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

CHARLESTON DIVISION

IN RE: COLOPLAST CORP.
PELVIC SUPPORT SYSTEM PRODUCTS LIABILITY LITIGATION

MDL No. 2387

THIS DOCUMENT RELATES TO ALL CASES

PRETRIAL ORDER # 15
(Amended Master Complaint; Revised Short Form and Amended Short Form Complaints re: removal of ABISS)

On December 13, 2012, I entered PTO # 10 (Direct Filing Order; Master Complaint, Short Form Complaint, Amended Short Form Complaint and Master Responsive Pleadings Due Date). [ECF 33.] On December 21, 2012, I entered PTO # 13 correcting PTO # 10 because the Short Form and Amended Short Form Complaints attached to the PTO did not include Ethicon, Inc. and Ethicon, LLC. [ECF 41.]

On January 3, 2013, the plaintiffs filed a Motion to Amend Master Complaint, Short Form Complaint, and Amended Short Form Complaint. [ECF 42.] In the motion, the plaintiffs seek to amend the Master Complaint and Short Form and Amended Short Form Complaints to dismiss

> Analytic Biosurgical Systems ("ABISS") as a defendant and to discontinue any actions as to ABISS at this time. Specifically, Plaintiffs seek leave to strike paragraph 4 of the Master Complaint setting forth allegations naming ABISS as a Defendant in this MDL proceeding. Plaintiffs further seek leave to add to the fourth sentence in paragraph 36 of the Master Complaint a reference to ABISS's full legal name, Analytic Biosurgical Solutions. Plaintiffs also request leave to delete the second sentence of paragraph 39 of the Master Complaint, which references a patent application. Additionally, Plaintiffs request that the Court

> remove ABISS as a defendant in paragraph 6.A. on the Short Form and Amended Short Form Complaints.

[ECF 42, p. 1.] Plaintiffs represent that counsel for the Coloplast entities and Mentor Worldwide LLC have agreed to the filing of the First Amended Master Complaint. Plaintiffs' counsel "understands that ABISS did not assent to be included in the Master Complaint in this MDL; therefore, ABISS presumably has no opposition to being removed as a named defendant in the proposed First Amended Master Complaint." [ECF 42, pp. 1-2.]

I find that the naming of ABISS as a defendant in the Master Complaint and on the Short Form and Amended Short Form Complaints in this MDL, and consequently, on the Short Form and Amended Short Form Complaints in the other MDLs assigned to me was, at a minimum, premature, and, clearly without the consent of ABISS, despite representations otherwise. While ABISS has been removed from the First Amended Master Long Form Complaint and Jury Demand and the Short Form and Amended Short Form Complaints in this and the other MDLs assigned to me, thereby preventing a party from naming ABISS directly in the Southern District of West Virginia, this does not prevent a plaintiff from naming ABISS in the appropriate district where an action may be brought, with subsequent transfer by the MDL Panel. To the extent the plaintiffs' motion suggests that "any actions" against ABISS should be discontinued at this time, I interpret this as any actions **filed directly in the Southern District of West Virginia by Short Form or Amended Short Form Complaint only.**

Pursuant to Rule 15 of the Federal Rules of Civil Procedure with the clarification provided in the preceding paragraph, it is **ORDERED** that the plaintiffs' motion is **GRANTED.** The court **DIRECTS** that the Clerk file the First Amended Master Long Form Complaint and Jury Demand attached hereto as Exhibit A. The court further **DIRECTS** that the Clerk post this pleading on the court's website. It is further **ORDERED** that PTO # 10 is amended to (1) add

the words "First Amended" in front of "Master" in paragraph A(1) and that "First Amended" shall precede the words "Master Complaint" throughout PTO # 10.

In addition, revised Short Form and Amended Short Form Complaints are attached hereto as Exhibits B and C, and the Clerk is **DIRECTED** to post these documents to the court's website as well. PTO # 10 otherwise remains in full force and effect, except as modified herein and by PTO # 13.

It is further ORDERED that to the extent plaintiffs have named ABISS by Short Form or Amended Short Form Complaint, they are granted leave to file an Amended Short Form Complaint dropping ABISS on or before February 8, 2013. This practice is consistent with the practice outlined by this court in the PTO related to direct filing. By filing an Amended Short Form Complaint that drops ABISS, the Clerk is permitted to terminate ABISS. In the alternative, plaintiffs may file a pleading in compliance with Rule 41 of the Federal Rules of Civil Procedure should they wish to dismiss their directly filed action naming ABISS and name ABISS and any other party in the appropriate district where the action may be brought.

The court **DIRECTS** the Clerk to file a copy of this order in 2:12-md-2387 and it shall apply to each member related case previously transferred to, removed to, or filed in this district, which includes counsel in all member cases up to and including civil action number 2:13-cv-00134. In cases subsequently filed in this district, a copy of the most recent pretrial order will be provided by the Clerk to counsel appearing in each new action at the time of filing of the complaint. In cases subsequently removed or transferred to this court, a copy of the most recent pretrial order will be provided by the Clerk to counsel appearing in each new action upon removal or transfer. It shall be the responsibility of the parties to review and abide by all pretrial

orders previously entered by the court. The orders may be accessed through the CM/ECF system or the court's website at www.wvsd.uscourts.gov.

ENTER: January 8, 2013

JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE

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

COLOPLAST CORP. PELVIC SUPPORT SYSTEMS PRODUCT LIABILITY LITIGATION

CHARLESTON DIVISION

MDL No. 2387
In Re: Coloplast Corp.,
Pelvic Support System Products Liability Litigation

FIRST AMENDED MASTER LONG FORM COMPLAINT AND JURY DEMAND

Plaintiffs, by and through their counsel, bring this First Amended Master Long Form 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 previously-filed Complaint and in any Short Form Complaint hereafter filed.

I. PARTIES

A. Plaintiffs

1. Plaintiffs include women who had one or more of Defendants' Pelvic Mesh Devices (defined below) inserted in their bodies to treat medical conditions, primarily pelvic organ prolapse and stress urinary incontinence.

2. Plaintiffs also include the spouses, as well as others with standing to file claims arising from Defendants' Products.

B. Defendants

3. Defendant Coloplast Corp. ("Coloplast Corp.") is a corporation organized and existing under the laws of the State of Delaware, maintaining its principal place of business at 1601 West River Road North, Minneapolis, Minnesota 55411. Coloplast Corp. is a wholly-

owned U.S. sales and marketing subsidiary of Coloplast A/S, a Denmark corporation.

4. Defendant Mentor Worldwide LLC ("Mentor Worldwide") is, a limited liability corporation, incorporated in Delaware with an address of 1209 Orange Street, Wilmington, DE 19801, with a principal place of business at 5425 Hollister Avenue, Santa Barbara, CA 93111. The citizenship of a limited liability company (LLC) is determined by the citizenship of each of its members for purposes of diversity. *See, e.g., Zambelli Fireworks Mfg. Co., Inc. v. Wood*, 592 F.3d 412 (3d Cir. 2010). Mentor Worldwide's sole member is Ethicon, Inc. Ethicon, Inc. is a wholly owned subsidiary of Johnson & Johnson located in Somerville, New Jersey.

5. Defendant Coloplast A/S is a corporation organized and existing under the laws of the Kingdom of Denmark maintaining its principal place of business at Holtedam 1, Humlebaek 3050, Kingdom of Denmark.

6. Defendant Coloplast Manufacturing US, LLC is a limited liability corporation organized and existing under Delaware, law maintaining its principal place of business as 1940 Commerce Drive, North Mankato, MN 56002. Its registered office is 560 Park Street, #6, St. Paul, Minnesota 55103. Coloplast Manufacturing US, LLC is a wholly-owned subsidiary of Coloplast Corp.

7. Defendant Porges S.A. ("Porges") is a corporation organized and existing under the laws of the France maintaining its principal place of business at Centre d'affaires La Boursidière 92357 Le Plessis-Robinson cdx., France. Porges is a wholly owned subsidiary of Coloplast A/S.

8. Coloplast Corp., Coloplast A/S, Coloplast Manufacturing US, LLC, and Porges are collectively referred to herein as "Coloplast."

9. Boston Scientific Corporation ("Boston Scientific");

10. American Medical Systems, Inc. (“AMS”);

11. Johnson & Johnson;

12. Ethicon, Inc.;

13. C.R. Bard, Inc. (“Bard”);

14. Sofradim Production SAS (“Sofradim”);

15. Tissue Science Laboratories (“TSL”); and / or

16. Defendants, JOHN DOES 1-20 (fictitious names) are entities and/or persons who are liable to Plaintiffs, but who have not yet been identified despite reasonable due diligence on the part of Plaintiffs.

17. To the extent Plaintiffs have asserted claims against one of the named Defendant(s) in Paragraph 5 and Paragraphs 10 through 16, Plaintiffs hereby incorporate by reference as if fully set forth herein the Master Long Form Complaint of that Defendant’s respective MDL.

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

II. JURISDICTION AND VENUE

19. 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 Defendants and the amount in controversy exceeds $75,000.00.

20. Venue and personal jurisdiction in a particular forum are alleged in each individual Short Form Complaint, and venue and personal jurisdiction are generally asserted herein. Defendants 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.

21. 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.

III. Defendants' Pelvic Mesh Products

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

23. The products include those known as T-Sling-Universal Polypropylene Sling, Aris-Transobturator Sling System, Supris-Suprapubic Sling System**,** Novasilk-Synthetic Flat Mesh, Exair-Prolapse Repair System, Restorelle, Smartmesh, Omnisure, and Minitape as well as any variations of these products and any unnamed Coloplast pelvic mesh product designed and sold for similar purposes, inclusive of the instruments and procedures for implementation. In addition, Coloplast manufactures, distributes, and sells products made of biologic materials known as Suspend-Tutoplast Processed Fascia Lata and Axis-Tutoplast Processed Dermis as well as any variations of these products and any unnamed Coloplast Pelvic Mesh Product designed and sold for similar purposes, inclusive of the instruments and procedures for

implementation

24. These products are collectively referenced as Defendants' "Pelvic Mesh Products" or "Products."

IV. Factual Background

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

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

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

28. Stress urinary incontinence is a type of incontinence characterized by leakage of urine during moments of physical stress.

29. Surgical mesh, including mesh used in Pelvic Mesh Products, is a medical device that is generally used to repair weakened or damaged tissue. It is made from porous absorbable or non-absorbable synthetic material or absorbable biologic material. In urogynecologic procedures, surgical mesh is permanently implanted to reinforce the weakened vaginal wall to repair pelvic organ prolapse or to support the urethra to treat urinary incontinence. Most Pelvic

Mesh Products are comprised of non-absorbable, synthetic, monofilament polypropylene mesh and / or collagen.

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

31. Furthermore, Defendants' Pelvic Mesh Products containing collagen cause hyper-inflammatory responses leading to problems including chronic pain and fibrotic reaction. Defendants' collagen-containing Products disintegrate after implantation into the female pelvis. The collagen-containing Products cause adverse tissue reactions, and are causally related to infection, as the collagen is a foreign organic material. Cross linked collagen is harsh upon the female pelvic tissues. It hardens the body.

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

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

34. On February 8, 2001, Mentor announced the purchase of Porges S.A., a subsidiary of Sanofi-Synthelabo. At the time, Porges held the leading market share for urological products in France and held a strong position throughout Europe was one of the largest manufacturers of urological products, supplying a complete range of products including pelvic mesh products.

35. In May 2005, Mentor announced the U.S. launch of its new Aris$^{(TM)}$ Trans-Obturator Tape. According to Mentor's launch reports, "specifically designed to utilize Mentor's patented Trans-Obturator Technique (T.O.T.$^{(TM)}$), Aris represents the newest technical achievement and advanced generation of trans-obturator slings for the treatment of stress urinary incontinence in women." "The introduction of Aris furthers Mentor's position as a pioneer of the trans-obturator method for treating stress incontinence in women," commented Joshua H. Levine, President and Chief Executive Officer of Mentor Corporation. "We are committed to driving innovation in the field of women's health to provide better solutions for physicians and the patients they serve." Analytic Biosurgical Solutions ("ABISS") FDA registration lists its proprietary device as "Mentor Aris Trans-Obturator Tape and Surgical Kit."

36. On October 12, 2005, ABISS and Mentor entered into a number of agreements

pursuant to which ABISS licensed a number of ABISS' products to Mentor, which were thereafter marketed by Mentor under its trademarks, including its Aris trademark. On June 2, 2006, Mentor sold its surgical, urological, clinical and consumer healthcare business segments to Coloplast for $461,145,398, including *inter alia*, Mentor's October 12, 2005 agreements with ABISS and Mentor's Aris and Novasilk Pelvic Mesh Products.

37. At all times, the product marketed and sold in the United States as "Mentor Aris Trans-Obturator Tape and Surgical Kit" was manufactured by ABISS and, at all times after October 2, 2006, the product "Mentor Aris Trans-Obturator Tape and Surgical Kit" was exclusively marketed and sold in the United States by Coloplast Corp. from its principal place of business in Minneapolis, Minnesota.

38. ABISS is registered with the FDA, Registration Number 3004756681, as the manufacturer of "Mentor Aris Trans-Obturator Tape and Surgical Kit."

39. On December 5, 2005, Mentor obtained 510(k) clearance for Mentor NovaSilk Mesh. Mentor NovaSilk Mesh is a permanent, synthetic knitted propylene mesh that is square in shape and is a sterile, single use device. The Mentor NovaSilk Mesh obtained 510(k) clearance based on substantial equivalence in material, function, performance, and design to the Gynemesh Prolene Soft (Polypropylene) Mesh cleared under 510(k) K013718 and knitted polypropylene already in use under Mentor's Aris Sling cleared under 510(k) K050148. Joshua H. Levine, President and Chief Executive Officer of Mentor Corporation commented, "The addition of NovaSilk to Mentor's expanding portfolio of women's health products for pelvic organ prolapse or stress urinary incontinence reinforces the commitment of our urology franchise to surgeons and the patients they serve by providing high quality product offerings and customer service and support."

40. Coloplast Corp.'s annual report for 2009-2010 reported that "the majority of our acquired patents and trademarks are associated with the acquisition of Mentor's urology, business in 2006." The annual report also said that Mentor signed "a non-competition clause prohibiting Mentor (the seller) from selling urology products for the next seven years…."

41. Coloplast Corp. began marketing the Exair Prolapse Repair System in May 2009 to treat pelvic organ prolapse. This product is made of NovaSilk Mesh, precut into the necessary shape with four mesh arms extending from the main body, which are used to implant the device. This product obtained 510(k) clearance based on its substantial equivalence with Coloplast Corp.'s (formerly Mentor's) NovaSilk Mesh, and Gynecare Prolift Total Pelvic Floor Repair System cleared under pre-market notification number K071512 on May 15, 2008.

42. Coloplast A/S received 510(k) clearance for the Supris Retropubic Sling System 510(k) K111233 in June 2011, as a device substantially equivalent to the Mentor Aris Suprapubic Surgical Kit.

43. On October 29, 2010, Coloplast Corp. acquired Mpathy Medical Devices, Inc. ("Mpathy"). Mpathy was founded in 2003, with the aim of developing less invasive surgical solutions for the treatment of female stress urinary incontinence and pelvic organ prolapse. Mpathy's core product lines included Minitape® and Omnisure® for stress urinary incontinence, and the Restorelle® family for pelvic organ prolapse. Defendant Coloplast Corp. said of the acquisition that Coloplast Corp.'s market position in Surgical Urology and Female Pelvic Health would immediately strengthen based on Mpathy's product portfolio including slings, mini-slings and meshes for stress urinary incontinence and pelvic floor repair and material portfolio including Smartmesh® technology.

44. Coloplast Corp.'s website describes its various products, including those for

treating (i) “Pelvic Organ Prolapse” and (ii) “Stress Urinary Incontinence,” including “Sling Procedures.” A press release issued by Coloplast Corp. described Coloplast Corp.’s new corporate headquarters at 1601 West River Road in Minneapolis and stated that “Denmark-based Coloplast…selected north Minneapolis as the new home for its North American headquarters in 2006.” According to the press release the new headquarters “will include one of the company’s three global Innovation Centers.”

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

46. 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).

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

48. Contemporaneously with the Safety Communication, the FDA released a

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

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

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

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

urologic surgeon specializing in female urology at the Mayo Clinic in Rochester, Minnesota.

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

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

53. 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."

54. 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.

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

56. 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.

57. 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. At the time Defendants began marketing each of its Pelvic Mesh Products, Defendants were aware that its Pelvic Mesh Products were associated with each and every one of the adverse events communicated by the FDA in its July 13, 2011, safety communication. Despite claims that polypropylene mesh is inert, the scientific evidence shows that this material as implanted in the relevant female Plaintiff set forth in the Short Form Complaint is biologically incompatible with human tissue and when used as a woven or knitted alloplastic textile prosthetic mesh for pelvic floor repair, polypropylene and other surgical polymers promote a severe foreign body reaction and chronic inflammatory response in a large subset of the population implanted with Defendants' Pelvic Mesh Products. This "host defense response" by a woman's pelvic tissues promotes degradation of the polypropylene mesh and the pelvic tissue, causes chronic inflammation of the pelvic tissue, causes shrinkage or contraction of the mesh leading to nerve entrapment, further inflammation, chronic infectious response and chronic pain, cause new-onset painful sexual relations, significant urinary dysfunction, vaginal shortening and anatomic deformation, and can contribute to the formation of severe adverse reactions to the polypropylene mesh.

58. 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."

59. Defendants make the following statements regarding their products:

> [Aris has] Low rate of particle release from the sling-**minimizes increase in inflammatory response**. Atraumatic, smooth edges allow for easy passage during implantation. Macroporous design allows for optimal tissue integration

60. Contrary to Defendants assertions that its products minimize increase in inflammatory response:

A. In September of 2009, results from a study were published in the BMC Women's Health relating to the comparison of host response and complications in patients implanted with Coloplast's Aris. Implants from the Defendant's Aris group showed an **increase risk of erosion which was quantified at 4%.**

> Kaelin-Gambirasio I, *Complications associated with transobturator sling procedures: analysis of 233 consecutive cases with a 27 months follow-up*. BMC Womens Health. 2009 Sep 25;9:28.

B. In September of 2012, results from a study were published in the World Journal of Urology relating to the comparison of TVT vs TOT slings. 15 of 71 patients suffered adverse events including infection and erosion, **two thirds of which were implanted with Defendant's Aris.**

> Wadie BS , *TVT versus TOT, 2-year prospective randomized study*. World J Urol. 2012 Sep 26.

61. Defendants make the following statements regarding their products:

> Novasilk is one of the lightest weight, thinnest mesh's on the market, which translates into a more conforming mesh that may **reduce cases of inflammation, infection, or erosion** by having less implanted material.

62. Contrary to Defendants assertions that its products are resistant to significant inflammation, infection or erosion:

A. Complications from mesh placement for pelvic organ prolapse include among other adverse events: acute and chronic infection, tissue contraction due to mesh shrinkage, erosion of the mesh into adjacent structures, and dyspareunia.

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

B. Erosion can be defined as the mesh wearing, or slowly grinding through the vaginal wall. This is a serious complication and moreover, there is evidence that meshes shrink *in vivo* leading to increased stiffness, pain and poor restoration of the normal properties of the vagina

Dora, C.D., et al., *Time dependent variations in biomechanical properties of cadaveric fascia, porcine dermis, porcine small intestine submucosa, polypropylene mesh and autologous fascia in the rabbit model: implications for sling surgery.* J Urol, 2004. **171**(5): p. 1970-3.

C. Larger pores within polypropylene mesh materials, allowing macrophage and leukocyte migration, reduce infection.

Birch C, Fynes MM. The role of synthetic and biological prosthesis in reconstructive pelvic floor surgery. *Curr Opin Obstet Gynecol*. 2002; 14:527–595. 22. Govier FE, Kobashi KC, Kozlowski PM, Kuznetsov DD, Begley SJ, McGonigle KF, et al. High complication rate identified in sacrocolpopexy patients attributed to silicone mesh. *J Urol*. 2005;65:1099–1103.

D. In a study published in August of 2012, Defendant's Novasilk was compared to other polypropylene on the market relating structural properties. Novasilk was found to have less porosity and increased stiffness than several of the other studied products supporting clinical observations among Plaintiffs' surgeons and the causative conclusion that properties of Defendant's mesh led to Plaintiffs' complications.

Feola A, *Characterizing the ex vivo textile and structural properties of synthetic prolapse mesh products*. Int Urogynecol J. 2012 Aug 11.

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

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

65. 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.

66. 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.

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

a. The use of polypropylene in the Products and the adverse tissue reactions and host defense response that result from such material, causing adverse reactions

and serious, permanent injuries including, but not limited to, painful recurrent erosions and associated intractable pain;

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

c. Biomechanical issues with the design of the Products which result in a non-anatomic condition leading to contraction or shrinkage of the mesh inside the body, that in turn causes surrounding tissue to become eroded, inflamed, fibrotic and infected, resulting in serious and permanent injury;

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

e. The propensity of the Products to become rigid and inflexible, causing them to be improperly mated to the delicate and sensitive areas of the vagina and pelvis where they are implanted, and causing discomfort and pain with normal daily

activities that involve movement in the pelvic region (e.g., intercourse, defecation, walking);

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

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

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

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

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

68. 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 migration;

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

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

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

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

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

h. The risk of de novo urinary dysfunction;

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

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

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

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

m. The hazards associated with the Products;

n. The Products' defects described herein;

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

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

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

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

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

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

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

69. Defendants under reported and continue 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.

70. Defendants under reported and continue 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.

71. 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.

72. 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.

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

74. 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.

75. 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.

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

77. 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. The injuries, conditions, and complications suffered by numerous women around the world who have been implanted with the Products include, but are not limited to, erosion, mesh contraction, infection, fistula, inflammation, scar tissue, organ perforation, dyspareunia (pain during sexual

intercourse), urinary dysfunction, blood loss, neuropathic and other acute and chronic nerve damage and pain, pudendal nerve damage, pelvic floor damage, and chronic pelvic pain. As a result of these life-altering and, in some cases, permanent injuries, Plaintiff has suffered severe emotional pain and injury and has suffered and will suffer apprehension of increased risk for injuries, infections, pain, mental anguish, discharge, and multiple corrective surgeries as a result of implantation of Pelvic Mesh Products.

78. 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.

79. 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.

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

81. 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.

82. 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.

83. 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.

84. 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.

85. 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.

86. The injuries, conditions, and complications suffered by numerous women around the world who have been implanted with the Products include, but are not limited to, erosion, mesh contraction, infection, fistula, inflammation, scar tissue, organ perforation, dyspareunia (pain during sexual intercourse), blood loss, neuropathic and other acute and chronic nerve damage and pain, pudendal nerve damage, pelvic floor damage, chronic pelvic pain, emotional distress and mental anguish, and other debilitating complications. In addition, Plaintiffs will need to be continuously monitored as a result of being implanted with Defendants' Products. A monitoring procedure exists for individuals experiencing physical and mental injuries from mesh implanted in patients with pelvic organ prolapsed and/or stress urinary incontinence. The monitoring procedure has been prescribed by a qualified physician and is reasonably necessary

according to contemporary scientific principles. As such, Plaintiffs are entitled to future medical monitoring and treatment directly related to the existing injuries caused by the defective products.

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

88. The medical and scientific literature studying the effects of Defendants' Pelvic Mesh 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.

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

90. 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.

91. 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.

92. 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.

93. 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.

94. 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.

V. Causes of Action

COUNT I: NEGLIGENCE

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

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

97. Defendants were negligent in failing to use reasonable care as described herein in designing, manufacturing, marketing, labeling, packaging and selling the Products. Defendants breached their aforementioned duty by:

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

98. 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 material in the Products and the immune reaction that results from such material, causing adverse reactions and injuries;

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

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

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

e. the propensity of the Products for migration 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); and

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

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

99. Defendant 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 migration;

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

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

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

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

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

h. The risk of de novo urinary dysfunction;

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

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

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

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

m. The hazards associated with the Products;

n. The Products' defects described herein;

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

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

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

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

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

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

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

100. Defendants likewise failed to conduct post-market vigilance or surveillance by:

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

b. Monitoring or investigating and evaluating reports in the FDA adverse event databases for their potential significance for Defendants' Pelvic Mesh Products; and

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

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

2) Failing to investigate reports of serious adverse events.

101. 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.

102. WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and request compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT II: STRICT LIABILITY-DESIGN DEFECT

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

104. 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 material 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 migration 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); and

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;

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.

105. 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.

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

107. WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and request compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT III: STRICT LIABILITY – MANUFACTURING DEFECT

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

109. The Product(s) 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.

110. 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.

111. Defendant is strictly liable to the female Plaintiff named in the complaint for designing, manufacturing, marketing, labeling, packaging and selling a defective product(s).

112. WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and request compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT IV: STRICT LIABILITY – FAILURE TO WARN

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

114. The Product(s) 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:

115. 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.

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

117. WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and request compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT V: STRICT LIABILITY – DEFECTIVE PRODUCT

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

119. At the time of Plaintiffs' injuries, the Defendants' Pelvic Mesh Products were defective and unreasonably dangerous to foreseeable consumers, patients, and users, including Plaintiffs, and the warnings labels, and instructions were deficient.

120. The Defendants' Pelvic Mesh Products are dangerous and defective, unfit and unsafe for their intended and reasonably foreseeable uses, and do not meet or perform to the

expectations of patients and their health care providers.

121. Plaintiffs from Alaska, Arizona, California, , Florida, Hawaii, Illinois, Iowa, Maryland, Massachusetts, Minnesota, Missouri, Nebraska, Nevada, New Hampshire, , New Mexico, New York, North Dakota, Oklahoma, Oregon, Rhode Island, Utah, Vermont, Washington, D.C., West Virginia, Wisconsin, Wyoming and such other states where the common law, the Restatement of Torts (Second) and/or the Restatement of Torts (Third) are adopted, bring strict product liability claims under the common law, Section 402A of the Restatement of Torts (Second), and/or Restatement of Torts (Third)) against Defendants.

122. Plaintiffs from jurisdictions that provide a statutory cause of action for strict liability assert each of these claims against Defendants.

123. As a proximate result of the Defendants' design, manufacture, marketing, sale, and distribution of the Pelvic Mesh Products, Plaintiffs have been injured, often catastrophically, and sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and consortium, economic damages, and death.

124. WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and request compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT VI: BREACH OF EXPRESS WARRANTY

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

126. 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.

127. 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.

128. 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.

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

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

131. 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.

132. WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and request compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as

the Court deems equitable and just.

COUNT VII: BREACH OF IMPLIED WARRANTY

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

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

135. 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.

136. 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.

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

138. 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.

139. 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.

140. WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and request compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT VIII: FRAUDULENT CONCEALMENT

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

142. Throughout the relevant time periods, it was known or knowable to Defendant(s) that their Pelvic Mesh Products caused large numbers of complications that were not rare. Moreover, it was known or knowable to Defendant(s) that the surgical technique and training of implanting physicians was not the cause of the adverse events associated with these devices. It was known or knowable to Defendant(s) that the safety and efficacy of its Pelvic Mesh Products had not been proven with respect to, among other things, the product, its components, its performance and its method of insertion. It was known or knowable to Defendant(s) that there was no evidence that its Pelvic Mesh Products were safe and effective and, in fact the evidence that was known or knowable to Defendant(s) was that its Pelvic Mesh Products were not safe and effective. Defendant continued to represent that its Pelvic Mesh Products were safe and effective.

143. Despite what was known or knowable to Defendant(s) about the lack of safety and efficacy of its Pelvic Mesh Products through the relevant time periods, Defendant(s) failed to disclose this information to the plaintiffs, to their physicians or to the public at large.

144. Despite this knowledge, Defendant(s) continued to market and sell their Pelvic

Mesh Products and procedures as being safe and efficacious with evidence to the contrary. Additionally, Defendant(s) wrongfully and intentionally, through their physician training program, provided physicians with the comfort that they had sufficient training, consistent with the 2008 FDA PHN, to minimize or eliminate adverse effects resulting from the devices.

145. At all times mentioned herein, Defendants, and each of them, had the duty and obligation to disclose to Plaintiff and to her physicians, the true facts concerning the aforesaid Products, that is, that said Products were dangerous and defective, lacking efficacy for its purported use and lacking safety in normal use, and how likely it was to cause serious consequences to users including permanent and debilitating injuries. Defendants concealed these material facts prior to the time that Plaintiffs were implanted with Defendants' Pelvic Mesh Products.

146. Defendants were under a duty to Plaintiffs to disclose and warn of the defective nature of the Products because:

a. Defendants were in a superior position to know the true quality, safety and efficacy of the Defendants' Pelvic Mesh Products;

b. Defendants knowingly made false claims about the safety and quality of the Defendants' Pelvic Mesh Products in the documents and marketing materials Defendants provided to the FDA, physicians, and the general public; and

c. Defendants fraudulently and affirmatively concealed the defective nature of the Defendants' Pelvic Mesh Products from Plaintiffs.

147. The facts concealed and/or not disclosed by Defendants to Plaintiffs were material facts that a reasonable person would have considered to be important in deciding whether or not to purchase and/or use the Defendants' Pelvic Mesh Products.

148. At all times herein mentioned, Defendants, and each of them, willfully, intentionally, and maliciously concealed facts as set forth above from Plaintiffs and their physicians, and therefore, Plaintiffs, with the intent to defraud as herein alleged.

149. Defendants intentionally concealed and/or failed to disclose the true defective nature of the Products so that Plaintiffs would request and purchase the Defendants' Pelvic Mesh Products, and that her healthcare providers would dispense, prescribe, and recommend the Defendants' Pelvic Mesh Products, and Plaintiffs justifiably acted or relied upon, to her detriment, the concealed and/or non-disclosed facts as evidenced by her purchase of the Defendants' Pelvic Mesh Products.

150. At all times herein mentioned, neither Plaintiffs nor their physicians were aware of the facts set forth above, and had they been aware of said facts, they would not have acted as they did, that is, would not reasonably relied upon said representations of safety and efficacy and utilized the Pelvic Mesh Products for treatment of stress urinary incontinence and pelvic organ prolapse. Defendants' failure to disclose this information was a substantial factor in Plaintiffs' physicians selecting defendant(s) Pelvic Mesh Products and procedures for treatment of stress urinary incontinence and pelvic organ prolapse. This failure to disclose also resulted in the provision of incorrect and incomplete information to the Plaintiff-patients.

151. As a direct and proximate result of this conduct, Plaintiffs were injured.

152. WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and request compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT IX: CONSTRUCTIVE FRAUD

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

154. Defendants are in a unique position of knowledge concerning the quality, safety and efficacy of the Defendants' Pelvic Mesh Products, which knowledge is not possessed by Plaintiffs or their physicians, and Defendants thereby hold a position of superiority over Plaintiffs and their physicians.

155. Despite their unique and superior knowledge regarding the defective nature of the Defendants' Pelvic Mesh Products, Defendants continue to suppress, conceal, omit, and/or misrepresent information to Plaintiffs, the medical community, and/or the FDA, concerning the severity of risks and the dangers inherent in the intended use of the Defendants' Pelvic Mesh Products, as compared to other products and forms of treatment.

156. For example, scientists in the recent study published in Obstetrics & Gynecology, August, 2010, found that the complication rate was so high that the clinical trial was halted early.

157. Defendants have concealed and suppressed material information, including limited clinical testing, that would reveal that the Defendants' Pelvic Mesh Products had a higher risk of adverse effects, in addition to, and exceeding those associated with alternative procedures and available devices. Instead, Defendants have misrepresented the safety and efficacy of the Products.

158. Upon information and belief, Defendants' misrepresentations are designed to induce physicians and Plaintiffs to prescribe, dispense, recommend and/or purchase the Defendants' Pelvic Mesh Products. Plaintiffs and the medical community have relied upon Defendants' representations.

159. Defendants took unconscionable advantage of their dominant position of knowledge with regard to Plaintiffs and their medical providers and engaged in constructive fraud in their relationship with Plaintiffs and their medical providers. Plaintiffs reasonably relied on Defendants' representations.

160. As a proximate result of the Defendants' conduct, Plaintiffs have been injured, and sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and consortium, economic damages, and death.

161. WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and request compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT X: DISCOVERY RULE, TOLLING, AND FRAUDULENT CONCEALMENT

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

163. 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.

164. 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.

165. 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.

166. The running of the statute of limitations in this cause is tolled due to equitable tolling. Defendant(s) 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 Defendant(s).

COUNT XI: NEGLIGENT MISREPRESENTATION

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

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

169. Defendants failed to exercise ordinary care in the representations concerning the Pelvic Mesh Products while they were involved in their manufacture, sale, testing, quality assurance, quality control, and distribution in interstate commerce, because Defendants

negligently misrepresented the Pelvic Mesh Products' high risk of unreasonable, dangerous, adverse side effects.

170. Defendants breached their duty in representing that the Defendants' Pelvic Mesh Products have no serious side effects different from older generations of similar products and/or procedures to Plaintiffs, Plaintiffs' physicians, and the medical and healthcare community.

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

172. As a direct and proximate result of the Defendants' conduct, Plaintiffs have been injured, and sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and consortium, economic damages, and death.

173. WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and request compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT XII :NEGLIGENT INFLICTION OF EMOTIONAL DISTRESS

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

175. Defendants carelessly and negligently manufactured, designed, developed, tested,

labeled, marketed and sold the Defendants' Pelvic Mesh Products to Plaintiffs, carelessly and negligently concealing the harmful effects of the Defendants' Pelvic Mesh Products from Plaintiffs, and carelessly and negligently misrepresented the quality, safety and efficacy of the Products.

176. Plaintiffs were directly impacted by Defendants' carelessness and negligence, in that Plaintiffs have sustained and will continue to sustain emotional distress, severe physical injuries and/or death, economic losses, and other damages as a direct result of being implanted with the Pelvic Mesh Products sold and distributed by Defendants and/or because of the nature of their relationship to the individual implanted with the Pelvic Mesh Products.

177. As a direct and proximate result of the Defendants' conduct, Plaintiffs have been injured, and sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and consortium, economic damages, and death.

178. WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and request compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT XIII: VIOLATION OF CONSUMER PROTECTION LAWS

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

180. Plaintiffs purchased and used the Defendants' Pelvic Mesh Products primarily for personal use and thereby suffered ascertainable losses as a result of Defendants' actions in violation of the consumer protection laws.

181. Had Defendants not engaged in the deceptive conduct described herein, Plaintiffs

would not have purchased and/or paid for the Defendants' Pelvic Mesh Products, and would not have incurred related medical costs and injury.

182. Defendants engaged in wrongful conduct while at the same time obtaining, under false pretenses, monies from Plaintiffs for the Pelvic Mesh Products that would not have been paid had Defendants not engaged in unfair and deceptive conduct.

183. Unfair methods of competition or deceptive acts or practices that were proscribed by law, including the following:

184. Representing that goods or services have characteristics, ingredients, uses benefits or quantities that they do not have;

185. Advertising goods or services with the intent not to sell them as advertised; and,

186. Engaging in fraudulent or deceptive conduct that creates a likelihood of confusion or misunderstanding.

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

188. Defendants have a statutory duty to refrain from unfair or deceptive acts or trade practices in the design, labeling, development, manufacture, promotion, and sale of the Defendants' Pelvic Mesh Products.

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

190. Defendants' 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 the state consumer protection statutes listed below.

191. Defendants' actions, as complained of herein, constitute unfair competition or unfair, unconscionable, deceptive or fraudulent acts, or trade practices in violation of state consumer protection statutes, as listed below.

192. Defendants have engaged in unfair competition or unfair or deceptive acts or trade practices or have made false representations in violation of the statutory provisions of the Plaintiffs' respective states.

193. Under the applicable statutes to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising, Defendants are the suppliers, manufacturers, advertisers, and sellers, who are subject to liability under such legislation for unfair, deceptive, fraudulent and unconscionable consumer sales practices.

194. Defendants violated the statutes that were enacted in these states to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising, by knowingly and falsely representing that the Defendants' Pelvic Mesh Products 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 marketing and promotional materials.

195. The actions and omissions of Defendants alleged herein are uncured or incurable deceptive acts under the statutes enacted in the states to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising.

196. Defendants had actual knowledge of the defective and dangerous condition of the Defendants' Pelvic Mesh Products and failed to take any action to cure such defective and dangerous conditions.

197. Plaintiffs and the medical community relied upon Defendants' misrepresentations and omissions in determining which product and/or procedure to undergo and/or perform (if any).

198. Defendants' deceptive, unconscionable or fraudulent representations and material omissions to patients, physicians and consumers, constituted unfair and deceptive acts and practices.

199. By reason of the unlawful acts engaged in by Defendants, and as a direct and proximate result thereof, Plaintiffs have suffered ascertainable losses and damages.

200. As a direct and proximate result of Defendants' violations of the states' consumer protection laws, Plaintiffs have sustained economic losses, injuries and other damages and are entitled to statutory and compensatory damages in an amount to be proven at trial.

201. WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and request restitution and disgorgement of profits, together with interest, cost of suit, attorneys' fees, and all such other and further relief as this Court deems just and proper.

COUNT XIV: GROSS NEGLIGENCE

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

203. The wrongs done by Defendants were aggravated by the kind of malice, fraud, and grossly negligent disregard for the rights of others, the public, and Plaintiffs for which the

law would allow, and which Plaintiffs will seek at the appropriate time under governing law for the imposition of exemplary damages, in that Defendants' conduct, including the failure to comply with applicable federal standards: was specifically intended to cause substantial injury to Plaintiffs; or when viewed objectively from 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 Defendants were actually, subjectively aware of the risk involved, but nevertheless proceeded with conscious indifference to the rights, safety, or welfare of others; or included a material representation that was false, with Defendants, knowing that it was false or with reckless disregard as to its truth and as a positive assertion, with the intent that the representation is acted on by Plaintiffs.

204. Plaintiffs relied on the representation and suffered injury as a proximate result of this reliance.

205. Plaintiffs therefore will seek to assert claims for exemplary damages at the appropriate time under governing law in an amount within the jurisdictional limits of the Court.

206. Plaintiffs also allege that the acts and omissions of named Defendants, whether taken singularly or in combination with others, constitute gross negligence that proximately caused the injuries to Plaintiffs. In that regard, Plaintiffs will seek exemplary damages in an amount that would punish Defendants for their conduct and which would deter other manufacturers from engaging in such misconduct in the future.

207. WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and request compensatory damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT XV: UNJUST ENRICHMENT

208. Plaintiffs incorporate by reference each and every paragraph of this Complaint as if fully set forth herein Defendants are and at all times relevant were the manufacturers, sellers, and/or suppliers of the Defendants' Pelvic Mesh Products.

209. Plaintiffs paid for the Defendants' Pelvic Mesh Products for the purpose of treatment of stress urinary incontinence and/ or pelvic organ prolapse or other similar conditions.

210. Defendants have accepted payment by Plaintiffs and others on Plaintiffs' behalf for the purchase of the Defendants' Pelvic Mesh Products.

211. Plaintiffs have not received the safe and effective medical devices for which they paid.

212. It would be inequitable for Defendants to keep this money since Plaintiffs did not in fact receive a safe and effective medical device as represented by Defendants.

213. WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and request compensatory damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT XVI: LOSS OF CONSORTIUM

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

215. 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 spousal consortium, companionship, society, affection, services and support.

216. WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and request compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT XVII: PUNITIVE DAMAGES

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

218. 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.

219. Defendants sold the Products to the female Plaintiff named in the Short Form Complaint'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 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.

220. 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, Defendants chose instead to continue to market and

sell the Products as safe and effective.

221. 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.

222. 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.

223. 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.

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

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

226. Defendants knew of the Products' defective and unreasonably dangerous nature, but continued 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.

227. 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.

228. 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.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly and severally and requests 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:

1. 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, health and medical care costs, together with interest and costs as provided by law;
2. Restitution and disgorgement of profits;
3. Reasonable attorneys' fees;
4. The costs of these proceedings;
5. All ascertainable economic damages;
6. Medical monitoring damages;
7. Punitive damages;
8. Survival damages (if applicable);
9. Wrongful death damages (if applicable); and
10. Such other and further relief as this Court deems just and proper.

Dated: January 3, 2013

Respectfully submitted,

/s/ Riley Burnett, Jr.

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LEAD ATTORNEY

DEMAND FOR JURY TRIAL

Plaintiffs hereby demand a trial by jury as to all issues.

Dated: January 3, 2013

Respectfully submitted,

/s/ Riley Burnett, Jr.

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LEAD ATTORNEY

PRINT FORM RESET FORM

Exhibit B

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

CHARLESTON DIVISION

In Re: Coloplast Corp.,
Pelvic Support System Products Liability Litigation
MDL No. 2387
Civil Action No.

SHORT FORM COMPLAINT

Come now the Plaintiff(s) named below, and for Complaint against the Defendants named below, incorporate The First Amended Master Complaint in MDL No. 2387 by reference. Plaintiff(s) further show the court as follows:

1. Female Plaintiff

2. Plaintiff Spouse

3. Other Plaintiff and capacity (i.e., administrator, executor, guardian, conservator)

4. State of Residence

5. District Court and Division in which venue would be proper absent direct filing

6. Defendants (Check Defendants against whom Complaint is made):

   ☐ A. Mentor Worldwide LLC

☐ B. Coloplast A/S

☐ C. Coloplast Corp.

☐ D. Coloplast Manufacturing US, LLC

☐ E. Porges S.A.

☐ F. American Medical Systems, Inc. ("AMS")

☐ G. American Medical Systems Holdings, Inc. ("AMS Holdings")

☐ H. Endo Pharmaceuticals, Inc.

☐ I. Endo Health Solutions Inc. (f/k/a Endo Pharmaceuticals Holdings, Inc.)

☐ J. Ethicon, Inc.

☐ K. Ethicon, LLC

☐ L. Johnson & Johnson

☐ M. Boston Scientific Corporation

☐ N. C. R. Bard, Inc. ("Bard")

☐ O. Sofradim Production SAS ("Sofradim")

☐ P. Tissue Science Laboratories Limited ("TSL")

7. Basis of Jurisdiction

☐ Diversity of Citizenship

☐ Other:

A. Paragraphs in First Amended Master Complaint upon which venue and jurisdiction lie:

B. Other allegations of jurisdiction and venue

_____

_____

_____

_____

8. Defendants' products implanted in Plaintiff (Check products implanted in Plaintiff)

☐ A. T-Sling-Universal Polypropylene Sling;

☐ B. Aris-Transobturator Sling System;

☐ C. Supris-Suprapubic Sling System;

☐ D. Novasilk-Synthetic Flat Mesh;

☐ E. Suspend-Tutoplast Processed Fascia Lata;

☐ F. Exair-Prolapse Repair System;

☐ G. Axis-Tutoplast Processed Dermis;

☐ H. Restorelle;

☐ I. Smartmesh;

☐ J. Omnisure;

☐ K. Minitape;

☐ L. Coloplast Mesh Product(s), specific product name(s) unknown at present;

☐ M. Non-Coloplast Mesh Product(s) known as _____; and/or

☐ N. Other: _____

_____

9. Defendants' Products about which Plaintiff is making a claim. (Check applicable products)

☐ A. T-Sling-Universal Polypropylene Sling;

☐ B. Aris-Transobturator Sling System;

☐ C. Supris-Suprapubic Sling System;

☐ D. Novasilk-Synthetic Flat Mesh;

☐ E. Suspend-Tutoplast Processed Fascia Lata;

☐ F. Exair-Prolapse Repair System;

☐ G. Axis-Tutoplast Processed Dermis;

☐ H. Restorelle;

☐ I. Smartmesh;

☐ J. Omnisure;

☐ K. Minitape;

☐ L. Coloplast Mesh Product(s), specific product name(s) unknown at present;

☐ M. Non-Coloplast Mesh Product(s) known as _____;

☐ N. Other: _____

_____

10. Date of Implantation as to Each Product

_____

_____

_____

11. Hospital(s) where Plaintiff was implanted (including City and State)

_____

_____

12. Implanting Surgeon(s)

_____

_____

13. Counts in the Master Complaint brought by Plaintiff(s)

☐ Count I - Negligence

☐ Count II - Strict Liability – Design Defect

☐ Count III - Strict Liability – Manufacturing Defect

☐ Count IV - Strict Liability – Failure to Warn

☐ Count V - Strict Liability – Defective Product

☐ Count VI - Breach of Express Warranty

☐ Count VII - Breach of Implied Warranty

☐ Count VIII - Fraudulent Concealment

☐ Count IX - Constructive Fraud

☐ Count X - Discovery Rule, Tolling and Fraudulent Concealment

☐ Count XI - Negligent Misrepresentation

☐ Count XII - Negligent Infliction of Emotional Distress

☐ Count XIII - Violation of Consumer Protection Laws

☐ Count XIV - Gross Negligence

☐ Count XV - Unjust Enrichment

☐ Count XVI - (By the Spouse) – Loss of Consortium

☐ Count XVII - Punitive Damages

☐ Other _____ (please state the facts supporting this Count in the space, immediately below)

Attorneys for Plaintiff

Address and bar information:

PRINT FORM RESET FORM

Exhibit C

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

CHARLESTON DIVISION

In Re: Coloplast Corp.,
Pelvic Support System Products Liability Litigation
MDL No. 2387
Civil Action No.

AMENDED SHORT FORM COMPLAINT

Come now the Plaintiff(s) named below, and for Complaint against the Defendants named below, incorporate The First Amended Master Complaint in MDL No. 2387 by reference. Plaintiff(s) further show the court as follows:

1. Female Plaintiff

2. Plaintiff Spouse

3. Other Plaintiff and capacity (i.e., administrator, executor, guardian, conservator)

4. State of Residence

5. District Court and Division in which venue would be proper absent direct filing

6. Defendants (Check Defendants against whom Complaint is made):

   ☐ A. Mentor Worldwide LLC

☐ B. Coloplast A/S

☐ C. Coloplast Corp.

☐ D. Coloplast Manufacturing US, LLC

☐ E. Porges S.A.

☐ F. American Medical Systems, Inc. ("AMS")

☐ G. American Medical Systems Holdings, Inc. ("AMS Holdings")

☐ H. Endo Pharmaceuticals, Inc.

☐ I. Endo Health Solutions Inc. (f/k/a Endo Pharmaceuticals Holdings, Inc.)

☐ J. Ethicon, Inc.

☐ K. Ethicon, LLC

☐ L. Johnson & Johnson

☐ M. Boston Scientific Corporation

☐ N. C. R. Bard, Inc. ("Bard")

☐ O. Sofradim Production SAS ("Sofradim")

☐ P. Tissue Science Laboratories Limited ("TSL")

7. Basis of Jurisdiction

☐ Diversity of Citizenship

☐ Other:

A. Paragraphs in First Amended Master Complaint upon which venue and jurisdiction lie:

B. Other allegations of jurisdiction and venue

_____

_____

_____

_____

8. Defendants' products implanted in Plaintiff (Check products implanted in Plaintiff)

☐ A. T-Sling-Universal Polypropylene Sling;

☐ B. Aris-Transobturator Sling System;

☐ C. Supris-Suprapubic Sling System;

☐ D. Novasilk-Synthetic Flat Mesh;

☐ E. Suspend-Tutoplast Processed Fascia Lata;

☐ F. Exair-Prolapse Repair System;

☐ G. Axis-Tutoplast Processed Dermis;

☐ H. Restorelle;

☐ I. Smartmesh;

☐ J. Omnisure;

☐ K. Minitape;

☐ L. Coloplast Mesh Product(s), specific product name(s) unknown at present;

☐ M. Non-Coloplast Mesh Product(s) known as _____; and/or

☐ N. Other: _____

_____

9. Defendants' Products about which Plaintiff is making a claim. (Check applicable products)

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☐ G. Axis-Tutoplast Processed Dermis;

☐ H. Restorelle;

☐ I. Smartmesh;

☐ J. Omnisure;

☐ K. Minitape;

☐ L. Coloplast Mesh Product(s), specific product name(s) unknown at present;

☐ M. Non-Coloplast Mesh Product(s) known as _____;

☐ N. Other: _____

_____

10. Date of Implantation as to Each Product

_____

_____

_____

11. Hospital(s) where Plaintiff was implanted (including City and State)

_____

_____

12. Implanting Surgeon(s)

_____

_____

13. Counts in the Master Complaint brought by Plaintiff(s)

☐ Count I - Negligence

☐ Count II - Strict Liability – Design Defect

☐ Count III - Strict Liability – Manufacturing Defect

☐ Count IV - Strict Liability – Failure to Warn

☐ Count V - Strict Liability – Defective Product

☐ Count VI - Breach of Express Warranty

☐ Count VII - Breach of Implied Warranty

☐ Count VIII - Fraudulent Concealment

☐ Count IX - Constructive Fraud

☐ Count X - Discovery Rule, Tolling and Fraudulent Concealment

☐ Count XI - Negligent Misrepresentation

☐ Count XII - Negligent Infliction of Emotional Distress

☐ Count XIII - Violation of Consumer Protection Laws

☐ Count XIV - Gross Negligence

☐ Count XV - Unjust Enrichment

☐ Count XVI - (By the Spouse) – Loss of Consortium

☐ Count XVII - Punitive Damages

☐ Other _____ (please state the facts supporting this Count in the space, immediately below)

Attorneys for Plaintiff

Address and bar information: