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Details of Filing

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Important Information

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Form 33
Rule 16.32

Defence

No. NSD244 of 2021

Federal Court of Australia

District Registry: New South Wales

Division: General

DEBRA FOWKES

Applicant

BOSTON SCIENTIFIC CORPORATION and another named in the Schedule

Respondents

In answer to the Statement of Claim filed on 25 March 2021 (**SOC**), the First Respondent (**Boston Scientific**) and the Second Respondent (**Boston Australia**) (collectively, the **Respondents**) state as follows.

Unless otherwise noted, and without admission, terms in this Defence have the same meaning as defined in the SOC.

PART A: THE PARTIES

i. Group Members

1 In relation to paragraph 1 of the SOC, the Respondents:

(a) say that the proceeding can only be brought on behalf of persons who had surgery to implant one or more of the Implants on or before 22 March 2021, being the date of the commencement of the proceeding (**Group Members**);

Filed on behalf of (name & role of party) Boston Scientific Corporation and Boston Scientific Pty Ltd, the Respondents
Prepared by (name of person/lawyer) Jason Betts and Merryn Quayle
Law firm (if applicable) Herbert Smith Freehills
Tel +61 2 9225 5000 Fax +61 2 9322 4000
Email Jason.Betts@hsf.com / Merryn.Quayle@hsf.com
Address for service (include state and postcode) Level 33, ANZ Tower, 161 Castlereagh Street, Sydney NSW 2000

(b) refer to and repeat paragraph (3(d)) below; and

(c) otherwise do not know and therefore cannot admit the allegations contained in the paragraph.

ii. The Applicant

2 The Respondents do not know and cannot admit paragraph 2 of the SOC.

3 In relation to paragraph 3 of the SOC, the Respondents:

(a) admit sub-paragraph (a);

(b) admit sub-paragraph (b);

(c) admit sub-paragraph (c);

(d) in relation to sub-paragraph (d), they:

i. say that Boston Scientific supplied the following medical devices to Boston Australia for distribution to hospitals and doctors in Australia during the following periods:

(POP Implants):

A. the Pinnacle, Anterior Apical, PFR Kit (UPN M0068317050) (Australian Register of Therapeutic Goods (**ARTG**) number 150342) from 2009 to 2015;

B. the Pinnacle, Posterior, PFR Kit (UPN M0068317100) (ARTG number 150342) from 2010 to 2016;

C. Pinnacle LITE Pelvic Floor Repair Kit, Anterior / Apical (UPN M0068317140) (ARTG number 150342) from 2011 to 2014;

D. Pinnacle LITE Pelvic Floor Repair Kit, Posterior (UPN M0068317150) (ARTG number 150342) from 2011 to 2014;

E. Pinnacle LITE Pelvic Floor Repair Kit, Posterior (UPN M0068318150) (ARTG number 246992) from 2015 to 2017;

F. Pinnacle Duet Pelvic Floor Repair Kit (UPN M0068317010) in 2011;

(A to E are collectively, the **Pinnacle Implants**);

G. the Uphold Vaginal Support System (UPN M0068317080) (ARTG number 150342) (the **Uphold Implants**) from 2010 to 2014;

H. the Uphold LITE Vaginal Support System (UPN M0068317170) from 2011 to 2015 and Uphold LITE with Capio SLIM (UPN M0068318170) (ARTG number 150342) from 2013 to about December 2017 (the **Uphold LITE Implants**);

I. the Upsylon Y-Mesh with Colpassist Vaginal Positioning Device Kit (UPN M0068318220) (ARTG number 150342) (the **Upsylon Implants**) from 2013 to about November 2020;

(SUI Implants):

J. the Advantage, Transvaginal Mid-Urethral Sling System (UPN M0068502000) (ARTG number 104326) from 2005 to 2020 and Advantage Blue System (UPN M0068502050) from in or around March 2019 to 2020 (**Advantage Implants**);

K. the Advantage Fit Transvaginal Mid-Urethral Sling System - single (UPN M0068502110) (ARTG number 104326) from 2009 to 2020, Advantage Fit Transvaginal Mid-Urethral Sling System - 5 pack (UPN M0068502111) (ARTG number 104326) from 2012 to 2017 and Advantage Fit Blue System (UPN M0068502120) from in or around March 2019 to 2020 (**Advantage Fit Implants**);

L. the Obtryx Transobturator Mid-Urethral Sling System, Curved (UPN M0068504000) (ARTG number 104326) in 2009, 2010, 2018 and 2019, the Obtryx Transobturator Mid-Urethral Sling System, Halo (UPN M0068505000) from 2005 to 2020 (ARTG number 104326) and the

Obtryx Transobturator Mid-Urethral Sling System, Halo – 5 pack (UPN M0068505001) from 2007 to 2014 and 2016 to 2017 (ARTG number 104326) (**Obtryx Implants**);

M. the Obtryx II, Transobturator Mid-Urethral Sling System - Halo, Single unit (UPN M0068505110) (ARTG number 104326) from 2013 to 2020 and the Obtryx II, Transobturator Mid-Urethral Sling System - Halo 5 pack (UPN M0068505111) (ARTG number 104326) from 2013 to 2016 (**Obtryx II Implants**);

N. the Lynx Suprapubic Mid-Urethral Sling System (UPN M0068503000) (ARTG number 104326) from 2005 to about November 2020 and Lynx Suprapubic Sling System 5-Pack (UPN M0068503001) (ARTG number 104326) in 2017 and the Lynx Blue System (UPN M0068503010) from 2019 to about November 2020 (**Lynx Implants**);

O. the Solyx Single Incision Sling System (UPN M0068507000) (ARTG number 104326) from 2010 to 2017 and Solyx Sing Incision Sling System 5-pack (UPN M0068507001) (**Solyx Implants**) in 2010;

ii. say that Boston Australia promoted, sold and distributed the products in Australia;

iii. says that Boston Scientific carried on business in Australia by supplying implants to Boston Australia for sale in Australia; and

iv. otherwise deny the allegations contained therein; and

(e) admit sub-paragraph (e).

4 In relation to paragraph 4 of the SOC, they:

(a) refer to and repeat paragraph 3(d) above; and

(b) otherwise admit the paragraph.

PART B: THE CONDITIONS OF POP AND SUI

5 In relation to paragraph 5 of the SOC, the Respondents:

(a) admit sub-paragraph (a);

(b) admit sub-paragraph (b) and say further that:

i. symptoms of POP include bulging, pelvic heaviness, pelvic pressure, pelvic pain, dyspareunia (painful sexual intercourse), loss of bladder or bowel control, recurrent bladder infections, excessive vaginal discharge, apareunia and infection; and

ii. in addition to the presentations of POP enumerated in sub-paragraph (b) of the SOC, there are additional ways in which POP can present, each of which can occur singularly or in combination, including:

A. anterior prolapse of the bladder (cystocele) occurs when the bladder prolapses into the anterior wall of the vagina;

B. apical or vault prolapse occurs when the uterus or vaginal cuff prolapses or when a prolapse of the small intestine (enterocele) occurs;

C. posterior prolapse of the rectum (rectocele) occurs when the bowel prolapses forward into the back wall of the vagina;

D. uterine prolapse occurs when the descent of the uterus into the top, or apex, of the vagina;

(c) admit sub-paragraph (c) and say further that POP is a life-altering condition; and

(d) in relation to sub-paragraph (d) they say that:

i. whether POP can be treated non-surgically depends on the severity of a patient's condition;

ii. whether POP can be treated surgically will depend on the patient's condition and medical history;

iii. in making an election about treatment for POP, the patient would as a matter of course:

A. have sought medical advice and consulted with a doctor who had undertaken training, or was otherwise familiar with surgical and non-surgical treatments for POP;

B. obtained, understood and assessed all relevant information about the patient's clinical needs, presenting symptoms, relevant medical and surgical history and their treatment preferences and goals;

C. considered the risks associated with surgical and non-surgical treatments, including by reference to the patient's individual circumstances and their treatment preferences and goals; and

D. determined for themselves the most appropriate course or method of treatment; and

iv. otherwise deny the sub-paragraph.

6 The Respondents admit the allegations in paragraph 6 of the SOC and say further that in addition to the symptoms of POP enumerated in paragraph 6 of the SOC:

(a) physical symptoms of POP, which can occur singularly or in combination, can include:

i. pelvic heaviness, pelvic pressure and/or pelvic pain;

ii. dyspareunia (painful sexual intercourse);

iii. bleeding during and/or after intercourse;

iv. apareunia;

v. loss of bladder or bowel control or bladder or bowel dysfunction;

vi. recurrent bladder infections;

vii. urinary tract infections;

viii. excessive vaginal discharge or bloody discharge;

ix. urinary tract infection; and

x. difficulty in standing, sitting or walking and associated pain; and

(b) women may experience psychiatric injury as a result of suffering from POP.

7 In relation to paragraph 7 of the SOC, the Respondents:

(a) admit sub-paragraph (a);

(b) admit sub-paragraph (b);

(c) in relation to sub-paragraph (c) they:

i. say that whether SUI can be treated non-surgically depends on the severity of a patient's condition;

ii. whether SUI can be treated surgically will depend on the patient's condition and medical history;

iii. in making an election about treatment for SUI, the patient would as a matter of course:

A. have sought medical advice and consulted with a doctor who had undertaken training, or was otherwise familiar with surgical and non-surgical treatments for SUI;

B. obtained, understood and assessed all relevant information about the patient's clinical needs, presenting symptoms, relevant medical and surgical history and their treatment preferences and goals;

C. considered the risks associated with surgical and non-surgical treatments, including by reference to the patient's individual circumstances and their treatment preferences and goals; and

D. determined for themselves the most appropriate course or method of treatment; and

iv. otherwise deny the sub-paragraph.

(d) say further that SUI can be caused by events that directly damage the pelvic floor muscles, including pregnancy and childbirth; and

(e) otherwise deny the allegations contained therein.

PART C: THE IMPLANTS, THEIR RISKS AND COMPLICATIONS

i. The Implants

8 In relation to paragraph 8 of the SOC, the Respondents:

(a) in relation to sub-paragraph (a), they:

i. say that the Implants differ from each other in materials, and quantities of material, including the quantities of polypropylene;

ii. refer to and repeat sub-paragraph (f) below; and

iii. otherwise admit the sub-paragraph;

(b) in relation to sub-paragraph (b), they:

i. say that the Implants differ in shape and implantation technique;

ii. refer to and repeat sub-paragraph (f) below; and

iii. otherwise deny the sub-paragraph;

(c) deny sub-paragraph (c);

(d) in relation to sub-paragraph (d), they:

i. say that the expected inflammatory response generated by the non-absorbable polypropylene mesh, which formed a component of each of the Implants was necessary for tissue ingrowth; and

ii. otherwise deny the sub-paragraph;

(e) in relation to sub-paragraph (e), they:

i. refer to and repeat sub-paragraph (d)i above; and

ii. otherwise deny the sub-paragraph.

(f) say further that:

i. the Pinnacle, Anterior Apical, PFR Kit (UPN M0068317050) (ARTG number 150342):

A. consists of a polypropylene knitted mesh assembly and 2 or 4 integrated leg assemblies including a needle, lead, dilator and protective sleeve. The leg assembly was designed to facilitate the passage of the mesh assembly through bodily tissues for placement through the sacrospinous ligament;

B. was designed for tissue reinforcement and stabilisation of fascial structures of the pelvic floor in vaginal wall prolapse, where surgical treatment is intended, either as mechanical support or bridging material for the fascial defect;

C. was implanted transvaginally; and

D. was not designed, manufactured or intended for use in the treatment of SUI;

ii. Pinnacle, Posterior, PFR Kit (UPN M0068317100) (ARTG number 150342):

A. consists of a polypropylene knitted mesh assembly and 2 or 4 integrated leg assemblies including a needle, lead, dilator and protective sleeve. The leg assembly was designed to facilitate the passage of the mesh assembly through bodily tissues for placement through the sacrospinous ligament ;

B. was designed for tissue reinforcement and stabilisation of fascial structures of the pelvic floor in vaginal wall prolapse, where surgical treatment is intended, either as mechanical support or bridging material for the fascial defect;

C. was implanted transvaginally; and

D. was not designed, manufactured or intended for use in the treatment of SUI;

iii. Pinnacle LITE Pelvic Floor Repair Kit, Posterior (UPN M0068317150) (ARTG number 150342) and Pinnacle LITE Pelvic Floor Repair Kit, Posterior (UPN M0068318150) (ARTG number 246992) each:

A. consists of a polypropylene knitted mesh assembly and 2 integrated leg assemblies including a needle, lead, dilator and protective sleeve. The leg assembly was designed to facilitate the passage of the mesh assembly through bodily tissues for placement through the sacrospinous ligament;

B. was designed for tissue reinforcement in women with pelvic organ prolapse, for the transvaginal repair of posterior vaginal vault prolapse and not for any other type of prolapse;

C. was implanted transvaginally; and

D. was not designed, manufactured or intended for use in the treatment of SUI;

iv. Pinnacle LITE Pelvic Floor Repair Kit, Anterior / Apical (UPN M0068317140) (ARTG number 150342):

A. consists of a polypropylene knitted mesh assembly and 2 integrated leg assemblies including a needle, lead, dilator and protective sleeve. The leg assembly was designed to facilitate the passage of the mesh assembly through bodily tissues for placement through the sacrospinous ligament;

B. was designed for tissue reinforcement and stabilisation of fascial structures of the pelvic floor in vaginal wall prolapse;

C. was implanted transvaginally; and

D. was not designed, manufactured or intended for use in the treatment of SUI;

v. Pinnacle Duet Pelvic Floor Repair Kit (UPN M0068317010):

A. consists of a polypropylene knitted mesh assembly and 2 or 4 integrated leg assemblies including a needle, lead, dilator and protective sleeve. The leg assembly was designed to facilitate the passage of the mesh assembly through bodily tissues for placement through the sacrospinous ligament and/or arcus tendineous fascia pelvis;

B. was designed for tissue reinforcement and stabilisation of fascial structures of the pelvic floor in vaginal wall prolapse where surgical treatment is intended, either as mechanical support or bridging material for the fascial defect;

C. was implanted transvaginally; and

D. was not designed, manufactured or intended for use in the treatment of SUI;

vi. the Uphold Implants:

A. consist of a polypropylene knitted mesh assembly and 2 integrated leg assemblies including a needle, lead, dilator and protective sleeve. The leg assembly was designed to facilitate the passage of the mesh assembly through bodily tissues for placement through the sacrospinous ligament;

B. were designed for tissue reinforcement and stabilisation of fascial structures of the pelvic floor in vaginal wall prolapse and not for any other type of prolapse;

C. were implanted transvaginally; and

D. were not designed, manufactured or intended for use in the treatment of SUI;

vii. the Uphold LITE Implants:

A. consist of a polypropylene knitted mesh assembly and 2 integrated leg assemblies including a needle, lead, dilator and protective sleeve. The leg assembly was designed to facilitate the passage of the mesh assembly through bodily tissues for placement through the sacrospinous ligament;

B. were designed for tissue reinforcement for the transvaginal repair of anterior and apical vaginal wall prolapse and not for any other type of prolapse;

C. were implanted transvaginally; and

D. were not designed, manufactured or intended for use in the treatment of SUI;

viii. the Upsylon Implants:

A. consist of a performed Y shaped lightweight polypropylene mesh consisting of two vaginal mesh arms and one sacral mesh arm;

B. were intended for use as a bridging material for sacrocolposuspension / sacrocolpopexy for vaginal vault prolapse;

C. were implanted transvaginally; and

D. were not designed, manufactured or intended for use in the treatment of SUI;

ix. the Advantage Implants:

A. consist of one delivery device and one mesh assembly. Each mesh assembly is comprised of a polypropylene knitted mesh protected by a disposable plastic sleeve. At the distal ends of the mesh assembly are two dilators designed to be placed over the needle end of the delivery device. The disposable delivery device consists of a handle with a curved needle, a sliding metal cannula with a blunt distal end and a pusher component. The

delivery device is designed to facilitate the passage of the mesh assembly through bodily tissues for transvaginal placement;

B. were intended for use as a suburethral sling for the treatment of stress urinary incontinence resulting from hypermobility and/or intrinsic sphincter deficiency;

C. were implanted transvaginally; and

D. were not designed, manufactured or intended for use in the treatment of POP;

x. the Advantage Fit Implants:

A. consist of one delivery device and one mesh assembly. Each mesh assembly is comprised of a polypropylene knitted mesh protected by a disposable plastic sleeve. At the distal ends of the mesh assembly are two dilators designed to be placed over the needle end of the delivery device. The disposable delivery device consists of a handle with a curved needle, a sliding metal cannula with a blunt distal end and a pusher component. The delivery device is designed to facilitate the passage of the mesh assembly through bodily tissues for transvaginal placement;

B. were designed for use as a suburethral sling for the treatment of stress urinary incontinence resulting from hypermobility and/or intrinsic sphincter deficiency;

C. were implanted transvaginally and abdominally; and

D. were not designed, manufactured or intended for use in the treatment of POP;

xi. the Obtryx Implants (Halo):

A. consist of two delivery devices and one mesh assembly. The mesh assembly is comprised of a polypropylene knitted mesh protected by a

disposable plastic sleeve. At the distal ends of the mesh assembly there are association loops designed to be placed in the needle slot of the distal end of the delivery device. The disposable delivery device consists of a handle with a stainless steel needle. The needle is designed to facilitate the passage of the mesh assemble through the bodily tissues for placement through the obturator foramen;

B. were designed for use as a suburethral sling for the treatment of stress urinary incontinence resulting from hypermobility and/or intrinsic deficiency;

C. were implanted transvaginally; and

D. were not designed, manufactured or intended for use in the treatment of POP;

xii. the Obtryx Implants (Curved):

A. consist of two delivery devices and one mesh assembly. The mesh assembly is comprised of a polypropylene knitted mesh protected by a disposable plastic sleeve. At the distal ends of the mesh assembly there are association loops designed to be placed in the needle slot of the distal end of the delivery device. The disposable delivery device consists of a handle with a stainless steel needle. The needle is designed to facilitate the passage of the mesh assemble through the bodily tissues for placement through the obturator foramen;

B. were designed for use as a suburethral sling for the treatment of stress urinary incontinence resulting from hypermobility and/or intrinsic deficiency;

C. were implanted transvaginally; and

D. were not designed, manufactured or intended for use in the treatment of POP;

xiii. the Obtryx II Implants (Halo):

A. consist of two delivery devices and one mesh assembly. The mesh assembly is comprised of a polyprolyene knitted mesh with dilator legs and a centre tab. At the distal ends of the dilator legs there are association loops designed to be placed in the needle slot of the distal end of the delivery device. The disposable delivery device consists of a handle with a stainless steel needle. The needle is designed to facilitate the passage of the mesh assembly through bodily tissues for placement through the obturator foramen;

B. were designed for use as a suburethral sling for the treatment of stress urinary incontinence resulting from hypermobility and/or intrinsic deficiency;

C. were implanted transvaginally; and

D. were not designed, manufactured or intended for use in the treatment of POP;

xiv. the Obtryx II Implants (Curved):

A. consist of two delivery devices and one mesh assembly. The mesh assembly is comprised of a polyprolyene knitted mesh with dilator legs and a centre tab. At the distal ends of the dilator legs there are association loops designed to be placed in the needle slot of the distal end of the delivery device. The disposable delivery device consists of a handle with a stainless steel needle. The needle is designed to facilitate the passage of the mesh assembly through bodily tissues for placement through the obturator foramen;

B. were designed for use as a suburethral sling for the treatment of stress urinary incontinence resulting from hypermobility and/or intrinsic deficiency;

C. were implanted transvaginally; and

D. were not designed, manufactured or intended for use in the treatment of POP;

xv. the Lynx Implants:

A. consist of two delivery devices and a mesh assembly. The mesh assembly is comprised of a polypropylene knitted mesh; protected by a disposable plastic sleeve. At the distal ends of the mesh assembly there are association loops designed to be placed in the need slot of the distal end. The device consists of a handle with a curved needle. The needle is designed to facilitate the passage of the mesh assembly through bodily tissues for suprapubic placement;

B. were designed for use as a suburethral sling for the treatment of stress urinary incontinence resulting from hypermobility and/or intrinsic sphincter deficiency;

C. were implanted transvaginally; and

D. were not designed, manufactured or intended for use in the treatment of POP;

xvi. the Solyx Implants:

A. consist of a delivery device and a mesh assembly. The mesh assembly is comprised of a polypropylene knitted mesh with polypropylene carriers at each end of the distal mesh. The carrier is designed to be placed on the tip of the delivery device. The disposable delivery device consists of a handle, a stainless steel shaft and a deployment mechanism. The delivery device is

designed to facilitate the passage of the mesh assembly through bodily tissues for placement into the obturator internus muscle;

B. were intended for use as a suburethral sling for the treatment of stress urinary incontinence resulting from hypermobility and/or intrinsic sphincter deficiency;

C. were implanted transvaginally; and

D. were not designed, manufactured or intended for use in the treatment of POP; and

(g) say that the directions for use for each Implant contain, amongst other information, information about the product indications, contraindications, warnings, precautions, adverse events and operating instructions for physicians who use the Implants.

PARTICULARS

Particulars are listed in

Attachment A to this Defence

9 The Respondents admit paragraph 9 of the SOC.

10 In relation to paragraph 10 of the SOC, the Respondents:

(a) say that the directions for use for each Implant indicated that each Implant was intended for use only by physicians with training in the treatment of POPs or SUIs (as the case may be);

PARTICULARS

Particulars are listed in

Attachment B to this Defence

(b) say that the Implants were licensed medical devices that were available to individual patients only by prescription;

(c) say that it was reasonable for the Respondents to expect before any implant surgery, the Applicant and each Group Member's treating doctor would as a matter of course have:

i. undertaken training, or otherwise been familiar with the surgical procedures and techniques involving meshes, prior to using an Implant, in accordance with the directions for use of the Implants;

ii. consulted with the Applicant and each Group Member about and obtained, understood and assessed all relevant information about the Applicant's or Group Member's clinical needs, presenting symptoms, relevant medical and surgical history and their surgical preferences and goals;

iii. provided the Applicant and each Group Member with information, advice and warnings tailored for the Applicant and each Group Member;

iv. determined the most appropriate course or method of treatment including implantation with one of more of the Implants, alternative treatments with or without another implant, alternative surgeries or no surgery depending on the Applicant's and each Group Member's individual circumstances, the information that the Applicant and each Group Member made available to their treating surgeon, personal preference and the treating surgeon's surgical training and expertise;

v. only recommended the use of an Implant if, in the opinion of the treating doctor, the likely of the Implant outweighed the risks of complications;

(d) say that it was reasonable for the Respondents to expect that before any Implant surgery, each Applicant and Group Member would be informed by their respective treating doctor(s) to the degree the doctor(s) judged appropriate, that such use carried risk, including the risk that the implantation of one or more of the Implants may not restore pelvic anatomy, may not alleviate the symptoms associated with their clinical

condition, may not improve the Applicant's or Group Member's quality of life or may require revision; and

(e) otherwise do not know and therefore cannot admit the allegations contained therein.

11 In relation to paragraph 11 of the SOC, the Respondents:

(a) say that the POP Implants differ from each other with respect to mesh volume, mesh configuration, placement location, fixation location, and number of leg assemblies;

(b) refer to and repeat paragraphs 8(f) and 10 above;

(c) refer to and repeat paragraph 20(b) below; and

(d) otherwise deny the allegations contained therein.

12 In relation to paragraph 12 of the SOC, the Respondents:

(a) say that the SUI Implants differ from each other in design, dimension, features, method of implantation, fixation and placement position;

(b) refer to and repeat paragraph 8(f) and 10 above;

(c) refer to and repeat paragraph 20(b) below; and

(d) otherwise deny the allegations contained therein.

ii The Implant Risks and Complications

13 In relation to paragraph 13 of the SOC, the Respondents:

(a) deny the allegations

(b) say that all surgical procedures present risks;

(c) admit that potential complications and adverse events from the implants included pain, vaginal erosion or exposure through the urethra or other surrounding tissue, incontinence, urinary tract obstruction and retention, constipation, dyspareunia, sexual dysfunction, infection, inflammation, organ perforation and nerve injury;

(d) say that the incidence and severity of potential complications caused by the Implants are largely influenced by surgical skill and patient factors including individual medical history and activities following surgery;

(e) say that not every occurrence of a complication will be clinically significant;

(f) refer to and repeat paragraph 10 above; and

(g) say that the causes of complications are many and varied and that there are potential complications in any SUI or POP surgery, regardless of whether mesh is used;

14 In relation to paragraph 14 of the SOC, the Respondents:

(a) refer to and repeat paragraphs 10 and 13 above; and

(b) otherwise deny the allegations contained therein.

15 In relation to paragraph 15 of the SOC, the Respondents:

(a) say that each patient has specific and particular underlying conditions and prior medical and health history and each physician and patient must undertake an individualised risk-benefit analysis as to the most appropriate course of treatment based on the patient's underlying health history, condition, lifestyle, desired outcome, risk tolerance and a multitude of other factors;

(b) say that contraindications and warnings were recorded in the Implant product brochures and/or directions for use for patients with, inter alia, autoimmune connective tissue disease, patients with a compromised immune system or any other condition that would compromise healing;

PARTICULARS

Particulars are listed in

Attachment C to this Defence

(c) repeat paragraphs 10 and 13 above; and

(d) otherwise deny the allegations contained therein.

16 In relation to paragraph 16 of the SOC, the Respondents:

(a) say that treatment for the alleged Implant Complications (if required at all) can involve surgical or non-surgical options;

(b) say that the nature of treatment for the alleged Implant Complications (if required at all) will depend on a number of factors specific and particular to the individual patient and the presentation of the complications and the severity of the complications;

PARTICULARS

Factors specific and particular to the individual patient may include duration of implant, the nature of the complications, the patient's medical history and comorbidities, and physician experience and preference.

(c) say that the tissue ingrowth that may, in certain cases, make mesh removal more difficult is a well-known, essential design feature of the Implants that provides the structural support necessary in treating SUI and POP;

(d) repeat paragraphs 10 and 13 above; and

(e) otherwise deny the allegations contained therein.

PART D: AVAILABILITY OF ALTERNATIVE TREATMENTS

17 In relation to paragraph 17 of the SOC, the Respondents:

(a) repeat paragraphs 5(d) and 7(c) above;

(b) say that surgery for the treatment of POP or SUI may be undertaken, depending on the specific patient's history, presenting symptoms, preference and the treating surgeon's judgment, experience and preferences, with or without the use of mesh implants;

(c) say that all surgical procedures present risks;

(d) say that Native Tissue Repair carries with it its own risks;

(e) otherwise deny the allegations contained therein

18 In relation to paragraph 18 of the SOC, the Respondents:

(a) refer to and repeat paragraphs 17(a) to 17(d) above;

(b) say that alternative surgical procedures carry with them their own risks; and

(c) otherwise deny the allegations contained therein.

PART E: FAILURE TO EVALUATE OR WARN

19 The Respondents deny the allegations in paragraph 19 of the SOC and say further that prior to the supply, distribution, marketing or promotion of the Implants in Australia, Boston Scientific conducted a number of tests to evaluate the safety and effectiveness of the Implants including:

(a) for the POP Implants:

i. biocompatibility testing on:

A. the mesh and dilator used in the POP devices, including tests to evaluate cytotoxicity, sensitization, intracutaneous reactivity, acute systemic toxicity, sub-acute toxicity, mutagenicity, mouse lymphoma, implantation, and USP physiochemical;

B. the protective sleeve, lead, and Capio suture delivery system used in the pelvic floor repair kits, including cytotoxicity, sensitization, intracutaneous reactivity, acute systemic toxicity, and USP Physiochemical;

C. the needle used in the pelvic floor repair kits, including cytotoxicity, sensitization, intracutaneous reactivity, and acute systemic toxicity; and

D. the finished pelvic floor repair kits and packaging, including cytotoxicity, USP physiochemical and latex;

ii. tests to compare the pelvic floor repair kits to the established product specification and acceptance criteria for bench top performance requirements, including leg assembly dimensions, needle/leader tensile, sleeve tensile, leg assembly flexibility, mesh/leg tensile, leader/dilator/sleeve tensile, and sleeve removal;

iii. comparison testing to compare the mesh used in its pelvic floor repair kits to mesh that was already on the market to treat POP; and

iv. cadaver testing; and

(b) for the SUI Implants:

i. biocompatibility testing of:

A. the mesh material, including tests to evaluate cytotoxicity, sensitization, pyrogenicity, intracutaneous reactivity, systemic toxicity, genotoxicity, implantation, hemocompatibility, USP physicochemical testing for plastics, acute systemic toxicity, subacute intravenous toxicity, subacute intraperitoneal toxicity, latex, mutagenicity, and mouse lymphoma; and

B. the polymer sleeve and eyelets of its SUI pelvic mesh systems, including tests to evaluate cytotoxicity, sensitization, irritation, acute systemic toxicity and pyrogenicity;

ii. functional testing of its SUI mesh including tests to evaluate, mesh thickness, mesh knit, pore size, mesh density, tensile strength, suture pullout (tear), stiffness, and burst strength

iii. final product specification testing on every bulk lot of mesh material to ensure adherence to the product specification. This includes testing to evaluate thickness, mesh density, pore size, burst strength, stiffness, residuals of heavy metals, and tensile strength

iv. comparison testing between the SUI products and mesh already on the market including included Scanning Electron Microscope tests, Energy Dispersive X-ray Spectroscope (EDX) Differential Scanning Calorimeter (DSC), Thermogravimetric Analyzer (TVA), and Fourier Transform Infrared Spectroscopy (FTIR); and

v. cadaver testing.

20 In relation to paragraph 20 of the SOC, the Respondents:

(a) repeat paragraphs 10 and 13 above;

(b) say that warnings were given in the POP and SUI Implant product brochures and directions for use of potential complications and adverse events including pain, vaginal erosion or exposure through the urethra or other surrounding tissue, incontinence, urinary tract obstruction and retention, constipation, dyspareunia, sexual dysfunction, infection, inflammation, organ perforation and nerve injury; and

PARTICULARS

Particulars are listed in

Attachment D to this Defence

(c) otherwise deny the allegations contained therein.

PART F: CLAIMS UNDER THE TPA AND CCA

21 The Respondents admit paragraph 21 of the SOC.

22 In relation to paragraph 22 of the SOC, the Respondents:

(a) admit that any Implants that were supplied to Group Members were supplied to those Group Members as consumers as that term is defined in section 4B of the TPA and section 3 of Schedule 2 to the CCA; and

(b) otherwise do not know and cannot admit the allegations in paragraph 22.

23 In relation to paragraph 23, the Respondents:

(a) refer to and repeat paragraphs 10, 13, 15, 17 and 20, above; and

(b) otherwise deny the allegations contained therein.

24 In relation to paragraph 24 of the SOC, the Respondents:

(a) refer to and repeat paragraphs 10, 13, 15, 17 and 20 above; and

(b) otherwise deny the allegations contained therein.

25 The Respondents deny paragraph 25 of the SOC.

26 The Respondents deny paragraph 26 of the SOC.

PART G: NEGLIGENCE

27 In relation to paragraph 27 of the SOC, the Respondents:

(a) says that each of the Implants were:

i. assessed by the Therapeutic Goods Administration before their use in Australia and then included on the ARTG;

ii. available only to hospitals for use by surgeons;

(b) say that the Respondents caused to be made available information about each of the Implants to those who would use the devices;

(c) repeat paragraphs 10, 13, 15, 17 and 20 above;

(d) further and in the alternative say that Boston Scientific satisfied any duty it had to exercise reasonable care and skill in the design, manufacture, marketing and supply of the Implants; and

(e) otherwise deny the allegations contained therein.

28 In relation to paragraph 28 of the SOC, the Respondents:

(a) refer to and repeat paragraphs 8(f), 11, 12 and 19 above; and

(b) otherwise deny the allegations contained therein.

29 In relation to paragraph 29 of the SOC, the Respondents:

(a) repeat paragraphs 8, 13, 14 15, 16, 27 and 28 above; and

(b) otherwise deny the allegations contained therein.

30 In relation to paragraph 30 of the SOC, the Respondents:

(a) refer to and repeat paragraph 29 above; and

(b) otherwise deny the allegations contained therein.

31 The Respondents deny paragraph 31 of the SOC.

32 In relation to paragraph 32 of the SOC, the Respondents:

(a) refer to and repeat paragraphs 10, 13, 15, 17, and 20(b) above;

(b) admit that Boston Scientific did not inform Group Members, Boston Australia and treating hospitals or treating doctors that Boston Scientific had not conducted adequate evaluation of the risks associated with use of the implants prior to their supply, distribution, marketing or promotion in Australia;

(c) refer to and repeat paragraph 19 above and say further that Boston Scientific did undertake such evaluations prior to the supply, distribution, marketing or promotion of the Implants in Australia; and

(d) otherwise deny the allegations contained therein.

33 In relation to paragraph 33 of the SOC, the Respondents:

(a) refer to and repeat paragraphs 27 to 32 above; and

(b) deny the allegations contained therein.

34 In relation to paragraph 34 of the SOC, the Respondents:

(a) refer to and repeat paragraph 33 above; and

(b) deny the allegations contained therein.

35 In relation to paragraph 35 of the SOC, the Respondents:

(a) say that each of the Implants were:

i. assessed by the Therapeutic Goods Administration before their use in Australia and then included on the ARTG;

ii. available only to surgeons, or to hospitals for use by surgeons;

(b) say that the Respondents caused to be made available information about each of those devices for surgeons who would use the devices;

(c) repeat paragraphs 10, 13, 15, 17 and 20 above;

(d) further and in the alternative say that Boston Australia satisfied any duty it had to exercise reasonable care and skill in the supply and marketing of the Implants; and

(e) otherwise deny the allegations contained therein.

36 In relation to paragraph 36 of the SOC, the Respondents:

(a) refer to and repeat paragraphs 8, 13, 14 15, 16, and 35 above; and

(b) otherwise deny the allegations contained therein.

37 In relation to paragraph 37 of the SOC, the Respondents:

(a) refer to and repeat paragraphs 10, 13, 15, 17 and 20(b) above;

(b) admit that Boston Scientific did not inform Group Members, Boston Australia and treating hospitals or treating doctors that Boston Scientific had not conducted adequate evaluation of the risks associated with use of the implants prior to their supply, distribution, marketing or promotion in Australia;

(c) refer to and repeat paragraph 19 above and say further that Boston Scientific did undertake such evaluations prior to the supply, distribution, marketing or promotion of the Implants in Australia; and

(d) otherwise deny the allegations contained therein.

38 In relation to paragraph 38 of the SOC, the Respondents:

(a) refer to and repeat paragraphs 34 to 36 above; and

(b) deny the allegations contained therein.

39 In relation to paragraph 39 of the SOC, the Respondents:

(a) refer to and repeat paragraphs 34 to 38 above; and

(b) deny the allegations contained therein.

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

40 The Respondents do not know and cannot admit the allegations in paragraph 40 of the SOC.

41 The Respondents do not know and cannot admit the allegations in paragraph 41 of the SOC.

42 The Respondents do not know and cannot admit the allegations in paragraph 42 of the SOC.

43 In relation to paragraph 43 of the SOC, the Respondents:

(a) repeat paragraphs 10, 13 and 20(b) above; and

(b) otherwise do not know and cannot admit the allegations contained therein.

44 The Respondents do not know and cannot admit the allegations in paragraph 44 of the SOC.

45 The Respondents do not know and cannot admit the allegations in paragraph 45 of the SOC.

46 The Respondents do not know and cannot admit the allegations in paragraph 46 of the SOC.

47 The Respondents do not know and cannot admit the allegations in paragraph 47 of the SOC.

48 The Respondents do not know and cannot admit the allegations in paragraph 48 of the SOC.

49 The Respondents do not know and cannot admit the allegations in paragraph 49 of the SOC.

50 The Respondents do not know and cannot admit the allegations in paragraph 50 of the SOC.

51 The Respondents do not know and cannot admit the allegations in paragraph 51 of the SOC.

52 The Respondents do not know and cannot admit the allegations in paragraph 52 of the SOC.

53 The Respondents do not know and cannot admit the allegations in paragraph 53 of the SOC.

54 The Respondents do not know and cannot admit the allegations in paragraph 54 of the SOC.

55 The Respondents do not know and cannot admit the allegations in paragraph 55 of the SOC.

56 The Respondents do not know and cannot admit the allegations in paragraph 56 of the SOC.

57 The Respondents do not know and cannot admit the allegations in paragraph 57of the SOC.

58 In relation to paragraph 58 of the SOC, the Respondents:

(a) repeat paragraphs 10, 13 and 16 above; and

(b) otherwise do not know and cannot admit the allegations contained therein.

59 In relation to paragraph 59 of the SOC, the Respondents:

(a) refer to and repeat paragraphs 10, 11, 12, 13, 16 and 58 above; and

(b) otherwise do not know and cannot admit the allegations contained therein.

60 In relation to paragraph 60 of the SOC, the Respondents:

(a) refer to and repeat paragraphs 42 to 58 above; and

(b) deny the allegations contained therein.

61 In relation to paragraph 61 of the SOC, the Respondents:

(a) refer to and repeat paragraph 60 above; and

(b) otherwise deny the allegations contained therein.

STATE OF SCIENTIFIC OR TECHNICAL KNOWLEDGE

62 Further, or in the alternative, in answer to the allegations in paragraphs 23, 24, 26, 33, 34, 38 and 39 of the SOC, the Respondents say that, at all material times, the state of scientific or technical knowledge was not such as to enable it to discover the matters alleged in paragraphs 23 and 24 of the SOC, if found to exist, such that:

(a) section 75AK(1)(c) of the TPA affords a complete defence to the claim under section 75AD of the TPA;

(b) section 142 of the *Australian Consumer Law (ACL)*, being Schedule 2 to the *Competition and Consumer Act* 2010 (Cth), affords a complete defence to the claim under section 138 of the ACL;

(c) the state of scientific or technical knowledge is one of the relevant circumstances for the purpose of sections 75AC and 75AD of the TPA to which the Court must have regard in determining whether the POP and SUI Implants were defective;

(d) the state of scientific or technical knowledge is one of the relevant circumstances for the purpose of sections 9 and 138 of the ACL to which the Court must have regard in determining whether the Implants were defective;

(e) the state of scientific or technical knowledge is one of the relevant circumstances for the purpose of section 74D(3) of the TPA to which the Court must have regard in determining whether the Implants were of merchantable quality;

(f) the state of scientific or technical knowledge is one of the relevant circumstances for the purpose of section 54(3) of the ACL to which the Court must have regard in determining whether the Implants were of acceptable quality; and

(g) the Respondents did not breach any duty of care owed under the general law.

LIMITATION PERIODS

63 Further, pending receipt of further particulars of the Group Members' claims, in answer to the allegations in paragraphs 21 to 61 of the SOC, the Respondents state that the Applicant's and the Group Members' causes of actions will be subject to, and the Respondents are relying upon, the limitation periods prescribed by the:

(a) *Limitation Act* 1969 (NSW);

(b) *Limitation of Actions Act* 1958 (Vic);

(c) *Limitation of Actions Act* 1974 (Qld);

(d) *Limitation Act* 2005 (WA);

(e) *Limitation Act* 1935 (WA);

(f) *Limitation Act* 1985 (ACT);

(g) *Limitation Act* 1974 (Tas);

(h) *Limitation of Actions Act* 1936 (SA);

(i) *Limitation Act* 1981 (NT);

(j) The TPA, including sections 74J(1) and (3), 75AO(1) and (2), 82(2), 87F, 87G and 87H; and

(k) the CCA, including sections 87F, 87G and 87H of the CCA and sections 143(1) and (2), 236(2) and 273 of the ACL.

64 Further, and in answer to the Applicant's claim for common law damages (which is denied), the Respondents state that:

(a) a cause of action for personal injury would have needed to be brought within three years after the date on which the cause of action is discoverable by the Applicant;

(b) the Applicant's alleged cause of action accrued more than 3 years before the commencement of these proceedings; and

(c) pursuant to subsection 27D(1) of the *Limitation of Actions Act 1958* (Vic), the Applicant's cause of action cannot be maintained, subject to the Court extending time in accordance with sections 23A and 27K of the *Limitation of Actions Act 1958* (Vic).

65 Further, and in answer to the Applicant's claim for compensation under the CCA (which is denied), the Respondents state that:

(a) the date the Applicant's alleged cause of action accrued, being the date of discoverability of the alleged injury, was more than 3 years before the commencement of these proceedings; and

(b) pursuant to the provisions pleaded at paragraph 61B(k), above, the Applicant's cause of action is statute barred.

Date: 20 September 2021

Signed by Jason Betts / Merryn Quayle
Lawyers for the Respondents

This pleading was prepared by Jason Betts and Merryn Quayle, lawyers for the Respondents, and Robert Craig QC and Jennifer Findlay of Counsel.

Certificate of lawyer

I Merryn Quayle certify to the Court that, in relation to the defence filed on behalf of the Respondents, the factual and legal material available to me at present provides a proper basis for:

(a) each allegation in the pleading; and

(b) each denial in the pleading; and

(c) each non admission in the pleading.

Date: 20 September 2021

Signed by Merryn Quayle
Lawyer for the Respondents

Attachment A

PARTICULARS TO PARAGRAPH 8(g)

(1) Boston Scientific Corporation, *Pinnacle Pelvic Floor Repair (PFR) Kit – Anterior Apical*, Directions for Use (2008);

(2) Boston Scientific Corporation, *Pinnacle Pelvic Floor Repair (PFR) Kit – Anterior Apical, Directions for Use* (October 2008);

(3) Boston Scientific Corporation, *Pinnacle Pelvic Floor Repair (PFR) Kit – Anterior Apical, Directions for Use* (December 2008);

(4) Boston Scientific Corporation, *Pinnacle Pelvic Floor Repair (PFR) Kit – Anterior Apical, Directions for Use* (2009);

(5) Boston Scientific Corporation, *Pinnacle Pelvic Floor Repair (PFR) Kit – Anterior Apical and Posterior, Directions for Use* (March 2009);

(6) Boston Scientific Corporation, *Pinnacle Pelvic Floor Repair (PFR) Kit – Anterior Apical and Posterior, Directions for Use* (December 2009);

(7) Boston Scientific Corporation, *Pinnacle Pelvic Floor Repair (PFR) Kit – Anterior Apical and Posterior, Directions for Use* (October 2010)

(8) Boston Scientific Corporation, *Pinnacle LITE with Capio Slim Pelvic Floor Repair Kit, Directions for Use* (2016)

(9) Boston Scientific Corporation, *Uphold Vaginal Support System with Mesh Leg Fixation, Directions for Use* (February 2009);

(10) Boston Scientific Corporation, *Uphold Vaginal Support System with Mesh Leg Fixation, Directions for Use* (October 2009);

(11) Boston Scientific Corporation, *Uphold Vaginal Support System with Mesh Leg Fixation, Directions for Use* (June 2010);

(12) Boston Scientific Corporation, *Uphold LITE Vaginal Support Systems with Mesh Leg Fixation, Directions for Use* (November 2011);

(13) Boston Scientific Corporation, *Uphold LITE Vaginal Support Systems with Capio Slim, Directions for Use* (April 2013);

(14) Boston Scientific Corporation, *Uphold LITE Vaginal Support Systems with Capio Slim, Directions for Use* (March 2015);

(15) Boston Scientific Corporation, *Uphold LITE Vaginal Support Systems with Mesh Leg Fixation, Directions for Use* (December 2015);

(16) Boston Scientific Corporation, *Uphold LITE Vaginal Support Systems with Capio Slim, Directions for Use* (January 2016);

(17) Boston Scientific Corporation, *Uphold LITE Vaginal Support Systems with Capio Slim, Directions for Use* (February 2017);

(18) Boston Scientific, *Advantage A/T Kit, Instructions for Use* (July 2002);

(19) Boston Scientific, *Advantage System, Instructions for Use* (April 2003);

(20) Boston Scientific, *Advantage System Mid-Urethral Sling, Directions for Use* (July 2003);

(21) Boston Scientific, *Advantage System Transvaginal Mid-Urethral Sling, Directions for Use* (June 2004);

(22) Boston Scientific, *Advantage System Transvaginal Mid-Urethral Sling, Directions for Use* (2006);

(23) Boston Scientific, *Advantage System Transvaginal Mid-Urethral Sling, Directions for Use* (August 2006);

(24) Boston Scientific, *Advantage System Advantage Fit System - Transvaginal Mid-Urethral Sling, Directions for Use* (2008);

(25) Boston Scientific, *Advantage System Advantage Fit System - Transvaginal Mid-Urethral Sling, Directions for Use* (March 2008);

(26) Boston Scientific, *Advantage System Advantage Fit System - Transvaginal Mid-Urethral Sling, Directions for Use* (April 2008);

(27) Boston Scientific, *Advantage System Advantage Fit System - Transvaginal Mid-Urethral Sling, Directions for Use* (December 2009);

(28) Boston Scientific, *Advantage System Advantage Fit System - Transvaginal Mid-Urethral Sling, Directions for Use* (December 2010);

(29) Boston Scientific, *Advantage System Advantage Fit System - Transvaginal Mid-Urethral Sling, Directions for Use* (January 2015);

(30) Boston Scientific, *Advantage System Advantage Fit System - Transvaginal Mid-Urethral Sling, Directions for Use* (March 2016);

(31) Boston Scientific, *Advantage System Advantage Fit System - Transvaginal Mid-Urethral Sling, Directions for Use* (June 2016);

(32) Boston Scientific Corporation, *Solyx SIS System*, Directions for Use (2008);

(33) Boston Scientific Corporation, *Solyx SIS System, Directions For Use* (3 November 2008);

(34) Boston Scientific Corporation, *Solyx SIS System, Directions For Use* (13 December 2008);

(35) Boston Scientific Corporation, *Solyx SIS System, Directions For Use* (22 December 2009);

(36) Boston Scientific Corporation, *Solyx SIS System, Directions For Use* (2010);

(37) Boston Scientific Corporation, *Solyx SIS System, Directions For Use* (7 January 2011);

(38) Boston Scientific Corporation, *Solyx SIS System, Directions For Use* (March 2016);

(39) Boston Scientific Corporation, *Solyx SIS System, Directions for Use* (May 2017);

(40) Boston Scientific Corporation, *Lynx System, Directions For Use* (February 2004);

(41) Boston Scientific Corporation, *Lynx System, Directions For Use* (March 2004);

(42) Boston Scientific Corporation, *Lynx System, Directions For Use* (May 2004);

(43) Boston Scientific Corporation, *Lynx System, Directions For Use* (June 2004);

(44) Boston Scientific Corporation, *Lynx System, Directions For Use* (August 2006);

(45) Boston Scientific Corporation, *Lynx System, Directions For Use* (December 2009);

(46) Boston Scientific Corporation, *Lynx System, Directions For Use* (December 2010);

(47) Boston Scientific Corporation, *Lynx System, Directions For Use* (February 2015);

(48) Boston Scientific Corporation, *Lynx System, Directions For Use* (March 2016);

(49) Boston Scientific Corporation, *Lynx System, Directions For Use* (March 2017);

(50) Boston Scientific Corporation, *Obtryx System - Halo, Directions For Use* (June 2004);

(51) Boston Scientific Corporation, *Obtryx System – Curved, Directions For Use* (June 2004);

(52) Boston Scientific Corporation, *Obtryx System – Curved, Directions For Use* (16 March 2005);

(53) Boston Scientific Corporation, *Obtryx System – Curved, Directions For Use* (24 March 2005);

(54) Boston Scientific Corporation, *Obtryx System - Halo, Directions For Use* (16 March 2005);

(55) Boston Scientific Corporation, *Obtryx System - Halo, Directions For Use* (24 March 2005);

(56) Boston Scientific Corporation, *Obtryx System – Curved, Directions For Use* (December 2009);

(57) Boston Scientific Corporation, *Obtryx System – Halo, Directions For Use* (2009);

(58) Boston Scientific Corporation, *Obtryx System – Curved, Directions For Use* (2010);

(59) Boston Scientific Corporation, *Obtryx System – Halo, Directions For Use* (2010);

(60) Boston Scientific Corporation, *Obtryx System – Curved, Directions For Use* (2015);

(61) Boston Scientific Corporation, *Obtryx System – Halo, Directions For Use* (2015);

(62) Boston Scientific Corporation, *Obtryx System – Halo, Directions For Use* (March 2016).

(63) Boston Scientific Corporation, *Obtryx System – Curved, Directions For Use* (March 2016);

(64) Boston Scientific Corporation, *Obtryx System – Halo, Directions For Use* (June 2016);

(65) Boston Scientific Corporation, *Obtryx System – Curved, Directions For Use* (June 2016);

(66) Boston Scientific Corporation, *Obtryx II System – Curved, Directions For Use* (August 2012);

(67) Boston Scientific Corporation, *Obtryx II System – Halo, Directions For Use* (August 2012);

(68) Boston Scientific Corporation, *Obtryx II System – Curved, Directions For Use* (September 2012);

(69) Boston Scientific Corporation, *Obtryx II System – Halo, Directions For Use* (September 2012);

(70) Boston Scientific Corporation, *Obtryx II System – Curved, Directions For Use* (January 2015);

(71) Boston Scientific Corporation, *Obtryx II System – Halo, Directions For Use* (January 2015);

(72) Boston Scientific Corporation, *Obtryx II System – Curved, Directions For Use* (March 2016);

(73) Boston Scientific Corporation, *Obtryx II System – Halo, Directions For Use* (March 2016);

(74) Boston Scientific Corporation, *Obtryx II System – Halo, Directions For Use* (August 2016).

(75) Boston Scientific Corporation, *Upsylon Traditional Y Mesh, Directions For Use* (2012).

(76) Boston Scientific Corporation, *Upsylon Traditional Y Mesh,, Directions For Use* (2013).

(77) Boston Scientific Corporation, *Upsylon Traditional Y Mesh, Directions For Use* (2016).

Attachment B

PARTICULARS TO PARAGRAPH 10(a)

(1) Boston Scientific Corporation, *Pinnacle Pelvic Floor Repair (PFR) Kit – Anterior Apical, Directions for Use* (2008), page 4;

(2) Boston Scientific Corporation, *Pinnacle Pelvic Floor Repair (PFR) Kit – Anterior Apical, Directions for Use* (October 2008), page 4;

(3) Boston Scientific Corporation, *Pinnacle Pelvic Floor Repair (PFR) Kit – Anterior Apical, Directions for Use* (December 2008), page 4;

(4) Boston Scientific Corporation, *Pinnacle Pelvic Floor Repair (PFR) Kit – Anterior Apical, Directions for Use* (2009), page 4;

(5) Boston Scientific Corporation, *Pinnacle Pelvic Floor Repair (PFR) Kit – Anterior Apical and Posterior, Directions for Use* (March 2009), page 4;

(6) Boston Scientific Corporation, *Pinnacle Pelvic Floor Repair (PFR) Kit – Anterior Apical and Posterior, Directions for Use* (December 2009), page 4;

(7) Boston Scientific Corporation, *Pinnacle Pelvic Floor Repair (PFR) Kit – Anterior Apical and Posterior, Directions for Use* (October 2010), page 4;

(8) Boston Scientific Corporation, *Pinnacle LITE with Capio Slim Pelvic Floor Repair Kit, Directions for Use* (2016), pages 5 - 6;

(9) Boston Scientific Corporation, *Uphold Vaginal Support System with Mesh Leg Fixation, Directions for Use* (February 2009), page 4;

(10) Boston Scientific Corporation, *Uphold Vaginal Support System with Mesh Leg Fixation, Directions for Use* (October 2009), page 4;

(11) Boston Scientific Corporation, *Uphold Vaginal Support System with Mesh Leg Fixation, Directions for Use* (June 2010), page 4;

(12) Boston Scientific Corporation, *Uphold LITE Vaginal Support Systems with Mesh Leg Fixation, Directions for Use* (November 2011), page 4;

(13) Boston Scientific Corporation, *Uphold LITE Vaginal Support Systems with Capio Slim, Directions for Use* (April 2013), page 5;

(14) Boston Scientific Corporation, *Uphold LITE Vaginal Support Systems with Capio Slim, Directions for Use* (March 2015), page 5;

(15) Boston Scientific Corporation, *Uphold LITE Vaginal Support Systems with Mesh Leg Fixation, Directions for Use* (December 2015), page 5;

(16) Boston Scientific Corporation, *Uphold LITE Vaginal Support Systems with Capio Slim, Directions for Use* (January 2016), page 5;

(17) Boston Scientific Corporation, *Uphold LITE Vaginal Support Systems with Capio Slim, Directions for Use* (February 2017), page 5;

(18) Boston Scientific, *Advantage A/T Kit, Instructions for Use* (July 2002), page 3;

(19) Boston Scientific, *Advantage System, Instructions for Use* (April 2003), page 1;

(20) Boston Scientific, *Advantage System Mid-Urethral Sling, Directions for Use* (July 2003), page 3;

(21) Boston Scientific, *Advantage System Transvaginal Mid-Urethral Sling, Directions for Use* (June 2004), page 3;

(22) Boston Scientific, *Advantage System Transvaginal Mid-Urethral Sling, Directions for Use* (2006), page 3;

(23) Boston Scientific, *Advantage System Transvaginal Mid-Urethral Sling, Directions for Use* (August 2006), page 3;

(24) Boston Scientific, *Advantage System Advantage Fit System - Transvaginal Mid-Urethral Sling, Directions for Use* (2008), page 3;

(25) Boston Scientific, *Advantage System Advantage Fit System - Transvaginal Mid-Urethral Sling, Directions for Use* (March 2008), page 3;

(26) Boston Scientific, *Advantage System Advantage Fit System - Transvaginal Mid-Urethral Sling, Directions for Use* (April 2008), page 3;

(27) Boston Scientific, *Advantage System Advantage Fit System - Transvaginal Mid-Urethral Sling, Directions for Use* (December 2009), page 2;

(28) Boston Scientific, *Advantage System Advantage Fit System - Transvaginal Mid-Urethral Sling, Directions for Use* (December 2010), page 2;

(29) Boston Scientific, *Advantage System Advantage Fit System - Transvaginal Mid-Urethral Sling, Directions for Use* (January 2015), page 2;

(30) Boston Scientific, *Advantage System Advantage Fit System - Transvaginal Mid-Urethral Sling, Directions for Use* (March 2016), page 2;

(31) Boston Scientific, *Advantage System Advantage Fit System - Transvaginal Mid-Urethral Sling, Directions for Use* (June 2016), page 2;

(32) Boston Scientific Corporation, *Solyx SIS System*, Directions for Use (2008), page 4;

(33) Boston Scientific Corporation, *Solyx SIS System, Directions For Use* (3 November 2008), page 4;

(34) Boston Scientific Corporation, *Solyx SIS System, Directions For Use* (13 December 2008), page 4;

(35) Boston Scientific Corporation, *Solyx SIS System, Directions For Use* (22 December 2009), page 4;

(36) Boston Scientific Corporation, *Solyx SIS System, Directions For Use* (2010), page 4;

(37) Boston Scientific Corporation, *Solyx SIS System, Directions For Use* (7 January 2011), page 4;

(38) Boston Scientific Corporation, *Solyx SIS System, Directions For Use* (March 2016), page 3;

(39) Boston Scientific Corporation, *Solyx SIS System, Directions for Use* (May 2017), page 3;

(40) Boston Scientific Corporation, *Lynx System, Directions For Use* (February 2004), page 5;

(41) Boston Scientific Corporation, *Lynx System, Directions For Use* (March 2004), page 5;

(42) Boston Scientific Corporation, *Lynx System, Directions For Use* (May 2004), page 5;

(43) Boston Scientific Corporation, *Lynx System, Directions For Use* (June 2004), page 5;

(44) Boston Scientific Corporation, *Lynx System, Directions For Use* (August 2006), page 5;

(45) Boston Scientific Corporation, *Lynx System, Directions For Use* (December 2009), page 5;

(46) Boston Scientific Corporation, *Lynx System, Directions For Use* (December 2010), page 5;

(47) Boston Scientific Corporation, *Lynx System, Directions For Use* (February 2015), page 5;

(48) Boston Scientific Corporation, *Lynx System, Directions For Use* (March 2016), page 2;

(49) Boston Scientific Corporation, *Lynx System, Directions For Use* (March 2017), page 3;

(50) Boston Scientific Corporation, *Obtryx System - Halo, Directions For Use* (June 2004), page 6;

(51) Boston Scientific Corporation, *Obtryx System – Curved, Directions For Use* (June 2004), page 6;

(52) Boston Scientific Corporation, *Obtryx System – Curved, Directions For Use* (16 March 2005), page 5;

(53) Boston Scientific Corporation, *Obtryx System – Curved, Directions For Use* (24 March 2005), page 5;

(54) Boston Scientific Corporation, *Obtryx System - Halo, Directions For Use* (16 March 2005), page 5;

(55) Boston Scientific Corporation, *Obtryx System - Halo, Directions For Use* (24 March 2005), page 5;

(56) Boston Scientific Corporation, *Obtryx System – Curved, Directions For Use* (December 2009), page 5;

(57) Boston Scientific Corporation, *Obtryx System – Halo, Directions For Use* (December 2009), page 5;

(58) Boston Scientific Corporation, *Obtryx System – Curved, Directions For Use* (2010), page 5;

(59) Boston Scientific Corporation, *Obtryx System – Halo, Directions For Use* (2010), page 5;

(60) Boston Scientific Corporation, *Obtryx System – Curved, Directions For Use* (2015), page 5;

(61) Boston Scientific Corporation, *Obtryx System – Halo, Directions For Use* (2015), page 5;

(62) Boston Scientific Corporation, *Obtryx System – Halo, Directions For Use* (March 2016), page 2;

(63) Boston Scientific Corporation, *Obtryx System – Curved, Directions For Use* (March 2016), page 2;

(64) Boston Scientific Corporation, *Obtryx System – Halo, Directions For Use* (June 2016), page 3;

(65) Boston Scientific Corporation, *Obtryx System – Curved, Directions For Use* (June 2016), page 3;

(66) Boston Scientific Corporation, *Obtryx II System – Curved, Directions For Use* (August 2012), page 6;

(67) Boston Scientific Corporation, *Obtryx II System – Halo, Directions For Use* (August 2012), page 6;

(68) Boston Scientific Corporation, *Obtryx II System – Curved, Directions For Use* (September 2012), page 6;

(69) Boston Scientific Corporation, *Obtryx II System – Halo, Directions For Use* (September 2012), page 6;

(70) Boston Scientific Corporation, *Obtryx II System – Curved, Directions For Use* (January 2015), page 6;

(71) Boston Scientific Corporation, *Obtryx II System – Halo, Directions For Use* (January 2015), page 6;

(72) Boston Scientific Corporation, *Obtryx II System – Curved, Directions For Use* (March 2016), page 3;

(73) Boston Scientific Corporation, *Obtryx II System – Halo, Directions For Use* (March 2016), page 3;

(74) Boston Scientific Corporation, *Obtryx II System – Halo, Directions For Use* (August 2016), page 3;

(75) Boston Scientific Corporation, *Upsylon Traditional Y Mesh, Directions For Use* (2012), page 3;

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Schedule

No. NSD244 of 2021

Federal Court of Australia

District Registry: New South Wales

Division: General

Second Respondent BOSTON SCIENTIFIC PTY LTD ACN 071 676 063