an Implant Complication may suffer one or more of the Implant Treatment and Removal Complications; and, or alternatively,

(h) the information, including the information contained in marketing materials and the product labelling, including the directions for use, which accompanied the Implants at the time of supply to treating hospitals or treating doctors as the case may be, did not give sufficient warning, advice or information as to the Implant Warning Matters

the safety of the Implants was not such as persons generally were entitled to expect and the Implants had a defect for the purposes of sections 75AC(1) and 75AD(1) of the TPA and, or alternatively, a safety defect for the purposes of sections 9 and 138 of Schedule 2 of the CCA.

Lack of merchantability or acceptable quality

24. By reason of the matters pleaded at subparagraph 23(a) to (h) above, the Implants acquired by each of the Group Members were not of merchantable quality within the meaning of section 74D(3) of the TPA, or acceptable quality within the meaning of section 54 of Schedule 2 of the CCA.

Loss and damage

25. In the premises, each of the Group Members has suffered loss and damage, by reason of the fact that:

    (a) the safety of any of the Implants was not such as persons generally were entitled to expect, and the Implants had a defect or a safety defect as pleaded at paragraph 23 above; and in addition, or in the alternative,

    (b) the Implants were not of merchantable or acceptable quality as pleaded at paragraph 24 above.

Particulars

Particulars of each Group Member's loss and damage (other than that of the Applicant) will be provided after the trial of common issues but is expected to include:

(i) personal injury including by reason that the Group Member has suffered one or more of the Implant Complications and Implant Treatment and Removal Complications;

(ii) health care expenses;

(iii) other out of pocket expenses;

(iv) economic loss;

(v) the need for attendant care provided on a gratuitous and/or commercial basis; and

(vi) non-economic loss.

26. In the premises, Boston Scientific and, or alternatively, Boston Australia is liable to compensate each of the Group Members for their loss and damage pursuant to:

    (a) section 75AD of the TPA, or section 138 of Schedule 2 of the CCA, as the case may be;

    (b) sections 74D(1) of the TPA, or sections 54, 271 and 272 of Schedule 2 of the CCA, as the case may be.

PART G: NEGLIGENCE

27. Boston Scientific owed each of the Group Members a duty to exercise reasonable care and skill in the design, manufacture, marketing and supply of the Implants .

28. Boston Scientific:

    (a) knew or ought to have known that the purpose for which the:

        (i) POP Implants were commonly supplied was the POP Purpose; and

        (ii) SUI Implants were commonly supplied was the SUI Purpose; and

    (b) did not undertake any, or any adequate, clinical or other evaluation of the Evaluation Matters prior to the release in Australia of the Implants and the supply, distribution, marketing or promotion in Australia of the Implants.

29. In the circumstances pleaded at paragraph 28 above, Boston Scientific, designed, manufactured, marketed and in addition, or alternatively, supplied the Implants containing:

    (a) the characteristics pleaded at paragraph 8 above; and in addition, or alternatively

    (b) a risk of, or susceptibility to cause, the:

        (i) Implant Complications; and

        (ii) the Implant Treatment and Removal Complications.

30. In addition to paragraph 29 above, Boston Scientific continued to design, manufacture, market and in addition, or alternatively, supply the Implants for the periods of time identified in Schedule A notwithstanding the matters pleaded in paragraph 29 above.

31. In addition, or alternatively, to paragraphs 29 and 30 above, Boston Scientific failed to conduct any, or any adequate, evaluation of the safety and effectiveness of the Implants in treating POP or SUI, as the case may be, after releasing them in Australia.

32. Boston Scientific:

    (a) failed to inform the Group Members of:

        (i) the matters pleaded in paragraphs 28 and 29 above; and, or alternatively

        (ii) the Implant Warning Matters; and

    (b) further or alternatively, failed to inform:

        (i) Boston Australia; and, or alternatively

        (ii) treating hospitals; and in addition, or alternatively treating doctors to whom the Implants were supplied,

    of the matters pleaded in subparagraph 32(a) above.

33. By reason of the matters pleaded at paragraphs 28 to 32 above, Boston Scientific breached the duty of care it owed to each of the Group Members pleaded at paragraph 27 above.

34. By reason of the breaches referred to at paragraph 33 above, each of the Group Members has suffered loss or damage.

Particulars

The particulars to paragraph 25 are repeated.

35. In addition, or in the alternative, to the matters pleaded at paragraphs 28 to 34 above, Boston Australia owed each of the Group Members a duty to exercise reasonable care and skill in the supply and marketing of the Implants.

36. Boston Australia marketed and in addition, or alternatively, supplied the Implants containing:

    (a) the characteristics pleaded at paragraph 8 above; and in addition, or alternatively

    (b) a risk of, and in addition, or alternatively, a susceptibility to causing the Implant Complications and in addition, or alternatively, the Implant Treatment and Removal Complications.

37. Boston Australia marketed or supplied the Implants in the circumstances referred to at paragraph 36 and failed to inform Group Members, their treating hospitals and, or alternatively, treating doctors of the Implant Warning Matters.

38. By reason of the matters pleaded at paragraphs 36 to 37 above, Boston Australia breached the duty of care it owed to each of the Group Members pleaded at paragraph 35 above.

39. By reason of the matters pleaded at paragraphs 35 to 38 above, each of the Group Members has suffered loss or damage.

Particulars

The particulars to paragraph 25 are repeated.

PART H: THE APPLICANT'S IMPLANT SURGERY, COMPLICATIONS AND LOSS AND DAMAGE

40. Mrs Fowkes:

    (a) was born on 2 October 1964; and

    (b) is married with five adult children.

41. By about March 2014, Ms Fowkes was experiencing symptoms of POP and mixed urinary incontinence including SUI.

Particulars

Mrs Fowkes had a cystocele, moderate rectocele, SUI and urge incontinence.

42. Prior to 13 March 2014, Mrs Fowkes' Treating Doctor, Dr Anna Rosamilia, urogynaecologist, advised Mrs Fowkes of the option to treat her SUI by use of a Sling Implant.

Particulars

A letter from Dr Rosamilia to Mrs Fowkes' referring general practitioner, Dr Bryony Taylor, dated 13 March 2014, confirms that the advice was given to Mrs Fowkes' on or around 13 March 2014.

43. By reason of the matters pleaded in paragraph 20 above, at no time before 26 March 2015, was Mrs Fowkes informed of the Implant Warning Matters in respect of the Sling Implant.

44. On 26 March 2015, Dr Rosamilia operated on Mrs Fowkes by:

    (a) implanting an Advantage Implant for the purpose of treating Mrs Fowkes' SUI (the **Implant Surgery**);

(b) performing a Native Tissue procedure for the purpose of treating Mrs Fowkes' POP, specifically, anterior and posterior repairs.

45. The purpose for which Mrs Fowkes received the Advantage Implant was the SUI Purpose.

46. After the Implant Surgery on 26 March 2015, Mrs Fowkes experienced vaginal pain and dyspareunia.

47. As at May 2017, Mrs Fowkes was suffering from:

(a) vaginal discharge;

(b) dyspareunia;

(c) SUI; and

(d) urge incontinence.

48. On 13 September 2017,

(a) Mrs Fowkes consulted with gynaecologist Dr Peter Lee, complaining of symptoms associated with the conditions pleaded at paragraph 47;

(b) Dr Lee scheduled Mrs Fowkes for an examination under anaesthetic, a cystoscopy and revision surgery in order to divide the Advantage Implant.

49. On 13 October 2017, Dr Peter Lee operated on Mrs Fowkes by:

(a) dividing the Advantage Implant; and

(b) performing a cystoscopy

(the **First Implant Revision Surgery**).

50. In January 2018, Mrs Fowkes was suffering from:

(a) dyspareunia; and

(b) pain and/or tenderness at the right pubic rami and the pubic arch.

51. By 13 June 2018, Mrs Fowkes had been suffering from dyspareunia for a period of about 6 months.

52. By about January 2019, Mrs Fowkes was suffering from persistent voiding dysfunction.

53. On 7 February 2019, Dr Natharnia Young operated on Mrs Fowkes by:

(a) performing a uretheral dilatation; and

(b) performing a cystoscopy.

54. As at 18 March 2019, Mrs Fowkes continued to suffer from dyspareunia.

55. On 4 April 2019, Dr Natharnia Young operated on Mrs Fowkes by:

(a) excising the Advantage Implant to the pubic symphysis left and right; and

(b) performing a cystoscopy before and after the excision procedure

(the **Second Implant Revision Surgery**).

56. As at 9 July 2019:

(a) Mrs Fowkes was no longer suffering from dyspareunia; and

(b) Mrs Fowkes was experiencing occasional incontinence.

57. By about 18 February 2020, Mrs Fowkes was experiencing pain in the form of a burning sensation in the vagina.

58. The complications pleaded at paragraphs 46, 47, 50, 51, 53, 55 and 56 are Implant Complications suffered by Mrs Fowkes as a result of being implanted with the Advantage Implant.

59. Further, or alternatively, the First and Second Revision Surgeries and the complications pleaded at paragraphs 50, 51, 53 and 56 are Implant Treatment and Removal Complications suffered by Mrs Fowkes as a result of being implanted with the Advantage Implant.

60. By reason of the matters pleaded at paragraphs 42 to 58, Mrs Fowkes has suffered loss and damage.

Particulars

A schedule of the particulars of loss and damage suffered by Ms Fowkes will be provided prior to trial. The loss and damage includes but is not limited to:

(A) Personal injury including one or more of the Implant Complications and Implant Treatment and Removal Complications including the complications pleaded at paragraphs 46, 47, 48, 50, 51, 53, 55 and 56 above.

(B) Health care expenses.

(C) Additional out of pocket expenses.

(D) Economic loss.

(E) The need for gratuitous and/or commercial care.

(F) Non-economic loss.

(G) Additional particulars may be provided following the service of evidence.

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61. Mrs Fowkes claims:

(a) damages as modified by the *Wrongs Act 1958* (Vic);

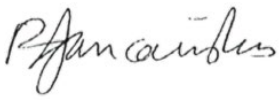
(b) damages pursuant to 138, s 236, s 259(4), s 271 and/or s 272 of Schedule 2 to the CCA;

(c) compensation pursuant to s 237 and/or s 259(3) of Schedule 2 to the CCA;

(d) interest;

(e) costs.

Date: 7 June 2022



Signed by Rebecca Jancauskas
Lawyer for the Applicant

This pleading was prepared by Rebecca Jancauskas, Shine Lawyers and ZM Hillman and APL Naylor of counsel.

Annexure A – Supply of the Implants in Australia

Implant	Period of supply in Australia
POP Implants	
Pinnacle Implants	From about February 2008 to about May 2019
Pinnacle LITE Implants	From about 2011 to about May 2019
Uphold Implants	From about February 2008 to about January 2018
Uphold LITE Implants	From about 2011 to about January 2018
Upsylon Implants	From about 2013 to date
Polyform Implants	From about 2007 to 2014
SUI Implants	
Advantage Implants	From about 2004 to date
Advantage Fit Implants	From about 2009 to date
Obtryx Implants	From about 2006 to date
Obtryx II Implants	From about 2012 to date
Lynx Implants	From about 2006 to date
Solyx Implants	From about 2009 to about January 2018

Schedule

No. of 20

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

Applicant

Debra Fowkes

Respondents

First Respondent: Boston Scientific Corporation

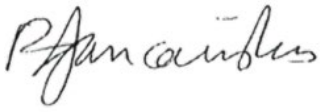
Second Respondent: Boston Scientific Pty Ltd (ACN 071 676 063)

Date: [date] 2022

Certificate of lawyer

I Rebecca Jancauskas certify to the Court that, in relation to the amended 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: 7 June 2022



Signed by Rebecca Jancauskas
Lawyer for the Applicant