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UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
AT TACOMA

HEIDI McKENNA and ANDREW McKENNA, wife and husband, Plaintiffs, v. BOSTON SCIENTIFIC CORPORATION, (d/b/a MANSFIELD SCIENTIFIC, INC. & MICROVASIVE, INC.), Defendant.	NO. COMPLAINT FOR PERSONAL INJURIES JURY DEMAND

A. PETITION

COMES NOW, Plaintiffs, HEIDI MCKENNA and ANDREW MCKENNA, wife and husband (hereinafter "Plaintiffs") and through their attorneys file this suit against Defendant, BOSTON SCIENTIFIC CORPORATION (d/b/a MANSFIELD SCIENTIFIC, INC. & MICTOVASIVE, INC. and (hereinafter Defendant or Manufacturing Defendant) and in support thereof allege as follows:

I. PARTIES & SERVICE OF PROCESS

1. Plaintiffs are individuals over the age of twenty-one (21) years and residents of Puyallup, Pierce County, Washington.

2. Defendant **BOSTON SCIENTIFIC CORPORATION (d/b/a MANSFIELD SCIENTIFIC, INC. & MICROVASIVE, INC**. is and was at all times herein mentioned, a Delaware corporation with its principal place of business in Massachusetts. All acts and omissions of 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. Defendant may be served with process through its registered agent at:

Corporation Service Company
300 Deschutes Way SW, Suite 304
Tumwater, WA 98501

II. JURISDICTION AND VENUE

3. This Court has jurisdiction over the non-resident Defendant because defendant has done business in the State of Washington, committed a tort in whole or in part in the State of Washington, and/or has continuing contacts with the State of Washington. Defendant is amenable to service by a Washington court. The Court has jurisdiction over the controversy because the damages are within jurisdictional limits. Venue of this case is proper in the United States District Court, Western Division of Washington because some or all of the cause of action arose in this jurisdiction, the Plaintiffs reside in this jurisdiction and the amount in controversy exceeds the jurisdictional amount.

III. FACTUAL BACKGROUND

4. On April 6, 2011, Plaintiff, Heidi McKenna, was surgically implanted with the "Solyx SIS System (hereinafter referred to as "Solyx Device") and the Pinnacle Pelvic Floor

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Repair Kit-Posterior (hereinafter referred to as "Pinnacle Device"), or collectively referenced herein as "Defendants' Pelvic Mesh Devices" or the "Devices."

5. At all times material to this action, Defendant has designed, patented, manufactured, labeled, marketed, sold and/or distributed a line of pelvic mesh devices, including the Solyx and Pinnacle Devices. These Devices were designed primarily for the purposes of treating stress urinary incontinence and pelvic organ prolapse. These Devices share common design elements and common defects. Moreover, both of these Devices were: cleared for sale in the U.S. after the Defendant made assertions to the Food and Drug Administration ("FDA") of "Substantial Equivalence" under Section 510(k) of the Food, Drug and Cosmetic Act, a clearance process that does not require the applicant to prove safety or efficacy.

6. Defendant's Pelvic Mesh Devices contain, among other things, monofilament polypropylene mesh. Despite claims that polypropylene is inert, the scientific evidence shows that these materials as implanted in Plaintiff, are often biologically incompatible and promote a negative immune response in a large subset of the population implanted with Defendant's Pelvic Mesh Devices. This negative response promotes inflammation of the pelvic tissue and can contribute to the formation of severe adverse reactions to the Devices. When the Devices are inserted in the female body according to the manufacturers' instructions, they create a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities.

7. Defendant sought and obtained FDA clearance to market their Pelvic Mesh Devices subject to the regulations in 21 CFR 1271 or under Section 510(k) of the Medical Device Amendment to the Food, Drug and Cosmetics Act. Section 510(k) provides for marketing of a medical device if the device is deemed "substantially equivalent" to other predicate devices marketed prior to May 28, 1976. No formal review for safety or efficacy is

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required, and no formal review for safety or efficacy was ever conducted with regard to either of the devices implanted in Plaintiff.

8. On July 13, 2011, the FDA issued a Safety Communication relating to Defendant's Pelvic Mesh and Biologic Devices, wherein the FDA stated:

> Surgical mesh 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.

9. The FDA Safety Communication also stated, "serious complications associated with surgical mesh for transvaginal repair of POP are **not rare**" and "*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).

10. 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 mesh inside the body as a serious complication associated with vaginal 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.

11. 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."

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12. The injuries of the Plaintiff, as more fully set forth below, are reported in the FDA Safety Communication and in the ACOG/AUGS Joint Committee Opinion.

13. The FDA Safety Communication further indicated that the benefits of using transvaginal mesh devices instead of other feasible alternatives did not outweigh the associated risks. The FDA defined the dangerous devices it was warning about as follows:

> "Surgical mesh 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."

14. 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 risk."

15. 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 the 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."

16. 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 risk." (Emphasis in original).

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17. The FDA White Paper further stated that the Defendant's Pelvic Mesh Devices, both synthetic and biologic, "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."

18. 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."

19. The FDA concludes its White Paper by stating that it "has identified serious safety and effectiveness concerns over the use of surgical mesh for the transvaginal repair of pelvic organ prolapse." The FDA's Safety Communication and White Paper specifically referenced synthetic devices, which would include the Solyx and Pinnacle devices.

20. On April 16, 2019, the FDA ordered Defendant to stop selling and distributing its products used in the transvaginal repair of pelvic organ prolapse.

21. Defendant knew or should have known about the Devices' risks and complications identified in the FDA Safety Communications and the ACOG/AUGS Joint Committee Opinion.

22. Defendant knew or should have known that their Pelvic Mesh Devices unreasonably exposed patients, including Plaintiff, to the risk of serious harm while conferring no benefit over available feasible alternatives that do not involve the same risks.

23. The MSDS for the Marlex polypropylene used in making the Pinnacle and Solyx came with the following warning: "MEDICAL APPLICATION CAUTION: Do not use this [polypropylene] material in medical applications involving permanent implantation in the human body or permanent contact with internal body fluids or tissues."

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24. Defendant ignored this warning and continued to make, market and sell the permanently implanted Pinnacle and Solyx devices for profit.

25. The scientific evidence shows that the various materials from which Defendant's Pelvic Mesh Devices are made or derived promote a negative immune response in a large subset of the population implanted with the Devices, including Plaintiff.

26. This negative response promotes inflammation of the pelvic tissue and contributes to the formation of severe adverse reactions to the Devices, such as those experienced by Plaintiff.

27. The FDA defines both "degradation" and "fragmentation" as "device problems" to which the FDA assigns a specific "device problem code." "Material Fragmentation" is defined as an "[i]ssue associated with small pieces of the device breaking off unexpectedly" and "degraded" as an "[i]ssue associated with a deleterious change in the chemical structure, physical properties, or appearance in the materials that are used in device construction." Defendant's Pelvic Mesh Devices were unreasonably susceptible to degradation and fragmentation inside the body.

28. Defendant's Pelvic Mesh Devices were unreasonably susceptible to shrinkage and contraction inside the body.

29. Defendant's Pelvic Mesh Devices were unreasonably susceptible to "creep" or the gradual elongation and deformation when subject to prolonged tension inside the body.

30. Defendant's Pelvic Mesh Devices have been and continue to be marketed to the medical community and to patients as safe, effective, reliable, medical devices, implanted by safe and effective, minimally invasive surgical techniques, and as safer and more effective as

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compared to available feasible alternative treatments of pelvic organ prolapse and stress urinary incontinence, and other competing devices.

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

32. Contrary to Defendant's representations and marketing to the medical community and to the patients themselves, Defendant's Pelvic Mesh Devices 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 Plaintiff, making them defective under the law.

33. The specific nature of Defendants' Pelvic Mesh Devices' defects includes, but is not limited to, the following:

a. the use of polypropylene in the Devices and the immune reactions that result from such material, causing adverse reactions and injuries;

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

c. biomechanical issues with the design of the Devices, including, but not limited to, the propensity of the Devices to contract or shrink inside the body, that in turn cause surrounding tissue to be inflamed, become fibrotic, and contract, resulting in injury;

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

e. the propensity of the Devices for "creep," or to gradually elongate and deform when subject to prolonged tension inside the body;

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

g. the propensity of the Devices for degradation, disintegrate or fragmentation over time, which causes a chronic inflammatory and fibrotic reaction, and results in continuing injuries including pain, recurrence, encapsulation, adhesions and other adverse reactions;

h. the hyper-inflammatory responses to the Devices leading to problems including chronic pain and fibrotic reaction;

i. the adverse tissue reactions caused by the Devices, which are causally related to infection, as they are foreign materials;

j. the harshness of the Devices upon the female pelvic tissue, and the hardening of the Device in the body; and

k. the creation of a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities when the Devices are implanted according to the manufacturers' instructions.

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34. Defendant's Pelvic Mesh Devices 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 Devices' propensities to contract, retract, and/or shrink inside the body;

b. the Devices' propensities for degradation, fragmentation and/or creep;

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

d. the rate and manner of mesh erosion or extrusion;

e. the risk of chronic inflammation resulting from the Devices;

f. the risk of chronic infections resulting from the Devices;

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

h. the risk of recurrent, intractable pelvic pain and other pain resulting from the Devices;

i. the need for corrective or revision surgery to adjust or remove the Devices and recurrence of POP or SUI;

j. the severity of complications that could arise as a result of implantation of the Devices;

k. the hazards associated with the Devices;

l. the Devices' defects described herein;

m. treatment of pelvic organ prolapse and stress urinary incontinence with the Devices is no more effective than feasible available alternatives;

n. treatment of pelvic organ prolapse and stress urinary incontinence with the Devices exposes patients to greater risk than feasible available alternatives;

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o. treatment of pelvic organ prolapse and stress urinary incontinence with the Devices makes future surgical repair more difficult than feasible available alternatives;

p. use of the Devices puts the patient at greater risk of requiring additional surgery than feasible available alternatives;

q. removal of the Devices due to complications may involve multiple surgeries and may significantly impair the patient's quality of life; and

r. complete removal of the Devices may not be possible and may not result in complete resolution of the complications, including pain.

35. Defendant has underreported information about the propensity of the Devices to fail and cause injury and complications and have made unfounded representations regarding the efficacy and safety of the Devices through various means, including the media. Defendant has also underreported information about the injuries caused by the use of the implantation kits and surgical technique instructions that accompany the Devices.

36. Defendant failed to perform proper and adequate testing and research in order to determine and evaluate the risks and benefits of their Devices.

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

38. Feasible and suitable alternatives to Defendant's Pelvic Mesh Devices have existed at all times relevant that do not present the same frequency or severity of risks as do the Devices.

39. Defendant's Pelvic Mesh Devices were at all times utilized and implanted in a manner foreseeable to Defendant, as Defendant generated the instructions for use, created the

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procedures for implanting the Devices, provided the surgical kits for implantation, and provided training for the implanting physician.

40. Defendant provided incomplete and insufficient training and information to physicians regarding the use of the Devices and the aftercare of patients implanted with the Devices.

41. Defendant's Pelvic Mesh Devices implanted in Plaintiff were in the same or substantially similar condition as they were when they left Defendant's possession, and in the condition directed by and expected by Defendant.

42. The injuries, conditions, and complications suffered by numerous women around the world who have been implanted with Defendant's Pelvic Mesh Devices include, but are not limited to, erosion, mesh contraction, infection, fistula, adhesions, inflammation, scar tissue, recurrence of POP or SUI, 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 and other debilitating complications.

43. In many cases, including Plaintiff's, the women have been forced to undergo extensive medical treatment, including, but not limited to, operations to locate and remove the Devices, 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.

44. The medical and scientific literature studying the effects of Defendant's Pelvic Mesh Devices, like the Solyx and Pinnacle devices implanted in Plaintiff, has examined each of these injuries, conditions, and complications, and has reported that they are causally related to the Devices.

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45. Removal of contracted, eroded and/or infected Devices can require multiple surgical interventions and results in scarring on fragile compromised pelvic tissue and muscles.

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

47. 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 Devices.

48. At all relevant times herein, Defendant failed to provide sufficient warnings and instructions that would have put Plaintiff, her implanting physician, and the general public on notice of the dangers and adverse effects caused by implantation of the Devices.

49. Defendant's Pelvic Mesh Devices 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 and efficacy.

50. As a result of having the Devices implanted in her, 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, and/or lost income, and other damages.

IV. CAUSES OF ACTION

COUNT I: VIOLATION OF THE WASHINGTON PRODUCT LIABILITY ACT

51. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein at length, and further allege:

52. Plaintiffs bring a product liability claim against Defendant under The Washington Product Liability Act ("WPLA"), Wash. Rev. Code § 7.72 et seq. and includes claims or actions

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brought for harm caused by the manufacture, production, making, construction, fabrication, design, formula, preparation, assembly, installation, testing, warnings, instructions, marketing, packaging, storage and/or labeling of the Defendant's Pelvic Mesh Devices.

53. Plaintiffs have previously put Defendant on notice that they are pleading all theories of liability allowed under the WPLA including, but not limited to design defect, negligence, and breach of express warranty.

A. DESIGN DEFECT (Wash. Rev. Code Chapter 7.72 et seq.)

54. Plaintiffs sue Defendant for Design Defect under the WPLA. The WPLA uses a strict liability standard for design defect claims. *Ayers v. Johnson & Johnson Baby Products Co.,* 117 Wash.2d 747, 761, 818 P.2d 1337 (1992).

55. Defendant's Pelvic Mesh Devices were not reasonably safe because adequate warnings or instructions were not provided with their devices at the time of manufacture. RCW 7.72.030(b).

56. At the time of their manufacture, the likelihood that Defendant's Pelvic Mesh Devices would cause the Plaintiff's injuries, and the seriousness of those injuries, outweighed the Defendant's burden and rendered the warnings or instructions of the Defendant inadequate. RCW 7.72.030(b).

57. Defendant could have provided the warnings or instructions regarding the true risks of their Pelvic Mesh at the time of manufacture because they knew or should have known of the risks associated with their devices at the time of manufacture. RCW 7.72.030(b). They, however, did not report them or provide adequate warnings in their labeling.

58. Defendant's Pelvic Mesh Devices implanted in Plaintiff were not reasonably safe for their intended uses and were defective as described herein with respect to their design. As

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previously stated, the Devices' design defects include, but are not limited to:

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

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

c. biomechanical issues with the design of the Devices, including, but not limited to, the propensity of the Devices to contract, shrink or disintegrate 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 Devices, 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 Devices for "creep," or to gradually elongate and deform when subject to prolonged tension inside the body;

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

g. the propensity of the Devices for degradation, disintegrate or fragmentation over time, which causes a chronic inflammatory and fibrotic reaction, and results in continuing injuries including pain, recurrence, encapsulation, adhesions and other adverse reactions;

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h. the hyper-inflammatory responses to the Devices leading to problems including chronic pain and fibrotic reaction;

i. the adverse tissue reactions caused by the Devices, which are causally related to infection, as they are foreign materials;

j. the harshness of Devices upon the female pelvic tissue, and the hardening of the Device in the body;

k. the Marlex used in the Pinnacle and Solyx was not intended to be used in medical applications; and

l. the creation of a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities when the Devices are implanted according to the manufacturers' instructions.

59. Defendant's Pelvic Mesh Devices were expected to and did reach the Plaintiff without substantial change in their condition as manufactured, created, designed, tested, labeled, sterilized, packaged, supplied, marketed, sold, advertised, warned and otherwise distributed.

60. Plaintiff used Defendant's' Pelvic Mesh Devices in a manner for which they were intended or in a reasonably foreseeable manner.

61. Defendant is strictly liable to Plaintiff for designing, manufacturing, marketing, labeling, packaging and/or selling a defective device(s).

62. As a direct and proximate result of the Devices' aforementioned defects as described herein, Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo future 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 compensatory

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and punitive damages in an amount to be proven at trial.

63. Defendant's actions described above were performed willfully, intentionally, with malice and/or with reckless disregard for the rights of Plaintiffs and the public. As such, Plaintiffs are entitled to punitive damages against defendant.

B. NEGLIGENCE (Wash. Rev. Code Chapter 7.72 et seq.)

64. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein at length, and further allege:

65. Plaintiffs sue Defendant for negligence under the WPLA. Defendant's Pelvic Mesh Devices were not reasonably safe because adequate warnings or instructions were not provided after their devices were manufactured. RCW 7.72.030(c).

66. At all relevant times, Defendant had a duty to individuals, including Plaintiffs, to use reasonable care in designing, manufacturing, marketing, labeling, packaging and selling Defendant's Pelvic Mesh Devices.

67. At all relevant times once their Pelvic Mesh Devices were manufactured, Defendant had and continue to have a duty to exercise reasonable care to issue warnings or instructions concerning dangers of their devices in the manner that a reasonably prudent manufacturer would act in the same or similar circumstances. RCW 7.72.030(c).

68. At all times relevant, Defendant owed a duty to properly warn consumers of the risks, dangers, and adverse events associated with their Pelvic Mesh Devices. *Macias v. Mine Safety Appliances Co.,* 158 Wash.App. 931, 980, 244 P.3d 978 (Wash. Ct. App. 2010).

69. Defendant was negligent in failing to use reasonable care as described herein in designing, manufacturing, marketing, labeling, packaging and selling Defendant's Pelvic Mesh Devices. Defendant breached their aforementioned duty by:

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

b. failing to manufacture the Devices so as to avoid an unreasonable risk of harm to women in whom the Devices were implanted, including Plaintiff;

c. failing to use reasonable care in the testing of the Devices so as to avoid an unreasonable risk of harm to women in whom the Devices were implanted, including Plaintiff;

d. failing to use reasonable care in inspecting the Devices so as to avoid an unreasonable risk of harm to women in whom the Devices were implanted, including Plaintiff; and

e. failing to provide adequate warnings or instructions to physicians and/or the women in whom the devices were implanted, including Plaintiff.

f. otherwise negligently or carelessly designing, manufacturing, marketing, labeling, packaging and/or selling the Devices.

70. The reasons that Defendants' negligence caused the Devices to be unreasonably dangerous and defective include, but are not limited to:

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

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

c. biomechanical issues with the design of the Devices, including, but not limited to, the propensity of the Devices to contract, shrink or disintegrate inside the body, that in turn cause surrounding tissue to be inflamed, become fibrotic, and contract, resulting

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in injury;

d. the use and design of arms and anchors in the Devices, 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 Devices for "creep," or to gradually elongate and deform when subject to prolonged tension inside the body;

f. the inelasticity of the Devices, 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, walking);

g. the propensity of the Devices for degradation, disintegrate or fragmentation over time, which causes a chronic inflammatory and fibrotic reaction, and results in continuing injuries including pain, recurrence, encapsulation, adhesions and other adverse reactions;

h. the hyper-inflammatory responses to the Devices leading to problems including chronic pain and fibrotic reaction;

i. the adverse tissue reactions caused by the Devices, which are causally related to infection, as they are foreign materials;

j. the harshness of the Devices upon the female pelvic tissue, and the hardening of the Device in the body;

k. the Marlex used in the Pinnacle and Solyx was not intended to be used in medical applications; and

l. the creation of a non-anatomic condition in the pelvis leading to chronic pain and

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functional disabilities when the Devices are implanted according to the manufacturers' instructions.

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

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

b. the Devices' propensities for degradation, fragmentation, disintegration and/or creep;

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

d. the rate and manner of mesh erosion or extrusion;

e. the risk of chronic inflammation resulting from the Devices;

f. the risk of chronic infections resulting from the Devices;

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

h. the risk of recurrent, intractable pelvic pain and other pain resulting from the Devices and recurrence of POP and/or SUI;

i. the need for corrective or revision surgery to adjust or remove the Devices;

j. the severity of complications that could arise as a result of implantation of the Devices;

k. the hazards associated with the Devices;

l. the Devices' defects described herein

m. the Marlex used in the Pinnacle and Solyx was not intended to be used in medical applications;

n. treatment of pelvic organ prolapse and stress urinary incontinence with the Devices is no more effective than feasible available alternatives;

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o. treatment of pelvic organ prolapse and stress urinary incontinence with the Devices exposes patients to greater risk than feasible available alternatives;

p. treatment of pelvic organ prolapse and stress urinary incontinence with the Devices makes future surgical repair more difficult than feasible available alternatives;

q. use of the Devices puts the patient at greater risk of requiring additional surgery than feasible available alternatives;

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

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

72. As a direct and proximate result of Defendant's conduct as described herein, Plaintiffs have experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo future 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 compensatory and punitive damages in an amount to be proven at trial.

73. Defendant's actions described above were performed willfully, intentionally, with malice and/or with reckless disregard for the rights of Plaintiff and the public. As such, Plaintiff is entitled to punitive damages against defendant.

C. BREACH OF EXPRESS WARRANTY (Wash. Rev. Code Chapter 7.72 et seq.)

74. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein at length, and further allege:

BERGMAN DRAPER OSLUND
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SEATTLE, WA 98104
TELEPHONE: 206.957.9510

75. Defendant, through description, affirmation of fact, and promise expressly warranted and made assurances as described herein to hospitals, health care professionals, and the public, including Plaintiffs, that their Pelvic Mesh Devices were safe and reasonably fit for their intended purposes.

76. These warranties came in the form of false and misleading written information, including but not limited to professional education materials, promotional materials, IFUs, patient brochures and advertisements which were published and distributed by Defendants and directed to consumers.

77. Plaintiff and/or her healthcare provider chose the Devices based upon Defendant's warranties and representations as described herein regarding the safety and fitness of the Devices.

78. Plaintiff, individually and/or by and through her physician, reasonably relied upon Defendant's express warranties and guarantees that their Pelvic Mesh Devices were safe, merchantable, and reasonably fit for their intended purposes.

79. Defendant breached these express warranties because the devices implanted in Plaintiff were unreasonably dangerous and defective as described herein and not as Defendant had represented.

80. Defendant's breach of their express warranties resulted in the implantation of the unreasonably dangerous and defective Pelvic Mesh Devices being implanted in the body Plaintiff, placing her health and safety in jeopardy.

81. As a direct and proximate result of Defendant's conduct as described herein, Plaintiffs have experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo future medical

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treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, lost income, and other compensatory and punitive damages in an amount to be proven at trial.

82. Defendant's actions described above were performed willfully, intentionally, with malice and/or with reckless disregard for the rights of Plaintiffs and the public. As such, Plaintiff is entitled to punitive damages against defendant.

COUNT II: STRICT LIABILITY – MANUFACTURING DEFECT

83. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein at length, and further allege:

84. Defendant's Pelvic Mesh Devices implanted in Plaintiff were not reasonably safe for their intended uses and were defective as described herein as a matter of law with respect to their manufacture, in that they deviated materially from Defendant's design and manufacturing specifications in such a manner as to pose unreasonable risks of serious bodily harm to Plaintiff.

85. As a direct and proximate result of Defendant's conduct as described herein, Plaintiffs have experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and/or corrective surgery and hospitalization, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages.

86. Defendant is strictly liable to Plaintiffs for designing, manufacturing, marketing, labeling, packaging and/or selling a defective device(s).

COUNT III: STRICT LIABILITY – FAILURE TO WARN

87. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein at length, and further allege:

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88. Defendant's Pelvic Mesh Devices implanted in Plaintiff were not reasonably safe for their intended uses and were defective as described herein as a matter of law due to their lack of appropriate and necessary warnings. Specifically, Defendant did not provide sufficient or adequate warnings regarding, among other subjects:

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

b. the Devices' propensities for degradation, fragmentation, disintegration and/or creep;

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

d. the rate and manner of mesh erosion or extrusion;

e. the risk of chronic inflammation resulting from the Devices;

f. the risk of chronic infections resulting from the Devices;

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

h. the risk of recurrent, intractable pelvic pain and other pain resulting from the Devices and recurrence of POP and/or SUI;

i. the need for corrective or revision surgery to adjust or remove the Devices;

j. the severity of complications that could arise as a result of implantation of the Devices;

k. the hazards associated with the Devices;

l. the Devices' defects described herein;

m. the Marlex used in the Pinnacle and Solyx was not intended to be used in medical applications;

n. treatment of pelvic organ prolapse and stress urinary incontinence with the Devices is no more effective than feasible available alternatives;

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o. treatment of pelvic organ prolapse and stress urinary incontinence with the Devices exposes patients to greater risk than feasible available alternatives;

p. treatment of pelvic organ prolapse and stress urinary incontinence with the Devices makes future surgical repair more difficult than feasible available alternatives;

q. use of the Devices puts the patient at greater risk of requiring additional surgery than feasible available alternatives;

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

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

89. As a direct and proximate result of Defendant's conduct as described herein, Plaintiffs have experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo future 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 compensatory and punitive damages in an amount to be proven at trial.

90. Defendant's actions described above were performed willfully, intentionally, with malice and/or with reckless disregard for the rights of Plaintiffs and the public. As such, Plaintiffs are entitled to punitive damages against defendant.

91. Defendant is strictly liable to Plaintiffs for designing, manufacturing, marketing, labeling, packaging and/or selling a defective device(s).

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COUNT IV: GROSS NEGLIGENCE

92. Plaintiffs incorporate all preceding paragraphs as if fully set forth herein and further alleges as follows:

93. The wrong done by Defendant was aggravated by the kind of malice, fraud, reckless disregard for the rights of others, the public and the Plaintiffs and conduct for which the law allows the imposition of exemplary damages, in that the Defendant's conduct:

a. specifically intended to cause substantial injury to the Plaintiff; or

b. when viewed objectively from Manufacturing Defendants' standpoint at the time of the conduct, involved an extreme degree of risk, considering the probability and magnitude of the potential harm to others, and the Manufacturing Defendants were actually, subjectively aware of the risk involved, but nevertheless proceeded with conscious indifference to the rights, safety, or welfare of others; or

c. made a material representation that was false, knowing that it was false or with reckless disregard as to its truth and as a positive assertion, with the intent that the representation be acted on by the Plaintiff. The Plaintiff relied on the representation and suffered injury as a result of this reliance.

94. Plaintiffs, therefore, seek exemplary damages in an amount within the jurisdictional limits of the court. Plaintiffs also allege that the acts and omissions of Defendant constitute gross negligence which proximately caused the injuries to Plaintiffs. In that regard, Plaintiffs seek exemplary damages in an amount which would punish such Defendant for their conduct and which would deter other manufacturers from engaging in such misconduct in the future.

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COUNT V: PUNITIVE DAMAGES

95. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein at length, and further allege:

96. As set forth in each and every claim for relief, Plaintiffs allege that the acts and omissions of Defendant constitute fraud, reckless disregard for the safety of the public and the Plaintiffs, malice, and/or gross neglect for which the Defendant should be assessed punitive damages.

97. Defendant sold their Products to the healthcare providers of Plaintiff and other healthcare providers in the state of implantation and throughout the United States without doing adequate testing to ensure that the Devices were reasonably safe for implantation in the female pelvic area.

98. Defendant sold their Pelvic Mesh Devices to Plaintiff's health care providers and other health care providers in the state of implantation and throughout the United States in spite of their knowledge that the devices can shrink, disintegrate and/or degrade inside the body, and cause the other problems heretofore set forth in this Complaint, thereby causing severe and debilitating injuries suffered by Plaintiff and numerous other women.

99. Defendant ignored reports from patients and health care providers throughout the United States and elsewhere of the Devices' failures to perform as intended, which lead to the severe and debilitating injuries suffered by the Plaintiff and numerous other women. Rather than doing adequate testing to determine the cause of these injuries, or to rule out the Devices' designs or the processes by which the Devices are manufactured as the cause of these injuries, Defendant choose instead to continue to market and sell the Devices as safe and effective.

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100. Defendant knew the Devices were unreasonably dangerous in light of their risks of failure resulting in pain and suffering, loss of life's enjoyment, remedial surgeries and treatments in an effort to cure the conditions proximately related to the use of the Devices, as well as other severe and personal injuries which were permanent and lasting in nature.

101. Defendant withheld material information from the medical community and the public in general, including Plaintiff, regarding the safety and efficacy of the Devices.

102. Defendans knew and recklessly disregarded the fact that the Devices caused debilitating and potentially life altering complications with greater frequency than feasible alternative methods and/or products used to treat pelvic organ prolapse and stress urinary incontinence.

103. Defendant misstated and misrepresented data and continue to misrepresent data so as to minimize the perceived risk of injuries caused by the Devices.

104. Notwithstanding the foregoing, Defendant continue to aggressively market the Devices to consumers, without disclosing the true risks associated with the Devices.

105. Defendant knew of the Devices' defective and unreasonably dangerous nature, but continued to manufacture, market, distribute, and sell the Devices so as to maximize sales and profits at the expense of the health and safety of the public, including Plaintiff.

106. Defendant continue to conceal and/or fail to disclose to the public, including the Plaintiff, the serious complications associated with the use of the Devices, to ensure continued and increased sales of the Devices.

107. Defendant's conduct as described herein shows willful misconduct, malice, fraud, wantonness, oppression, or that entire want of care which raises the presumption of conscious indifference to consequences, thereby justifying an award of punitive damages.

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COUNT VI: VIOLATION OF CONSUMER PROTECTION LAWS
Wash. Rev. Code §§ 19.86.010 et seq.

108. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein at length, and further allege:

109. Plaintiffs purchased and used Defendant's Pelvic Mesh Devices primarily for personal use and thereby suffered ascertainable losses as a result of Defendant's actions in violation of the consumer protection laws.

110. Had Defendant not engaged in the deceptive conduct described herein, Plaintiffs would not have purchased and/or paid for Defendant's Pelvic Mesh Devices, and would not have incurred related medical costs and injury.

111. Defendant engaged in wrongful conduct while at the same time obtaining, under false pretenses, moneys from Plaintiffs for the Devices that would not have been paid had Defendant not engaged in unfair and deceptive conduct.

112. Unfair methods of competition or deceptive acts or practices that were proscribed by law, including the following: representing that goods or services have characteristics, ingredients, uses, benefits or quantities that they do not have; advertising goods or services with the intent not to sell them as advertised; and engaging in fraudulent or deceptive conduct that creates a likelihood of confusion or misunderstanding.

113. Plaintiffs were injured by the cumulative and indivisible nature of Defendant's conduct. The cumulative effect of Defendant's conduct directed at patients, physicians and consumers was to create demand for and sell Defendant's Pelvic Mesh Devices. Each aspect of Defendant's conduct combined to artificially create sales of the Defendant's Pelvic Mesh Devices.

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114. Defendant has a statutory duty to refrain from unfair or deceptive acts or trade practices in the design, labeling, development, manufacture, promotion, and sale of Defendant's Pelvic Mesh Devices.

115. Had Defendant not engaged in the deceptive conduct described above, Plaintiffs would not have purchased and/or paid for the devices and would not have incurred related medical costs.

116. Defendant's deceptive, unconscionable, or fraudulent representations and material omissions to patients, physicians and consumers, including Plaintiffs, constituted unfair and deceptive acts and trade practices in violation of consumer protection laws.

117. Defendant's actions, as complained of herein, constitute unfair competition or unfair, unconscionable, deceptive or fraudulent acts or trade practices in violation of the consumer protection laws.

118. Defendant has engaged in unfair competition or unfair or deceptive acts or trade practices or have made false representations in violation of the consumer protection laws.

119. Under Wash. Rev. Code §§ 19.86.010 et seq., Defendant is the suppliers, manufacturers, advertisers, and/or sellers, who are subject to liability under such legislation for unfair, deceptive, fraudulent and unconscionable consumer sales practices.

120. Defendant violated consumer protection laws enacted to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising, by knowingly and falsely representing that Defendant's Pelvic Mesh Devices were fit to be used for the purpose for which they were intended, when in fact they were defective and dangerous, and by other acts alleged herein. These representations were made in uniform promotional materials.

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121. The actions and omissions of Defendant alleged herein are uncured or incurable deceptive acts. Wash. Rev. Code §§ 19.86.010 et seq. was enacted to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising.

122. Defendant had actual knowledge of the defective and dangerous condition of Defendant's Pelvic Mesh Devices and failed to take any action to cure such defective and dangerous conditions.

123. Plaintiffs and the medical community relied upon Defendant's misrepresentations and omissions in determining to use Defendant's Pelvic Mesh Devices.

124. Defendant's deceptive, unconscionable and/or fraudulent representations and material omissions made to patients, physicians and consumers, constituted unfair and deceptive acts and practices.

125. By reason of the unlawful acts engaged in by Defendant, and as a direct and proximate result of Defendant's violations of the states' consumer protection laws, Plaintiffs have sustained economic losses and other damages and is entitled to statutory and compensatory damages in an amount to be proven at trial.

COUNT VII: LOSS OF CONSORTIUM

126. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein at length, and further allege:

127. As a direct and proximate result of the above-described injuries sustained by Plaintiff, her husband has suffered a loss of his wife's consortium, companionship, society, affection, services and support.

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WHEREFORE, Plaintiffs pray for judgment against Defendant in an amount to compensate Plaintiffs fully for their injuries and in an amount above the minimal jurisdictional limits of this Court, for prejudgment and post-judgment interest, for attorney fees if appropriate, for the costs of this action and for such other relief as the Court may deem just and equitable.

DATED this 12th day of June, 2019.

BERGMAN DRAPER OSLUND, PLLC

/s Glenn S. Draper
Glenn S. Draper, WSBA #24419
Justin Olson, WSBA #51332
821 2nd Avenue, Suite 2100
Seattle, WA 98104
Phone: (206) 957-9510
Fax: (206) 957-9549
Email: glenn@bergmanlegal.com
justin@bergmanlegal.com
Attorneys for Plaintiffs

DEMAND FOR JURY TRIAL

Plaintiffs demand trial by jury of all issues as set forth herein.

BERGMAN DRAPER OSLUND, PLLC

/s Glenn S. Draper
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Attorneys for Plaintiffs

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JS 44 (Rev. 02/19)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS

Heidi McKenna and Andrew McKenna

(b) County of Residence of First Listed Plaintiff Pierce County
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Bergman Draper Oslund
821 2nd Avenue, Suite 2100, Seattle, WA 98104
(206) 957-9510

DEFENDANTS

Boston Scientific Corporation (d/b/a Mansfield Scientific, Inc. & Microvasive, Inc.

County of Residence of First Listed Defendant Middlesex County, MA
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ☐ 1 U.S. Government Plaintiff
- ☐ 3 Federal Question *(U.S. Government Not a Party)*
- ☐ 2 U.S. Government Defendant
- ☒ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☒ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☒ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

Click here for: Nature of Suit Code Descriptions.

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Personal Injury - Medical Malpractice

PERSONAL INJURY
- ☒ 365 Personal Injury - Product Liability
- ☐ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

CIVIL RIGHTS
- ☐ 440 Other Civil Rights
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 445 Amer. w/Disabilities - Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 448 Education

PRISONER PETITIONS

Habeas Corpus:
- ☐ 463 Alien Detainee
- ☐ 510 Motions to Vacate Sentence
- ☐ 530 General
- ☐ 535 Death Penalty

Other:
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition
- ☐ 560 Civil Detainee - Conditions of Confinement

FORFEITURE/PENALTY
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Management Relations
- ☐ 740 Railway Labor Act
- ☐ 751 Family and Medical Leave Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Employee Retirement Income Security Act

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 465 Other Immigration Actions

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 835 Patent - Abbreviated New Drug Application
- ☐ 840 Trademark

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ☐ 375 False Claims Act
- ☐ 376 Qui Tam (31 USC 3729(a))
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit
- ☐ 485 Telephone Consumer Protection Act
- ☐ 490 Cable/Sat TV
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 895 Freedom of Information Act
- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes

V. ORIGIN *(Place an "X" in One Box Only)*

☐ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☒ 4 Reinstated or Reopened ☐ 5 Transferred from Another District *(specify)* ☐ 6 Multidistrict Litigation - Transfer ☐ 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing ***(Do not cite jurisdictional statutes unless diversity)***:
28 U.S.C. 1332

Brief description of cause:
PERSONAL INJURIES DUE TO DEFECTIVE PRODUCT

VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A **CLASS ACTION** UNDER RULE 23, F.R.Cv.P.

DEMAND $

CHECK YES only if demanded in complaint:
JURY DEMAND: ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE Joseph R. Goodwin DOCKET NUMBER 2:12-md-02326

DATE 06/12/2019

SIGNATURE OF ATTORNEY OF RECORD Glenn S. Draper

FOR OFFICE USE ONLY

RECEIPT # AMOUNT APPLYING IFP JUDGE MAG. JUDGE

INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

I.(a) **Plaintiffs-Defendants.** Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.

(b) **County of Residence.** For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)

(c) **Attorneys.** Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".

II. **Jurisdiction.** The basis of jurisdiction is set forth under Rule 8(a), F.R.Cv.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.
United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.
United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.
Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.
Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below**; NOTE: federal question actions take precedence over diversity cases.**)

III. **Residence (citizenship) of Principal Parties.** This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.

IV. **Nature of Suit.** Place an "X" in the appropriate box. If there are multiple nature of suit codes associated with the case, pick the nature of suit code that is most applicable. Click here for: Nature of Suit Code Descriptions.

V. **Origin.** Place an "X" in one of the seven boxes.
Original Proceedings. (1) Cases which originate in the United States district courts.
Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441.
Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.
Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.
Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.
Multidistrict Litigation – Transfer. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407.
Multidistrict Litigation – Direct File. (8) Check this box when a multidistrict case is filed in the same district as the Master MDL docket. **PLEASE NOTE THAT THERE IS NOT AN ORIGIN CODE 7.** Origin Code 7 was used for historical records and is no longer relevant due to changes in statue.

VI. **Cause of Action.** Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity.** Example: U.S. Civil Statute: 47 USC 553 Brief Description: Unauthorized reception of cable service

VII. **Requested in Complaint.** Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.
Demand. In this space enter the actual dollar amount being demanded or indicate other demand, such as a preliminary injunction.
Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.

VIII. **Related Cases.** This section of the JS 44 is used to reference related pending cases, if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.

Date and Attorney Signature. Date and sign the civil cover sheet.

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

Western District of Washington

HEIDI McKENNA and ANDREW McKENNA, wife and husband

Plaintiff(s)

v.

BOSTON SCIENTIFIC CORPORATION, (d/b/a MANSFIELD SCIENTIFIC, INC. & MICROVASIVE, INC.)

Defendant(s)

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* BOSTON SCIENTIFIC CORPORATION
C/O CORPORATION SERVICE COMPANY
300 DESCHUTES WAY SW, SUITE 304
TUMWATER, WA 98501

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

GLENN S. DRAPER, WSBA #24419
JUSTIN OLSON, WSBA #51332
BERGMAN DRAPER OSLUND, PLLC
821 2ND AVENUE, SUITE 2100
SEATTLE, WA 98104

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: 06/12/2019

Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____ was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc: