IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

REGINA OESTERLE and BENJAMIN OESTERLE,

Plaintiffs,

v.

BOSTON SCIENTIFIC CORPORATION,

Defendant.

CIVIL ACTION

Case No. _____

COMPLAINT AND JURY DEMAND

Plaintiffs, Regina and Benjamin Oesterle, by and through their undersigned counsel, bring this action for damages against Defendant, Boston Scientific Corporation, and allege as follows:

I. PARTIES

A. Plaintiffs

1. Plaintiffs, Regina and Benjamin Oesterle, are citizens of Sunbury, Delaware County, Ohio.

B. Defendant

2. Defendant Boston Scientific Corporation ("Boston Scientific") is a corporation organized and existing under the laws of the State of Delaware, with its corporate headquarters in Massachusetts.

3. Defendant, Boston Scientific, is a corporation organized and existing under the laws of the United States maintaining its principal place of business at 300 Boston Scientific Way, Marlborough, MA 01752-1234.

4. All acts and omissions of the above-referenced Defendant as described herein were done by its agents, servants, employees, and/or owners, acting in the course and scope of their respective agencies, services, employments, and/or ownership.

II. JURISDICTION AND VENUE

5. This Court has subject matter jurisdiction over the parties pursuant to 28 U.S.C. §1332(a) because the parties are citizens of different states and the amount in controversy exceeds $75,000.00, exclusive of interest and cost.

6. Venue for this action lies in the United States District Court of Massachusetts, because the Defendant resides in this District and the wrongful acts upon which this lawsuit is based occurred, in part, in this District. Venue is also proper pursuant to 28 U.S.C. §1391(c) because Defendant has substantial, systematic, and continuous contacts in the District of Massachusetts, and it is subject to personal jurisdiction in this District.

III. DEFENDANT'S PELVIC MESH PRODUCTS

7. At all times material to this action, Defendant has designed, patented, manufactured, packaged, labeled, marketed, sold, and distributed a line of pelvic mesh products, which are delineated below. These products were designed primarily for the purposes of treating stress urinary incontinence and pelvic organ prolapse. Each of these products was cleared for sale in the United States after the Defendant made assertions to the Food and Drug Administration of "Substantial Equivalence" under Section 510(k) of the Food, Drug and Cosmetic Act; this clearance process does not require the applicant to prove safety or efficacy, One or more of Defendant's pelvic mesh products was implanted in Plaintiff.

8. The products include those known as Uphold Vaginal Support System, Pinnacle Pelvic Floor Repair Kit, Advantage Transvaginal Mid-Urethral Sling System, Advantage Fit

System, Lynx Suprapubic Mid-Urethral Sling System, Obtryx Transobturator Mid-Urethral Sling System, Prefyx PPS System, Solyx SIS System, as well as any variations of these products and any unnamed Boston Scientific pelvic mesh product designed and sold for similar purposes, inclusive of the instruments and procedures for implementation.

9. These products are collectively referenced as Defendant's "Pelvic Mesh Products" or "Products."

IV. FACTUAL BACKGROUND

10. At all relevant times, Defendant was in the business of developing, designing, licensing, manufacturing, distributing, selling, marketing, advertising, and delivering, and introducing into interstate commerce, including, *inter alia*, within the United States, either directly or indirectly through third parties, subsidiaries or related entities, Pelvic Mesh Products.

11. At all relevant times, Pelvic Mesh Products were used to treat pelvic organ prolapse and stress urinary incontinence.

12. A pelvic organ prolapse occurs when a pelvic organ, such as the bladder, drops ("prolapses") from its normal position and pushes against the walls of the vagina. Prolapse can happen if the muscles that hold the pelvic organs in place become weak or stretched from aging, weight gain, childbirth or any surgery, among other things. More than one pelvic organ can prolapse at the same time. Organs that can be involved in a pelvic organ prolapse include the bladder, the uterus, the bowel and the rectum.

13. Stress urinary incontinence is a type of incontinence characterized by leakage of urine during moments of physical stress, like coughing, sneezing, or exercise.

14. Surgical mesh, including mesh used in Pelvic Mesh Products, is a medical device that is generally used to repair weakened or damaged tissue. It is made from porous absorbable or

non-absorbable synthetic material or absorbable biologic material. In urogynecologic procedures, surgical mesh is permanently implanted to reinforce the weakened vaginal wall to repair pelvic organ prolapse or to support the urethra to treat urinary incontinence. Most Pelvic Mesh Products are comprised of non-absorbable, synthetic, monofilament polypropylene mesh and/or collagen.

15. Despite claims that polypropylene mesh is inert, the scientific evidence shows that this material as implanted in the Plaintiff is biologically incompatible with human tissue and when used as a woven or knitted alloplastic textile prosthetic mesh for pelvic floor repair, polypropylene and other surgical polymers promote a severe foreign body reaction and chronic inflammatory response in a large subset of the population implanted with Defendant's Pelvic Mesh Products. This "host defense response" by a woman's pelvic tissues causes chronic inflammation of the pelvic tissue, shrinkage or contraction of the mesh leading to nerve entrapment, further inflammation, chronic infectious response and chronic pain. It also can cause new-onset painful sexual relations, significant urinary dysfunction, vaginal shortening and anatomic deformation, and can contribute to the formation of severe adverse reactions to the mesh.

16. Furthermore, Defendant's Pelvic Mesh Products cause hyper-inflammatory responses leading to problems including chronic pain and fibrotic reaction. The Pelvic Mesh Products cause adverse tissue reactions, and are causally related to infection, as collagen is a foreign organic material. Mesh is harsh upon the female pelvic tissues. It hardens in the body and becomes inflexible, as does the scar tissue surrounding it.

17. When these Pelvic Mesh Products are inserted in the female body according to the manufacturers' instructions, it creates a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities.

18. In 1996, the FDA cleared the first Pelvic Mesh Products for use in the treatment of stress urinary incontinence (SUI). These products include Products manufactured, marketed, and distributed by Defendant. These products are approved by the FDA under the abbreviated 510(k) approval process. Section 510(k) provides for marketing of a medical device if the device is deemed "substantially equivalent" to other predicate devices marketed before May 28, 1976. No formal review for safety or efficacy is required, and no formal review for safety or efficacy was ever conducted with regard to the Pelvic Mesh Products.

19. On July 13, 2011, the FDA issued a new warning regarding serious complications associated with Pelvic Mesh Products, such as the Products manufactured, marketed, and distributed by Defendant. In this warning, the FDA indicated that "serious complications associated with surgical mesh for transvaginal repair of POP are **not rare**." (emphasis in the original). The FDA had also received increased reports of complications associated with the Pelvic Mesh Products used in both pelvic organ prolapse and stress urinary incontinence cases.

20. The FDA Safety Communication also stated, "*Mesh contraction* (shrinkage) is a *previously unidentified risk* of transvaginal POP repair with mesh that has been reported in the published scientific literature and in adverse event reports to the FDA ... Reports in the literature associate mesh contraction with vaginal shortening, vaginal tightening and vaginal pain." (Emphasis in original).

21. The FDA Safety Communication further indicated that the benefits of using Pelvic Mesh Products instead of other feasible alternatives did not outweigh the associated risks. Specifically, the FDA Safety Communication stated: "it is not clear that transvaginal POP repair with mesh is more effective than traditional non-mesh repair in all patients with POP and it may expose patients to greater risks."

22. Contemporaneously with the Safety Communication, the FDA released a publication titled "Urogynecologic Surgical Mesh: Update on the Safety and Effectiveness of Transvaginal Placement for Pelvic Organ Prolapse" (the "White Paper"), In the White Paper, the FDA noted that published, peer-reviewed literature demonstrates that "[p]atients who undergo POP repair with mesh are subject to mesh-related complications that are not experienced by patients who undergo traditional surgery without mesh."

23. The FDA summarized its findings from its review of the adverse event reports and applicable literature stating that it "has NOT seen conclusive evidence that using transvaginally placed mesh in POP repair improves clinical outcomes any more than traditional POP repair that does not use mesh, and it may expose patients to greater risks," (Emphasis in original).

24. The White Paper further stated that "these products are associated with serious adverse events.... Compounding the concerns regarding adverse events are performance data that fail to demonstrate improved clinical benefit over traditional non-mesh repair," In its White Paper, the FDA advises doctors to, *inter alia*, "[r]ecognize that in most cases POP can be treated successfully without mesh thus avoiding the risk of mesh related complications," The White Paper concludes by stating that the FDA "has identified serious safety and effectiveness concerns over the use of surgical mesh for the transvaginal repair of pelvic organ prolapse."

25. On August 25, 2011, Public Citizen, a consumer advocacy group, submitted a petition to the FDA seeking to ban the use of Pelvic Mesh Products in pelvic repair procedures, In its Petition, Public Citizen warned that Pelvic Mesh Products should be recalled because they offer no significant benefits, but expose patients to serious risks and the potential for permanent life-altering harm. Joining Public Citizen as co-petitioners were Dr. L. Lewis Wall, a professor of

obstetrics and gynecology at Washington University in St. Louis, and Dr. Daniel S. Elliott, a urologic surgeon specializing in female urology at the Mayo Clinic in Rochester, Minnesota.

26. In a December 2011 Joint Committee Opinion, the American College of Obstetricians and Gynecologists ("ACOG") and the American Urogynecologic Society ("AUGS") also identified physical and mechanical changes to the transvaginal mesh inside the body as a serious complication associated with transvaginal mesh, stating:

> There are increasing reports of vaginal pain associated with changes that can occur with mesh (contraction, retraction, or shrinkage) that result in taut sections of mesh . . . Some of these women will require surgical intervention to correct the condition, and some of the pain appears to be intractable.

27. The ACOG/AUGS Joint Committee Opinion also recommended, among other things, that "[p]elvic organ prolapse vaginal mesh repair should be reserved for high-risk individuals in whom the benefit of mesh placement may justify the risk."

28. As is known to the Defendant, the risks associated with POP repair are the same as risks associated with SUI repair. However, the data regarding the magnitude and frequency of these known risks are not as developed as the data on POP repair. The FDA recognized this, as demonstrated by its Section 522 Orders issued to manufacturers of Pelvic Mesh Products used to treat SUI in January of 2012.

29. In September 2011, the FDA acknowledged the need for additional data and noted in "Surgical Mesh For Treatment of Women with Pelvic Organ Prolapse and Stress Urinary Incontinence" that the literature and information developing on SUI repair with Pelvic Mesh Products "indicate[] that serious complications can occur ... [and] a case can be made for additional premarket and/or post market studies to better address the risk/benefit of all mesh products used for SUL."

30. Defendant did not, and has not, adequately studied the extent of the risks associated with the SUI repair Products. In January 2012, the FDA recognized the risk to women and mandated additional studies to further investigate these risks associated with the Products used to repair SUIs.

31. Defendant knew or should have known that its Pelvic Mesh Products unreasonably exposed patients to the risk of serious harm while conferring no benefit over available feasible alternatives that do not involve the same risks. At the time Defendant began marketing its Pelvic Mesh Products, Defendant was aware that its Pelvic Mesh Products were associated with each and every one of the adverse events communicated by the FDA in its July 13, 2011, safety communication. Despite claims that polypropylene mesh is inert, the scientific evidence shows that this material as implanted in the Plaintiff set forth below is biologically incompatible with human tissue. When used as a woven or knitted alloplastic textile prosthetic mesh for pelvic floor repair, polypropylene and other surgical polymers promote a severe foreign body reaction and chronic inflammatory response in a large subset of the population implanted with Defendant's Pelvic Mesh Products. This "host defense response" by a woman's pelvic tissues causes chronic inflammation of the pelvic tissue, causes shrinkage or contraction of the mesh leading to nerve entrapment, further inflammation, chronic infectious response and chronic pain, cause new-onset painful sexual relations, significant urinary dysfunction, vaginal shortening and anatomic deformation. scarring, and can contribute to the formation of severe adverse reactions to the polypropylene mesh.

32. Complications from mesh placement for pelvic organ prolapse include among other adverse events: acute and chronic infection, tissue contraction due to mesh shrinkage, erosion of the mesh into adjacent structures, and dyspareunia. 15 Cosson, M., et al., *Mechanical*

properties of synthetic implants used in the repair of prolapse and urinary incontinence in women: which is the ideal material? Int Urogynecol J Pelvic Floor Dysfunct, 2003. **14**(3): p. 169-78; discussion 178. Jones, K.A., et al., *Tensile properties of commonly used prolapse meshes.* Int Urogynecol J Pelvic Floor Dysfunct, 2009. **20**(7): p. 847-53. Margulies, R.U., et al., *Complications requiring reoperation following vaginal mesh kit procedures for prolapse.* Am J Obstet Gynecol, 2008. **199**(6): p. 678 e1-4.

33. The Products were unreasonably susceptible to shrinkage or contraction inside the body; intense foreign body reaction; chronic inflammatory response; chronic wound healing; chronic infections in and around the mesh fibers; nerve entrapment and scar formation. Defendant knew or should have known of these serious risks and should have, therefore, warned physicians and patients regarding these risks; to the extent they were known or knowable.

34. To this day, the Products continue to be marketed to the medical community and to patients as safe, effective and reliable medical devices, implanted by safe, effective and minimally invasive surgical techniques, and as safer and more effective as compared to available feasible alternative treatments of pelvic organ prolapse and stress urinary incontinence, and other competing products.

35. Defendant omitted and downplayed the risks, dangers, defects, and disadvantages of the Products, and advertised, promoted, marketed, sold and distributed the Products as safe medical devices when Defendant knew or should have known that the Products were not safe for their intended purposes, and that the Products would cause, and did cause, serious medical problems, and in some patients, including the Plaintiff, catastrophic injuries. Further, while some

of the problems associated with the Products were made known to physicians, the magnitude and frequency of these problems were not disclosed and were hidden from physicians.

36. Contrary to Defendant's representations and marketing to the medical community and to the patients themselves, the Products have high rates of failure, injury, and complications, fail to perform as intended, require frequent and often debilitating re-operations, and have caused severe and irreversible injuries, conditions, and damage to a significant number of women, including the Plaintiff, making them defective under the law.

37. The specific nature of the Products' defects includes, but is not limited to, the following:

a. The use of polypropylene in the Products and the adverse tissue reactions and host defense response that result from such material, causing adverse reactions and serious, permanent injuries including, but not limited to, painful recurrent erosions and associated intractable pain;

b. The design of the Products to be inserted into and through an area of the body that is blood vessel rich, nerve dense, and bacteria laden leading to excessive blood loss and vascular damage, permanent nerve injury and associated chronic, intractable neuropathic pain, contaminated permanently-implanted mesh causing chronic infections, subclinical infections and biofilms, enhanced chronic inflammatory response, chronic wound healing with tissue destruction, as well as numerous other adverse reactions and serious and permanent injuries;

c. Biomechanical issues with the design of the Products which result in a nonanatomic condition leading to contraction or shrinkage of the mesh

inside the body, that in turn causes surrounding tissue to become scarred, eroded, inflamed, fibrotic and infected, resulting in serious and permanent injury;

d. The propensity of the mesh design characteristics of the Products for plastic deformation when subjected to tension both during implantation and once implanted inside the body which causes the mesh, or portions thereof, to be encapsulated in a rigid scar plate which leads to nerve entrapment, bacterial entrapment, tissue destruction, enhanced inflammatory and fibrotic response and chronic pain;

e. The propensity of the Products to become rigid and inflexible, causing them to be improperly mated to the delicate and sensitive areas of the vagina and pelvis where they are implanted, and causing discomfort and pain with normal daily activities that involve movement in the pelvic region (e.g., intercourse, defecation, walking);

f. The propensity of the Products for degradation or fragmentation over time, which causes an increased surface area that leads to enhanced chronic inflammatory and fibrotic reaction, causes a “barbed wire” or “saw blade” effect by the fragmented surface “sawing” through the tissue, leads to bacteria harboring in the fragmented, peeled and split fiber surface which in tum leads to chronic infections at the mesh surface, and results in continuing injury over time;

g. The hyper-inflammatory responses leading to problems including chronic inflammatory response, chronic pain and fibrotic reaction as well as infections and other serious adverse events;

h. The harshness of mesh upon the female pelvic tissue, and the hardening of the product in the body; and

i. The inability of surgeons to effectively treat many of these conditions due to the integration of the mesh into the pelvic tissue and thus the inability to safely remove or excise the mesh once a complication occurs;

38. The Products are also defective due to Defendant's failure to adequately warn or instruct the Plaintiff and/or her health care providers of subjects including, but not limited to, the following:

a. The Products' propensities to contract, retract, and/or shrink inside the body;

b. The Products' inelasticity preventing proper mating with the pelvic floor and vaginal region;

c. The frequency and manner of transvaginal mesh erosion or extrusion;

d. The risk of chronic inflammation resulting from the Products;

e. The risk of chronic infections resulting from the Products;

f. The risk of permanent vaginal or pelvic scarring as a result of the Products;

g. The risk of de novo urinary dysfunction;

h. The risk of de novo dyspareunia or painful sexual relations;

i. The risk of recurrent, intractable pelvic pain and other pain resulting from the Products;

j. The need for corrective or revision surgery, or surgeries, to adjust or remove the Products which in some cases is not feasible nor possible;

k. The severity of complications that could arise as a result of implantation of the Products;

l. The hazards associated with the Products;

m. The Products' defects described herein;

n. Treatment of pelvic organ prolapse and stress urinary incontinence with the Products is no more effective than feasible, available and safer alternatives;

o. Treatment of pelvic organ prolapse and stress urinary incontinence with the Products exposes patients to greater risk than feasible, available and safer alternatives;

p. Treatment of pelvic organ prolapse and stress urinary incontinence with the Products makes future surgical repair more difficult than feasible, available and safer alternatives;

q. Use of the Products puts the patient at greater risk of requiring additional surgery than feasible, available and safer alternatives;

r. Removal of the Products due to complications may involve multiple surgeries and may significantly impair the patient's quality of life; and

s. Complete removal of the Products may not be possible and may not result in complete resolution of the complications, including pain.

39. As a result of these life-altering and, in some cases, permanent injuries, Plaintiff has suffered severe emotional pain and injury and has suffered and will suffer apprehension of increased risk for injuries, infections, pain, mental anguish, discharge, and multiple corrective surgeries as a result of implantation of mesh.

40. Defendant underreported and continues to underreport information about the propensity of the Products to fail and cause injury and complications, and has made unfounded representations regarding the efficacy and safety of the Products through various means and media.

41. Defendant failed to perform proper and adequate testing and research prior to marketing and after introduction to the market in order to determine and evaluate the nature, magnitude and frequency of the risks attendant to the Products.

42. Defendant failed to design and establish a safe, effective procedure for removal of the Products, or to determine if a safe, effective procedure for removal of the Products exists.

43. Feasible, suitable and safer alternatives to the Products have existed at all times relevant that do not present the same frequency or severity of risks as do the Products.

44. The Products were at all times utilized and implanted in a manner foreseeable to Defendant, as Defendant generated the instructions for use, created the procedures for implanting the devices, and trained the implanting physician.

45. Defendant knowingly provided incomplete and insufficient training and information to physicians regarding the use of the Products and the aftercare of patients implanted with the Product.

46. As a result of these life-altering and, in some cases, permanent injuries, Plaintiff has suffered severe emotional pain and injury and has suffered and will suffer apprehension of increased risk for injuries, infections, pain, mental anguish, discharge, and multiple corrective surgeries as a result of implantation of mesh.

47. The Product implanted in the Plaintiff was in the same or substantially similar condition as it was when it left Defendant's possession, and in the condition directed by and expected by the Defendant. The injuries, conditions, and complications suffered by numerous women around the world who have been implanted with the Products include, but are not limited to, erosion, mesh contraction, infection, fistula, inflammation, scar tissue, organ perforation, dyspareunia (pain during sexual intercourse), urinary dysfunction, blood loss, neuropathic and other acute and chronic nerve damage and pain, pudendal nerve damage, pelvic floor damage, and chronic pelvic pain. As a result of these life-altering and, in some cases, permanent injuries, Plaintiff has suffered severe emotional pain and injury and has suffered and will suffer apprehension of increased risk for injuries, infections, pain, mental anguish, discharge, and multiple corrective surgeries as a result of implantation of Pelvic Mesh Products.

48. In many cases, including the Plaintiff, women have been forced to undergo extensive medical treatment including, but not limited to, operations to locate and remove mesh, operations to attempt to repair pelvic organs, tissue, and nerve damage, the use of pain control and other medications, injections into various areas of the pelvis, spine, and the vagina, and operations to remove portions of the female genitalia.

49. The medical and scientific literature studying the effects of the Products, like that of the Product implanted in the Plaintiff, has examined each of these injuries, conditions, and complications, and has reported that they are causally related to the Products.

50. Removal of contracted, eroded and/or infected transvaginal mesh can require multiple surgical interventions for removal of mesh and results in scarring on fragile compromised pelvic tissue and muscles.

51. At all relevant times herein, Defendant continued to promote the Products as safe and effective even when no clinical trials had been done supporting long- or short-term efficacy or safety.

52. In doing so, Defendant failed to disclose the known risks and failed to warn of known or scientifically knowable dangers and risks associated with the Products, including the magnitude and frequency of these risks.

53. At all relevant times herein, Defendant failed to provide sufficient warnings and instructions that would have put the Plaintiffs and the general public on notice of the dangers and adverse effects caused by implantation of the Products.

54. The Products as designed, manufactured, distributed, sold and/or supplied by Defendant were defective as marketed due to inadequate warnings, instructions, labeling and/or inadequate testing in the presence of Defendant's knowledge of lack of safety.

55. The injuries, conditions, and complications suffered by numerous women around the world who have been implanted with the Products include, but are not limited to, erosion, mesh contraction, infection, fistula, inflammation, scar tissue, organ perforation, dyspareunia (pain during sexual intercourse), blood loss, neuropathic and other acute and chronic nerve damage and pain, pudendal nerve damage, pelvic floor damage, chronic pelvic pain, emotional distress and mental anguish, and other debilitating complications. In addition, Plaintiff will need to be continuously monitored as a result of being implanted with Defendant's Product. A monitoring procedure exists for individuals experiencing physical and mental injuries from mesh implanted

in patients with pelvic organ prolapsed and/or stress urinary incontinence. The monitoring procedure has been prescribed by a qualified physician and is reasonably necessary according to contemporary scientific principles. As such, Plaintiff is entitled to future medical monitoring and treatment directly related to the existing injuries caused by the defective products.

56. In many cases, including the Plaintiff, the women have been forced to undergo extensive medical treatment, including, but not limited to, operations to locate and remove mesh, operations to attempt to repair pelvic organs, tissue, and nerve damage, the use of pain control and other medications, injections into various areas of the pelvis, spine, and the vagina, and operations to remove portions of the female genitalia.

57. The medical and scientific literature studying the effects of Defendant's Pelvic Mesh Products, like that of the product(s) implanted in the Plaintiff, has examined each of these injuries, conditions, and complications, and has reported that they are causally related to the Products.

58. Removal of contracted, eroded and/or infected transvaginal mesh can require multiple surgical interventions for removal of mesh and results in scarring on fragile compromised pelvic tissue and muscles.

59. At all relevant times herein, Defendant continued to promote the Products as safe and effective even when no clinical trials had been done supporting long- or short-term efficacy.

60. In doing so, Defendant failed to disclose the known risks and failed to warn of known or scientifically knowable dangers and risks associated with the Products.

61. At all relevant times herein, Defendant failed to provide sufficient warnings and instructions that would have put the Plaintiffs and the general public on notice of the dangers and adverse effects caused by implantation of the Products.

62. The Products as designed, manufactured, distributed, sold and/or supplied by Defendant were defective as marketed due to inadequate warnings, instructions, labeling and/or inadequate testing in the presence of Defendant's knowledge of lack of safety.

V. THE DISCOVERY RULE AND TOLLING OF LIMITATIONS PERIODS APPLY.

63. Prescribing physicians, healthcare providers and Plaintiff, neither knew, nor had reason to know at the time the mesh product was implanted in her body, that the product had the aforementioned defects. Ordinary consumers such as Plaintiff would not have recognized the potential risks or side effects, which Defendants concealed through promotion of its Products as safe and effective for treating stress urinary incontinence and pelvic organ prolapse. Prescribing and implanting physicians likewise would not and could not recognize these risks because of Defendant's concealment of them through their marketing of the Products.

64. At all times herein mentioned, due to Defendant's marketing of the Products and Defendant's failures to correct the same, the Product was prescribed and implanted as intended by Defendant and in a manner reasonably foreseeable to Defendant. Defendant knew or should have known that consumers, such as Plaintiff, would foreseeably suffer injury as a result of Defendant's failures to exercise reasonable care.

65. Plaintiffs file this lawsuit within the applicable limitations period of first suspecting that Defendant's wrongful conduct caused her to suffer an appreciable harm. Plaintiff could not, by the exercise of reasonable diligence, have discovered the wrongful conduct that caused her injuries at an earlier time. Plaintiff did not suspect, nor did Plaintiff have reason to suspect, the tortious nature of the conduct causing her injuries until a short time before filing of this action. Additionally, Plaintiff was prevented from discovering this information sooner because: (1) Defendant has misrepresented to the public and to the medical community that its Products are safe for the

treatment of stress urinary incontinence and pelvic organ prolapse; and (2) Defendants fraudulently concealed facts and information that could have led Plaintiff to discover a potential cause of action.

66. The discovery rule tolls the running of the statute of limitations until Plaintiff knew, or in the exercise of reasonable care and due diligence should have known, of fact indicating that Plaintiff had been injured, the cause of the injury, and the tortious nature of the wrongdoing that caused the injury.

VI. CASE SPECIFIC ALLEGATIONS

67. Plaintiff underwent transvaginal surgery on or about July 21, 2020, at which time the Boston Scientific Obtryx Transobturator Mid-Urethral Sling System was implanted.

68. Plaintiff has suffered significant pain, unnecessary expense, embarrassment, disfigurement and harm as a result of the implant of Defendant's defective Product.

69. Plaintiff may have to undergo additional surgery in the future and may continue to suffer significant pain, unnecessary medical expense for medical care, treatment and therapies long into the future.

70. Plaintiff has sustained and will continue to sustain severe and debilitating injuries, serious bodily injury, mental and physical pain and suffering and has incurred economic loss, which losses may continue far into the future.

VII. CAUSES OF ACTION

COUNT I: PRODUCT LIABILITY- DEFECTIVE MANUFACTURE AND DESIGN

71. Plaintiffs incorporate by reference each and every paragraph of this Complaint as if fully set forth herein.

72. Boston Scientific's Pelvic Mesh Products were defective, unfit, unsafe, inherently dangerous and unreasonably dangerous for their intended and reasonably foreseeable uses. These

Products were in said condition when they entered the stream of commerce and were received by Plaintiff. The Products do not meet or perform to the expectations of patients and their health care providers. Boston Scientific's Products were dangerous to an extent beyond that which would be contemplated by the ordinary consumer.

73. The Products create a risk to the health and safety of the patients that are far more significant and devastating than the risks posed by other products and procedures available to treat the corresponding medical conditions, and which far outweigh the utility of the Products.

74. Boston Scientific has intentionally and recklessly designed, manufactured, marketed, labeled, sold and distributed the Products with wanton and willful disregard for the health of the Plaintiff and others, and with malice, placing their economic interest above the health and safety of the Plaintiff.

75. The Products used by Plaintiff's physicians were not substantially changed, modified, or altered at any time in any manner whatsoever prior to use. The subject Products reached the Plaintiff in such a condition that was unreasonably dangerous to her. The Pelvic Mesh Product was used in the manner for which it was intended. This use resulted in injuries and harm to Plaintiff.

76. At no time did Plaintiff have reason to believe that the Pelvic Mesh Product was in a condition not suitable for its proper and intended use among patients.

77. Plaintiff was not able to discover, nor could she have discovered through the exercise of reasonable care, the defect of the Products. Furthermore, in no way could Plaintiff have known that Boston Scientific had manufactured the Product in such a way as to increase the risk of harm or injury to the patient receiving the implant.

78. As a direct and proximate result of Boston Scientific's wrongful conduct, including Boston Scientific's design, manufacture, labeling, marketing, sale and distribution of Pelvic Mesh Products, Plaintiff has sustained and will continue to sustain severe and debilitating injuries, serious bodily injury, mental and physical pain and suffering, and has incurred economic loss.

WHEREFORE, Plaintiffs demand judgment against the Defendant and request compensatory damages together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT II: PRODUCT LIABILITY -FAILURE TO WARN

79. Plaintiffs incorporate by reference each and every paragraph of this Complaint as if fully set forth herein.

80. The Products were defective by reason of failure of Boston Scientific to provide an adequate warning or instructions.

81. Boston Scientific failed to properly and adequately warn and instruct the Plaintiff and/or her health care providers as to the risks and benefits of Boston Scientific's Pelvic Mesh Products.

82. Boston Scientific failed to properly and adequately warn and instruct the Plaintiff and/or her health care providers with regard to the inadequate research and testing of the Pelvic Mesh Products, and the lack of a safe, effective procedure for removal of the Products.

83. Boston Scientific failed to provide such adequate warning or instruction that a manufacturer exercising reasonable care would have provided to physicians who implanted the Products or to the women who had been implanted with the Products, concerning the following

risks, Boston Scientific had actual or constructive knowledge of the following risks at the time the Products left Boston Scientific's control and were being marketed:

a. The unacceptably high failure rate of the Products;

b. The unacceptably high rate of infection and abscesses caused by the Products;

c. The unacceptably high rate of vaginal erosions and extrusions caused by the Products;

d. The unacceptably high rate of chronic pain caused by the Products;

e. The severity of the infections, erosions, pain, urinary dysfunction, scarring, dyspareunia caused by the products;

f. The necessity to remove the Products from the patient's body in the event of product failure, infections, abscesses, erosion, extrusion, or other complications; and

g. The difficulty in removing the Products from the patient's body, including the complete lack of a safe, effective procedure for full removal of the Pelvic Mesh Products;

h. The need for multiple surgeries or other treatments to treat conditions caused by mesh and/or to remove it.

84. After receiving notices of numerous bodily injuries resulting from the Products, Boston Scientific failed to provide such post-marketing or post-sale warnings or instructions that a manufacturer exercising reasonable care should have provided to physicians who implanted the Products or those women who had been implanted with the Products that the products were causing an unreasonably high rate of complications such as mesh erosion, extrusion/protrusion, chronic pain, mesh contraction, infection, abscesses, fistula, inflammation, scar tissue, organ perforation, dyspareunia, bleeding, neuropathic and other acute and chronic nerve damage and pain, vaginal

scarring, vaginal shrinkage, pelvic floor damage, pelvic pain, urinary and fecal problems, and prolapse organs. Furthermore, Boston Scientific failed to provide post-marketing or post- sale warnings or instructions concerning the necessity to remove the Products from the patient's body in the event of the product failure or other complications.

85. Boston Scientific intentionally, recklessly, and maliciously misrepresented the safety, risks and benefits of the Boston Scientific Pelvic Mesh Products, understating the risks and exaggerating the benefits in order to advance their own financial interests, with wanton and willful disregard for the rights and health of the Plaintiffs.

86. Absence of a warning or instruction renders the product unreasonably dangerous for its intended use.

87. Boston Scientific is strictly liable in tort to the Plaintiffs for their wrongful conduct pursuant to common law.

88. As a direct and proximate result of Boston Scientific's wrongful conduct, including Boston Scientific's wrongful design, manufacture, marketing, sale and distribution of the Pelvic Mesh Products, both at the time of marketing and after the sale of the Products, Plaintiff has sustained and will continue to sustain severe and debilitating injuries, serious bodily injury, mental and physical pain and suffering and has incurred economic loss.

WHEREFORE, Plaintiffs demand judgment against Defendant and request compensatory damages together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT III: NEGLIGENCE

89. Plaintiffs incorporate by reference each and every paragraph of this Complaint as if fully set forth herein.

90. Defendant had a duty to individuals, including Plaintiffs, to use reasonable care in designing, researching, manufacturing, marketing, labeling, packaging, supplying, distributing and selling the Products.

91. Defendant was negligent in failing to use reasonable care as described herein in designing, manufacturing, marketing, labeling, packaging and selling the Products. Defendant breached its duty by:

a. Failing to design the Products so as to avoid unreasonable risk of harm to women in whom the Products were implanted, including Plaintiff;

b. Failing to use reasonable care in the testing of the Products, before and after on the market, so as to avoid an unreasonable risk of harm to women in whom the Products were implanted, including Plaintiff;

c. Otherwise negligently or carelessly designing, manufacturing, marketing, labeling, packaging and/or selling the Products.

92. The reasons that Defendant's negligence caused the Products to be unreasonably dangerous and defective include, but are not limited to:

a. the use of polypropylene material in the Products and the immune reaction that results from such material, causing adverse reactions and injuries;

b. the design of the Products to be inserted into and through an area of the body with high levels of bacteria that adhere to the mesh causing immune reactions and subsequent tissue breakdown and adverse reactions and injuries;

c. biomechanical issues with the design of the Products, including, but not limited to, the propensity of the Products to contract or shrink inside the

body, that in turn cause surrounding tissue to be inflamed, become fibrotic, and contract, resulting in injury;

d. the use and design of arms and anchors in the Products, which, when placed in the women, are likely to pass through contaminated spaces and injure major nerve routes in the pelvic region;

e. the propensity of the Products for migration, erosion, and/or to gradually elongate and deform when subject to prolonged tension inside the body;

f. the inelasticity of the Products, causing them to be improperly mated to the delicate and sensitive areas of the pelvis where they are implanted, and causing pain upon normal daily activities that involve movement in the pelvis (e.g., intercourse, defecation);

g. the propensity of the Products to cause a chronic inflammatory and fibrotic reaction, and results in continuing injury over time;

h. the propensity of the Products to cause long standing inflammatory response altering the effective porosity of the mesh resulting in poor outcomes including bridging fibrosis, compromise of tissues in contact with or surrounding the mesh, erosion, nerve damage and resulting neuromas; and

i. the creation of a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities when the mesh is implanting according to the manufacturers' instructions.

93. Defendant also negligently failed to warn or instruct the Plaintiff and/or her health care providers of subjects including, but not limited to, the following:

a. The Products' propensities to contract, retract, and/or shrink inside the body;

b. The Products' propensities for migration and erosion;

c. The Products' inelasticity preventing proper mating with the pelvic floor and vaginal region;

d. The frequency and manner of mesh erosion or extrusion;

e. The risk of chronic inflammation resulting from the Products;

f. The risk of chronic infections resulting from the Products;

g. The risk of permanent vaginal or pelvic scarring as a result of the Products;

h. The risk of de novo urinary dysfunction;

i. The risk of de novo dyspareunia or painful sexual relations;

j. The risk of recurrent, intractable pelvic pain and other pain resulting from the Products;

k. The need for corrective or revision surgery to adjust or remove the Products which in some cases is not feasible nor possible;

l. The severity of complications that could arise as a result of implantation of the Products;

m. The hazards associated with the Products;

n. The Products' defects described herein;

o. Treatment of pelvic organ prolapse and stress urinary incontinence with the products is no more effective than feasible, available and safer alternatives;

p. Treatment of pelvic organ prolapse and stress urinary incontinence with the Products exposes patients to greater risk than feasible, available and safer alternatives;

q. Treatment of pelvic organ prolapse and stress urinary incontinence with the Products makes future surgical repair more difficult than feasible, available and safer alternatives;

r. Use of the Products puts the patient at greater risk of requiring additional surgery than feasible, available and safer alternatives;

s. Removal of the Products due to complications may involve multiple surgeries and may significantly impair the patient's quality of life; and

t. Complete removal of the Products may not be possible and may not result in complete resolution of the complications, including pain.

u. As a result of these life-altering and, in some cases, permanent injuries, Plaintiff has suffered severe emotional pain and injury and has suffered and will suffer apprehension of increased risk for injuries, infections, pain, mental anguish, discharge, and multiple corrective surgeries as a result of implantation of mesh.

94. Defendant likewise failed to conduct post-market vigilance or surveillance by:

a. Monitoring or acting on findings in the scientific and medical literature;

b. Monitoring or acting on information received from physicians and women implanted with the Products;

c. Monitoring or investigating and evaluating reports in the FDA adverse

event databases for their potential significance for Defendant's Pelvic Mesh Products; and

d. Failing to comply with manufacturer requirements of the Medical Device Reporting (MDR) Regulations, specifically:

i. Failing to report MDRs (Medical Device [adverse event] Reports); and

ii. Failing to investigate reports of serious adverse events.

95. As a direct and proximate result of Defendant's negligence, Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, lost income, and other damages.

WHEREFORE, Plaintiffs demand judgment against Defendant and request compensatory damages together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT IV: NEGLIGENT MISREPRESENTATION

96. Plaintiffs incorporate by reference each and every paragraph of this Complaint as if fully set forth herein.

97. Defendant had a duty to accurately and truthfully represent to the medical and healthcare community, Plaintiffs, and the public, that the Pelvic Mesh Products had not been adequately tested and found to be safe and effective for the treatment of incontinence and prolapse. The representations made by Defendant, in fact, were false.

98. Defendant failed to exercise ordinary care in the representations concerning the Pelvic Mesh Products while they were involved in their manufacture, sale, testing, quality assurance, quality control, and distribution in interstate commerce, because Defendant negligently misrepresented the Pelvic Mesh Products' high risk of unreasonable, dangerous, adverse side effects.

99. Defendant breached its duty in representing that the Defendant's Pelvic Mesh Products have no serious side effects different from older generations of similar products and/or procedures to Plaintiff, Plaintiff's physicians, and the medical and healthcare community.

100. As a foreseeable, direct and proximate result of the negligent misrepresentation of Defendant as set forth herein, Defendant knew, and had reason to know, that the Pelvic Mesh Products had been insufficiently tested, or had not been tested at all, and that they lacked adequate and accurate warnings, and that they created a high risk, and/or higher than acceptable risk, and/or higher than reported and represented risk, of adverse side effects, including, erosion, pain and suffering, surgery to remove the Products, and other severe and personal injuries, which are permanent and lasting in nature.

101. As a direct and proximate result of the Defendant's conduct, Plaintiff has been injured, and sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and consortium, economic damages, and death.

WHEREFORE, Plaintiffs demand judgment against Defendant and request compensatory damages together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT V
Breach of Express Warranty
(M.G.L. ch. 106 § 2-313)

102. Plaintiffs reallege and incorporate by reference every allegation of this Complaint as if each were set forth fully and completely herein.

103. At all relevant and material times, Defendant manufactured, distributed, advertised, promoted, and sold pelvic mesh products.

104. At all relevant times, Defendant intended that its pelvic mesh products be used in the manner that Plaintiff in fact used them and Defendant expressly warranted that each product was safe and fit for use by consumers, that they were of merchantable quality, that their side effects were minimal and comparable to other pelvic mesh products, and that they were adequately tested and fit for their intended use.

105. At all relevant times, Defendant was aware that consumers, including Plaintiff, would use their pelvic mesh products; which is to say that Plaintiff was a foreseeable user of Defendant's pelvic mesh products.

106. Plaintiff and/or her implanting physicians were at all relevant times in privity with Defendant.

107. Defendant's pelvic mesh products were expected to reach and did in fact reach consumers, including Plaintiff and her implanting physicians, without substantial change in the condition in which they were manufactured and sold by Defendant.

108. Defendant breached various express warranties with respect to its pelvic mesh products including the following particulars:

a. Defendant represented to Plaintiff and her physicians and healthcare providers through their labeling, advertising, marketing materials, detail persons, seminar

presentations, publications, notice letters, and regulatory submissions that their pelvic mesh products were safe and fraudulently withheld and concealed information about the substantial risks of serious injury associated with using the pelvic mesh products;

b. Defendant represented to Plaintiff and her physicians and healthcare providers that their pelvic mesh products were as safe, and/or safer than other alternative procedures and devices and fraudulently concealed information, which demonstrated that the products were not safer than alternatives available on the market; and

c. Defendant represented to Plaintiff and her physicians and healthcare providers that their pelvic mesh products were more efficacious than other alternative medications and fraudulently concealed information, regarding the true efficacy of the products.

109. In reliance upon Defendant's express warranty, Plaintiff was implanted with Defendant's pelvic mesh products as prescribed and directed, and therefore, in the foreseeable manner normally intended, recommended, promoted, and marketed by Defendant.

110. At the time of making such express warranties, Defendant knew or should have known that its pelvic mesh products did not conform to these express representations because its pelvic mesh products were not safe and had numerous serious side effects, many of which Defendant did not accurately warn about, thus making its pelvic mesh products unreasonably unsafe for their intended purpose.

111. Members of the medical community, including physicians and other healthcare professionals, as well as Plaintiff and the Public relied upon the representations and warranties of

Defendant in connection with the use recommendation, description, and/or dispensing of their pelvic mesh products.

112. Defendant breached its express warranties to Plaintiff in that Defendant's pelvic mesh products were not of merchantable quality, safe and fit for their intended uses, nor were they adequately tested.

113. Defendant's actions, when viewed objectively from Defendant's standpoint at the time of the occurrence, involved an extreme degree of risk, considering the probability and magnitude of the potential harm to others, and Defendant had an actual, subjective awareness of the risk involved but nevertheless proceeded with conscious indifference to the rights, safety, or welfare of others.

114. As a proximate result of Defendant's conduct, Plaintiff has been injured, catastrophically, and sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and economic damages.

WHEREFORE, Plaintiffs demand judgment against Defendant, and request compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT VI
Breach of Implied Warranty
(M.G.L. ch. 106, § 2-314)

115. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

116. At all relevant and material times, Defendant manufactured, distributed, advertised, promoted, and sold pelvic mesh products.

117. At all relevant times, Defendant intended that its pelvic mesh products be implanted for the purposes and in the manner that Plaintiff or Plaintiff's implanting physicians in fact used them and Defendant impliedly warranted each product to be of merchantable quality, safe and fit for such use, and were not adequately tested.

118. Defendant was aware that consumers, including Plaintiff or Plaintiff's physicians, would implant its pelvic mesh products in the manner directed by the instructions for use; which is to say that Plaintiff was a foreseeable user of the pelvic mesh products.

119. Plaintiff and/or her physicians were at all relevant times in privity with Defendant.

120. Defendant's pelvic mesh products were expected to reach and did in fact reach consumers, including Plaintiff or Plaintiff's physicians, without substantial change in the condition in which they were manufactured and sold by Defendant.

121. Defendant breached various implied warranties with respect to Defendant's pelvic mesh products, including the following particulars:

a. Defendant represented through its labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that its pelvic mesh products were safe and fraudulently withheld and concealed information about the substantial risks of serious injury associated with using the pelvic mesh products;

b. Defendant represented that its pelvic mesh products were safe, and/or safer than other alternative devices or procedures and fraudulently concealed information, which demonstrated that Defendant's pelvic mesh products were not as safe or safer than alternatives available on the market; and

c. Defendant represented that its pelvic mesh products were more efficacious than alternative pelvic mesh products and procedures and fraudulently concealed information, regarding the true efficacy of the pelvic mesh products.

122. In reliance upon Defendant's implied warranty, Plaintiff used the pelvic mesh products as prescribed and in the foreseeable manner normally intended, recommended, promoted, and marketed by Defendant.

123. Defendant breached its implied warranty to Plaintiff in that its pelvic mesh products were not of merchantable quality, safe and fit for their intended use, or adequately tested.

124. Defendant's actions, when viewed objectively from Defendant's standpoint at the time of the occurrence, involved an extreme degree of risk, considering the probability and magnitude of the potential harm to others, and Defendant had an actual, subjective awareness of the risk involved but nevertheless proceeded with conscious indifference to the rights, safety, or welfare of others.

125. As detailed in Plaintiff's Complaint, Defendant failed to warn Plaintiff of the potential for revision surgeries, the removal of mesh, serious bodily injury, and mental and physical pain and suffering, all of which Plaintiff experienced as a result of Defendant's breach of implied warranty.

126. As a proximate result of the Defendants' conduct, Plaintiff has been injured, catastrophically, and sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and economic damages.

WHEREFORE, Plaintiffs demand judgment against Defendant, and request compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT VII: LOSS OF CONSORTIUM

127. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein and further alleges as follows.

128. At all relevant times, Plaintiff, Benjamin Oesterle, has been lawfully married to Plaintiff, Regina Oesterle, and, as such, is entitled to the services, society and companionship of his spouse.

129. As a direct and proximate result of the foregoing, Plaintiff, Benjamin Oesterle has suffered and will continue to suffer loss of love, companionship, comfort, care, assistance, protection, affection, society, and moral support of his spouse, Plaintiff, Regina Oesterle; and the loss of the enjoyment of sexual relations with his spouse, Plaintiff Regina Oesterle. Plaintiff, Benjamin Oesterle's injuries and damages are permanent and will continue into the future.

WHEREFORE, Plaintiffs demand judgment against Defendant for compensatory damages together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

PRAYERS FOR RELIEF

WHEREFORE, Plaintiffs pray for the following relief:

A. Judgment in favor of Plaintiffs and against Defendant, for damages in such amounts as may be proven at trial;

B. Compensation for both economic and non-economic losses, including but not limited to medical expenses, disfigurement, pain and suffering, mental anguish and emotional distress, in such amounts as may be proven at trial;

C. Restitution and disgorgement of all revenue that Defendant has obtained through the manufacture, marketing, sale and administration of the Pelvic Mesh Devices;

D. Attorneys' fees and costs where applicable;

E. Pre-and post-judgment interest; and

F. Any and all further relief, both legal and equitable, that the Court may deem just and proper.

JURY DEMAND

Plaintiffs hereby demand a trial by jury.

Dated: August 11, 2023

Respectfully submitted,

/s/ Robert T. Naumes, Jr.
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