IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

In re Boston Scientific Corp. Pelvic Repair System Products Liability Litigation **MDL No. 2326**

MASTER LONG FORM COMPLAINT AND JURY DEMAND

Plaintiffs, by and through their counsel, bring this Master Long Form Complaint (Master Complaint) as an administrative device to set forth potential claims individual Plaintiffs may assert against Defendants in this litigation. By operation of the Order of this Court, all allegations pled herein are deemed pled in any Short Form Complaint hereafter filed.

PARTIES, JURISDICTION & VENUE

PLAINTIFFS

1.

Plaintiffs include women who had one or more of Defendants' Pelvic Mesh Products (the "Products") listed in Paragraph 7 of this Master Complaint inserted in their bodies to treat medical conditions, primarily pelvic organ prolapse (POP) and stress urinary incontinence (SUI), or other products as identified in Paragraphs 8 and 9 of the Short Form Complaint. Plaintiffs also include the spouses of some of said women, as well as others with standing to file claims arising from the Products.

DEFENDANTS

2.

Defendant(s) is/are the following or more entities as identified in the Short Form Complaint:

a) Boston Scientific Corporation (Boston Scientific);

b) American Medical Systems, Inc.;

c) Johnson & Johnson;

d) Ethicon, Inc.;

e) C. R. Bard, Inc. (Bard);

f) Sofradim Production SAS (Sofradim); and/or

g) Tissue Science Laboratories, Ltd. (TSL).

To the extent Plaintiffs have asserted claims against one of the above-named Defendant(s) in b. through g., Plaintiffs hereby incorporate by reference as if fully set forth herein the Master Long Form Complaint of that Defendant's respective MDL.

3.

Boston Scientific is a Delaware corporation with its corporate headquarters in Massachusetts. All acts and omissions of Boston Scientific 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.

JURISDICTION AND VENUE

4.

Federal subject matter jurisdiction in the constituent actions is based upon 28 U.S.C. § 1332(a), in that in each of the constituent actions there is complete diversity among Plaintiffs and Defendant(s) and the amount in controversy exceeds $75,000.

5.

Defendant(s) have significant contacts with the federal judicial district identified in the Short Form Complaint such that they are subject to the personal jurisdiction of the court in said district.

6.

A substantial part of the events and omissions giving rise to Plaintiffs' causes of action occurred in the federal judicial district identified in the Short Form Complaint. Pursuant to 28 U.S.C. § 1391(a), venue is proper in said district.

THE PELVIC MESH PRODUCTS

7.

Defendant Boston Scientific's Pelvic Mesh Products (the "Products") include, at least, the following:

a) The Uphold Vaginal Support System;

b) The Pinnacle Pelvic Floor Repair Kit;

c) The Advantage Transvaginal Mid-Urethral Sling System;

d) The Advantage Fit System;

e) The Lynx Suprapubic Mid-Urethral Sling System;

f) The Obtryx Transobturator Mid-Urethral Sling System;

g) The Prefyx PPS System; and

h) The Solyx SIS System.

8.

Boston Scientific designed, manufactured, packaged, labeled, marketed, sold, and distributed the following Pelvic Mesh Products, including that which was implanted in any Plaintiff so indicated in a Short Form Complaint: Pinnacle Pelvic Floor Repair Kit, Uphold Vaginal Support System, 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, and/or Other.

FACTUAL BACKGROUND

9.

Defendants' Pelvic Mesh Products contain monofilament polypropylene mesh and/or collagen. Despite claims that polypropylene is inert, the scientific evidence shows that this material as implanted in the relevant female Plaintiff set forth in the Short Form Complaint is biologically incompatible with human tissue and promotes a negative immune response in a large subset of the population implanted with the Products. This negative response promotes inflammation of the pelvic tissue and can contribute to the formation of severe adverse reactions to the mesh. Furthermore, Defendants' collagen products cause hyper-inflammatory responses leading to problems including chronic pain and fibrotic reaction. Defendants' collagen products disintegrate after implantation in the female pelvis. The collagen products cause adverse tissue reactions, and are causally related to infection, as the collagen is a foreign material derived from animal and/or human tissue. The collagen is harsh upon the female pelvic tissue. When mesh is

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.

10.

Surgical mesh products have been used to repair abdominal hernias since the 1950s. In the 1970s, gynecologists began using surgical mesh products that were designed for hernia repair for abdominal repair to surgically repair prolapsed organs. In the 1990s, gynecologists began using this surgical mesh for the surgical treatment of POP and SUI. Manufacturers, including Boston Scientific, began to modify the mesh used in hernia repair to be used as products specifically intended to correct POP and/or SUI. Today, Boston Scientific sells pelvic mesh "kits" which can include not only the surgical mesh, but also tissue fixation anchors and insertion tools. The Products manufactured by Defendants are considered Class II medical devices.

11.

Defendants sought and obtained FDA clearance to market the Products 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 required, and no formal review for safety or efficacy was ever conducted by Boston Scientific with regard to the Products.

12.

On July 13, 2011, the FDA issued a Safety Communication wherein the FDA stated that "serious complications associated with surgical mesh for transvaginal repair of POP are **not rare**" (emphasis in the original).

13.

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).

14.

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.

15.

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."

16.

The injuries of the female Plaintiff, as will be more fully established in Discovery, are reported in the FDA Safety Communication and in the ACOG/AUGS Joint Committee Opinion.

17.

The FDA Safety Communication further indicated that the benefits of using transvaginal 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 risk."

18.

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."

19.

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).

20.

The FDA 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."

21.

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 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."

22.

As is known to the Defendants, the risks associated with POP repair are the same as 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.

23.

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 mesh "indicates 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 SUI."

24.

Defendants did not, and have not, adequately studied the extent of the risks associated with the Products. In January 2012, the FDA recognized the risk to women and mandated additional studies to further investigate these risks.

25.

Defendant(s) knew or should have known about the Products' risks and complications identified in the FDA Safety Communication and the ACOG/AUGS Joint Committee Opinion.

26.

Defendants knew or should have known that the 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.

27.

The scientific evidence shows that the material from which the Products are made is biologically incompatible with human tissue and promotes a negative immune response in a large subset of the population implanted with the Products, including the female Plaintiff named in the Short Form Complaint.

28.

This negative response promotes inflammation of the pelvic tissue and contributes to the formation of severe adverse reactions to the mesh, such as those experienced by the female Plaintiff named in the Short Form Complaint.

29.

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." The Products were unreasonably susceptible to degradation and fragmentation inside the body.

30.

The Products were unreasonably susceptible to shrinkage and contraction inside the body. Defendants should have known of this serious risk and warned physicians and patients.

31.

The Products were unreasonably susceptible to "creep" or the gradual elongation and deformation when subject to prolonged tension inside the body.

32.

To this day, the Products 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 compared to available feasible alternative treatments of pelvic organ prolapse and stress urinary incontinence, and other competing products.

33.

A woman who elects to have her SUI or POP surgically treated has several options. SUI can be corrected through traditional abdominal surgery using sutures to attach the urethra to a ligament in the pelvis (known as the "Burch procedure"). SUI can also be surgically addressed using synthetic materials placed under the urethra to provide support. POP can be corrected through abdominal or transvaginal surgery and using biologic, composite, or synthetic materials.

34.

Defendants 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 Defendants 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 female Plaintiff named in the Short Form Complaint, 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.

35.

Contrary to Defendants' 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 female Plaintiff named in the Short Form Complaint, making them defective under the law.

36.

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

a) The use of polypropylene and collagen in the Products and the immune reactions that result 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 can 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 that can injure major nerve routes in the pelvic region;

e) The propensity of the Products for "creep," 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 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 Products for degradation or fragmentation over time, which causes a chronic inflammatory and fibrotic reaction, and results in continuing injury over time;

h) The hyper-inflammatory responses to collagen leading to problems including chronic pain and fibrotic reaction;

i) The propensity of the collagen products to disintegrate after implantation in the female pelvis, causing pain and other adverse reactions;

j) The adverse tissue reactions caused by the products, which are causally related to infection, as the mesh is a foreign organic material from animals and/or human cadavers;

k) The harshness of collagen upon the female pelvic tissue, and the hardening of the product in the body; and

l) 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.

37.

The Products are also defective due to Defendants' failure to adequately warn or instruct the female Plaintiff named in the Short Form Complaint 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 degradation, fragmentation and/or creep;

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 recurrent, intractable pelvic pain and other pain resulting from the Products;

i) The need for corrective or revision surgery to adjust or remove the Products;

j) The severity of complications that could arise as a result of implantation of the Products;

k) The hazards associated with the Products;

l) The Products' defects described herein;

m) Treatment of pelvic organ prolapse and stress urinary incontinence with the Products is no more effective than feasible available alternatives;

n) Treatment of pelvic organ prolapse and stress urinary incontinence with the Products exposes patients to greater risk than feasible available alternatives;

o) Treatment of pelvic organ prolapse and stress urinary incontinence with the Products makes future surgical repair more difficult than feasible available alternatives;

p) Use of the Products puts the patient at greater risk of requiring additional surgery than feasible available alternatives;

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

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

38.

Defendants under reported and continues to underreport information about the propensity of the Products to fail and cause injury and complications, and have made unfounded representations regarding the efficacy and safety of the Products through various means and media.

39.

Defendants failed to perform proper and adequate testing and research in order to determine and evaluate the nature, magnitude and frequency of the risks attendant to the Products.

40.

Defendant(s) 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.

41.

Feasible and suitable 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.

42.

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

43.

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

44.

The Products implanted in the female Plaintiff named in the Short Form Complaint were in the same or substantially similar condition as they were when they left Defendants' possession, and in the condition directed by and expected by Defendants.

45.

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, and chronic pelvic pain.

46.

In many cases, including the female Plaintiff named in the Short Form Complaint, 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.

47.

The medical and scientific literature studying the effects of the Products, like that of the product(s) implanted in the relevant female Plaintiff named in the Short Form Complaint, has examined each of these injuries, conditions, and complications, and has reported that they are causally related to the Products.

48.

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

49.

At all relevant times herein, Defendants 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.

50.

In doing so, Defendants 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.

51.

At all relevant times herein, Defendants failed to provide sufficient warnings and instructions that would have put the female Plaintiff named in the Short Form Complaint and the general public on notice of the dangers and adverse effects caused by implantation of the Products.

52.

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

53.

As a result of having the Products implanted in her, the female Plaintiff named in the Short Form Complaint 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.

CAUSES OF ACTION

COUNT I: NEGLIGENCE

54.

All previous paragraphs of this Master Complaint are hereby incorporated by reference as if fully set forth herein.

55.

Defendants had a duty to individuals, including the female Plaintiff named in the Short Form Complaint, to use reasonable care in designing, manufacturing, marketing, labeling, packaging and selling the Products.

56.

Defendants were negligent in failing to use reasonable care as described herein in designing, manufacturing, marketing, labeling, packaging and selling the Products. Defendant(s) breached their aforementioned duty by, among other things:

a) Failing to design the Products so as to avoid an unreasonable risk of harm to women in whom the Products were implanted, including the female Plaintiff named in the Short Form Complaint;

b) Failing to manufacture the Products so as to avoid an unreasonable risk of harm to women in whom the Products were implanted, including the female Plaintiff named in the Short Form Complaint;

c) Failing to use reasonable care in the testing of the Products so as to avoid an unreasonable risk of harm to women in whom the Products were implanted, including the female Plaintiff named in the Short Form Complaint;

d) Failing to use reasonable care in inspecting the Products so as to avoid an unreasonable risk of harm to women in whom the Products were implanted, including the female Plaintiff named in the Short Form Complaint;

e) Failing to use reasonable care in the training and instruction to physicians for the safe use of the Products;

f) Failing to use reasonable care in studying the Products to evaluate their safety and to determine the nature, magnitude, and frequency of serious, life threatening complications that were known or knowable; and

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

57.

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

a) The use of polypropylene and/or collagen 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 "creep," 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 for degradation or fragmentation over time, which causes a chronic inflammatory and fibrotic reaction, and results in continuing injury over time;

h) The hyper-inflammatory responses to collagen leading to problems including chronic pain and fibrotic reaction;

i) The propensity of the collagen products to disintegrate after implantation in the female pelvis, causing pain and other adverse reactions;

j) The adverse tissue reactions caused by the collagen products, which are causally related to infection, as the collagen is a foreign organic material from animals;

k) The harshness of collagen upon the female pelvic tissue; and

l) 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.

58.

Defendants also negligently failed to warn or instruct the female Plaintiff named in the Short Form Complaint 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 degradation, fragmentation and/or creep;

c) The Products' 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 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 recurrent, intractable pelvic pain and other pain resulting from the Products;

i) The need for corrective or revision surgery to adjust or remove the Products;

j) The severity of complications that could arise as a result of implantation of the Products;

k) The hazards associated with the Products;

l) The Products' defects described herein;

m) Treatment of pelvic organ prolapse and stress urinary incontinence with the Products is no more effective than feasible available alternatives;

n) Treatment of pelvic organ prolapse and stress urinary incontinence with the Products exposes patients to greater risk than feasible available alternatives;

o) Treatment of pelvic organ prolapse and stress urinary incontinence with the Products makes future surgical repair more difficult than feasible available alternatives;

p) Use of the Products puts the patient at greater risk of requiring additional surgery than feasible available alternatives;

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

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

59.

As a direct and proximate result of Defendants' negligence, the female Plaintiff named in the Short Form Complaint 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.

COUNT II: STRICT LIABILITY – DESIGN DEFECT

60.

All previous paragraphs of this Master Complaint are hereby incorporated by reference as if fully set forth herein.

61.

The Products implanted in the female Plaintiff named in the Short Form Complaint were not reasonably safe for their intended uses and were defective as described herein with respect to their design. As previously stated, the Products' design defects include, but are not limited to:

a) The use of polypropylene and/or collagen 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 "creep," 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 for degradation or fragmentation over time, which causes a chronic inflammatory and fibrotic reaction, and results in continuing injury over time;

h) The hyper-inflammatory responses to collagen leading to problems including chronic pain and fibrotic reaction;

i) The propensity of the collagen products to disintegrate after implantation in the female pelvis, causing pain and other adverse reactions;

j) The adverse tissue reactions caused by the collagen products, which are causally related to infection, as the collagen is a foreign organic material from animals and/or human cadavers;

k) The harshness of collagen upon the female pelvic tissue, and the hardening of the product in the body;

l) 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, and

m) The use of polypropylene material in the products and the failure to provide adequate directions for use (DFU) and training.

62.

As a direct and proximate result of the Products' aforementioned defects as described herein, the female Plaintiff named in the Short Form Complaint 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 damages.

63.

Defendants are strictly liable to the female Plaintiff named in the Short Form Complaint for designing, manufacturing, marketing, labeling, packaging and selling a defective product(s).

COUNT III: STRICT LIABILITY – MANUFACTURING DEFECT

64.

All previous paragraphs of this Master Complaint are hereby incorporated by reference as if fully set forth herein.

65.

The Products implanted in the female Plaintiff named in the Short Form Complaint 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 Defendants' design and manufacturing specifications in such a manner as to pose unreasonable risks of serious bodily harm to the female Plaintiff named in the Short Form Complaint.

66.

As a direct and proximate result of the Products' aforementioned defects as described herein, the female Plaintiff named in the Short Form Complaint has 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.

67.

Defendants are strictly liable to the female Plaintiff named in the Short Form Complaint for designing, manufacturing, marketing, labeling, packaging and selling defective products.

COUNT IV: STRICT LIABILITY – FAILURE TO WARN

68.

All previous paragraphs of this Master Complaint are hereby incorporated by reference as if fully set forth herein.

69.

The Products implanted in the female Plaintiff named in the Short Form Complaint 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, Defendants did not provide sufficient or adequate warnings regarding, among other subjects:

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

b) The Products' propensities for degradation, fragmentation, disintegration and/or creep;

c) The Products' 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 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 recurrent, intractable pelvic pain and other pain resulting from the Products;

i) The need for corrective or revision surgery to adjust or remove the Products;

j) The severity of complications that could arise as a result of implantation of the Products;

k) The hazards associated with the Products;

l) The Products' defects described herein;

m) Treatment of pelvic organ prolapse and stress urinary incontinence with the Products is no more effective than feasible available alternatives;

n) Treatment of pelvic organ prolapse and stress urinary incontinence with the Products exposes patients to greater risk than feasible available alternatives;

o) Treatment of pelvic organ prolapse and stress urinary incontinence with the Products makes future surgical repair more difficult than feasible available alternatives;

p) Use of the Products puts the patient at greater risk of requiring additional surgery than feasible available alternatives;

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

r) Complete removal of the Products may not be possible and may not result in complete resolution of the complications, including pain; and

s) The nature, magnitude and frequency of complications that could arise as a result of implantation of the Products.

70.

As a direct and proximate result of the Products' aforementioned defects as described herein, the female Plaintiff named in the Short Form Complaint 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.

71.

Defendants are strictly liable to the female Plaintiff named in the Short Form Complaint for designing, manufacturing, marketing, labeling, packaging and selling a defective product(s).

COUNT V: BREACH OF EXPRESS WARRANTY

72.

All previous paragraphs of this Master Complaint are hereby incorporated by reference as if fully set forth herein.

73.

Defendants made assurances as described herein to the general public, hospitals and health care professionals that the Products were safe and reasonably fit for their intended purposes.

74.

The female Plaintiff named in the Short Form Complaint and/or her healthcare provider chose the Products based upon Defendants' warranties and representations as described herein regarding the safety and fitness of the Products.

75.

The female Plaintiff named in the Short Form Complaint, individually and/or by and through her physician, reasonably relied upon Defendants' express warranties and guarantees that the Products were safe, merchantable, and reasonably fit for their intended purposes.

76.

Defendants breached these express warranties because the Products implanted in the female Plaintiff named in the Short Form Complaint were unreasonably dangerous and defective as described herein and not as Defendant(s) had represented.

77.

Defendants' breach of their express warranties resulted in the implantation of an unreasonably dangerous and defective products in the body of the female Plaintiff named in the Short Form Complaint, placing said Plaintiff's health and safety in jeopardy.

78.

As a direct and proximate result of Defendants' breach of the aforementioned express warranties, the female Plaintiff named in the Short Form Complaint 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.

COUNT VI: BREACH OF IMPLIED WARRANTY

79.

All previous paragraphs of this Master Complaint are hereby incorporated by reference as if fully set forth herein.

80.

Defendants impliedly warranted that the Products were merchantable and were fit for the ordinary purposes for which they were intended.

81.

When the Products were implanted in the female Plaintiff named in the Short Form Complaint to treat her pelvic organ prolapse and/or stress urinary incontinence, the Products were being used for the ordinary purposes for which they were intended.

82.

The female Plaintiff named in the Short Form Complaint, individually and/or by and through her physician, relied upon Defendants' implied warranties of merchantability in consenting to have the Products implanted in her.

83.

Defendants breached these implied warranties of merchantability because the Products implanted in the female Plaintiff named in the Short Form Complaint were neither merchantable nor suited for their intended uses as warranted.

84.

Defendants' breach of their implied warranties resulted in the implantation of unreasonably dangerous and defective products in the body of the female Plaintiff named in the Short Form Complaint, placing said Plaintiff's health and safety in jeopardy.

85.

As a direct and proximate result of Defendants' breach of the aforementioned implied warranties, the female Plaintiff named in the Short Form Complaint 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.

COUNT VII: LOSS OF CONSORTIUM

86.

All previous paragraphs of this Master Complaint are hereby incorporated by reference as if fully set forth herein.

87.

As a direct and proximate result of the above-described injuries sustained by the female Plaintiff named in the Short Form Complaint, where applicable, her spouse named in the Short Form Complaint has suffered a loss of consortium, companionship, society, affection, services and support.

COUNT VIII: DISCOVERY RULE, TOLLING AND FRAUDULENT CONCEALMENT

88.

All previous paragraphs of this Master Complaint are hereby incorporated by reference as if fully set forth herein.

89.

Plaintiffs assert all applicable state statutory and common law rights and theories related to the tolling or extension of any applicable statute of limitations, including equitable tolling, class action tolling, delayed discovery, discovery rule, and fraudulent concealment.

90.

Plaintiffs plead that the discovery rule should be applied to toll the running of the statute of limitations until Plaintiffs knew, or through the exercise of reasonable care and diligence should have known, of facts indicating that Plaintiffs had been injured, the cause of the injury, and the tortious nature of the wrongdoing that caused the injury.

91.

Despite diligent investigation by Plaintiffs, including the female Plaintiff named in Plaintiff's Short-Form Complaint, into the cause of their injuries, including consultations with Plaintiffs' medical providers, the nature of Plaintiffs' injuries and damages, and their relationship to the Products was not discovered, and through reasonable care and due diligence could not have been discovered, until a date within the applicable statute of limitations for filing Plaintiffs' claims. Therefore, under appropriate application of the discovery rule, Plaintiffs' suit was filed well within the applicable statutory limitations period.

92.

The running of the statute of limitations in this cause is tolled due to equitable tolling. Defendants are estopped from asserting a statute of limitations defense due to Defendants' fraudulent concealment, through affirmative misrepresentations and omissions, from Plaintiffs and Plaintiffs' physicians of the true risks associated with the Products. As a result of Defendants' fraudulent concealment, Plaintiffs and Plaintiffs' physicians were unaware, and could not have known or have learned through reasonable diligence that Plaintiffs had been exposed to the risks alleged herein and that those risks were the direct and proximate result of the wrongful acts and omissions of the Defendants.

COUNT IX: PUNITIVE DAMAGES

93.

All previous paragraphs of this Master Complaint are hereby incorporated by reference as if fully set forth herein.

94.

Defendants sold their Products to the healthcare providers of the Plaintiff named in the Short Form Complaint and other healthcare providers in the state of implantation and throughout the United States without doing adequate testing to ensure that the Products were reasonably safe for implantation in the female pelvic area.

95.

Defendants sold the Products to Plaintiffs', including the female Plaintiff named in the Short Form Complaint, 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 Products 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 the Plaintiff named in the Short Form Complaint and numerous other women.

96.

Defendants ignored reports from patients and health care providers throughout the United States and elsewhere of the Products' failures to perform as intended, which lead to the severe and debilitating injuries suffered by the Plaintiff named in the Short Form Complaint and numerous other women. Rather than doing adequate testing to determine the cause of these injuries, or to rule out the Products' designs or the processes by which the Products are manufactured as the cause of these injuries, Defendant(s) chose instead to continue to market and sell the Products as safe and effective.

97.

Defendants knew the Products were unreasonably dangerous in light of their risks of failure, 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 Products, as well as other severe and personal injuries which were permanent and lasting in nature.

98.

Defendants withheld material information from the medical community and the public in general, including the female Plaintiff named in the Short Form Complaint, regarding the safety and efficacy of the Products.

99.

Defendants knew and recklessly disregarded the fact that the Products 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.

100.

Defendants misstated and misrepresented data and continue to misrepresent data so as to minimize the perceived risk of injuries caused by the Products.

101.

Notwithstanding the foregoing, Defendants continue to aggressively market the Products to consumers, without disclosing the true risks associated with the Products.

102.

Defendants knew of the Products' defective and unreasonably dangerous nature, but continued to mislead physicians and patients and to manufacture, market, distribute, and sell the Products so as to maximize sales and profits at the expense of the health and safety of the public, including the female Plaintiff named in the Short Form Complaint.

103.

Defendants continue to conceal and/or fail to disclose to the public, including the Plaintiff named in the Short Form Complaint, the serious complications associated with the use of the Products to ensure continued and increased sales of the Products.

104.

Defendants' 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.

WHEREFORE, the Plaintiffs demand judgment against Defendants, and each of them, individually, jointly and severally, and request compensatory damages, together with interest, cost of suit, attorneys' fees, and all such other relief as the Court deems just and proper as well as:

- Compensatory damages to Plaintiffs for past, present, and future damages, including but not limited to, pain and suffering for severe and permanent personal injuries sustained by Plaintiffs, emotional distress, mental anguish, physical disfigurement and impairment; health and medical care costs, together with pre- and post-judgment interest and costs as provided by law;
- Restitution and disgorgement of profits;
- Reasonable attorneys' fees;
- The costs of these proceedings;
- All ascertainable economic damages;
- Punitive damages;
- Survival damages (if applicable);
- Wrongful death damages (if applicable); and
- Such other and further relief as this Court deems just and proper.

PLAINTIFFS DEMAND A TRIAL BY JURY.

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