UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF TEXAS ABILENE DIVISION

LINDA CHANNELL,	§	
	§	
Plaintiff,	§	
	§	Civil Action No.
vs.	§	
	§	
COLOPLAST CORPORATION, COLOPLAST A/S, COLOPLAST MANUFACTURING, US, LLC, ANALYTIC BIOSURGICAL SOLUTIONS, and MENTOR WORLDWIDE, LLC,	§	COMPLAINT AND JURY DEMAND
Defendant(s).		

COMPLAINT AND DEMAND FOR JURY TRIAL

COMES NOW the Plaintiff, Linda Channell and files this Original Complaint against the Defendants Coloplast Corporation, Coloplast A/S, Coloplast Manufacturing, US, LLC, Analytic Biosurgical Solutions, Johnson & Johnson and Mentor Worldwide, LLC (hereinafter jointly referred to as "Coloplast") as follows:

NATURE OF CASE

1. This is an action for damages suffered by Linda Channell ("Plaintiff"), as a direct and proximate result of Coloplast's wrongful conduct in connection with the development, design, manufacture, marketing, distribution and selling of Coloplast's Pelvic Mesh Products[1] inserted in her body to treat medical conditions, primarily pelvic organ prolapse and stress urinary incontinence.

[1] The term Pelvic Mesh Products includes Coloplast's mesh, hammock and sling products used to treat pelvic organ prolapse and/or stress urinary incontinence. The term Pelvic Mesh Products also specifically includes the Coloplast products implanted into Plaintiff, which include the Coloplast Aris Transobturator Tape System (hereinafter "Products").

2. Plaintiff, by her undersigned counsel, brings this action against Coloplast related to the design, manufacture, marketing, distribution and sale of Defendants' Aris Transobturator Tape System. This action is for compensator, equitable, injunctive, and declaratory relief. Plaintiff is making the following allegations based upon her individual personal knowledge as to her own acts, and upon information and belief, as well as upon her attorneys' investigative efforts as to Coloplast's actions and misconduct, and alleges as follows:

PARTIES

3. Plaintiff Linda Channell is a citizen of the State of Texas, County of Dallas, and the City of Dallas.

4. Defendant Analytic Biosurgical Solutions ("ABISS") is a corporation organized and existing under the laws of the Republic of France, maintaining its principal place of business at 14 Rue de la Telematique, St. Etienne, Loire 42000, Republic of France. ABISS' registered United States Food and Drug Administration ("FDA") Agent is Elizabeth A. Boots, Coloplast Corporation, 1601 West River Road North, Minneapolis, Minnesota 55411. Ms. Boots is the Vice President of Quality Assurance for Coloplast Corporation.

5. Defendant Mentor Worldwide, LLC ("Mentor") is a Delaware limited liability company which has their principal place of business at 201 Mentor Drive, Santa Barbara, California. Mentor Corporation was founded in Minneapolis, MN in 1969 and represents that it is a leading supplier of medical products for the global healthcare market. Mentor Corporation develops, manufactures and markets innovative, science-based products for the aesthetics, urologic specialties and clinical and consumer healthcare markets around the world. Mentor Corporation designed and launched the Aris Transobturator Tape in 2005. Mentor Corporation then merged with and into Mentor Worldwide, LLC on December 4, 2009.

6. 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, Humleback 3050, Kingdom of Denmark, and maintaining its North American principal place of business at 1601 West River Road North, Minneapolis, Minnesota 55411. Coloplast A/S moved its North America Headquarters to Minneapolis in June 2006.

7. Defendant Coloplast Corporation ("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.

8. 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 5600 Park Street, #6, St. Paul, Minnesota 55103. Coloplast Manufacturing US, LLC is a wholly owned subsidiary of Coloplast Corp.

JURISDICTION AND VENUE

9. This Court has jurisdiction pursuant to 28 U.S.C. § 1332(a) because Plaintiff and Defendants Coloplast are citizens of different States and the amount in controversy exceeds $75,000 exclusive of interest and costs.

10. Venue in this action properly lies in this judicial district pursuant to 28 U.S.C. § 1391(a), as a substantial number of the events, actions or omissions giving rise to Plaintiffs' claims occurred in this district. At all times material hereto, Coloplast was a for profit corporation with its headquarters in this district as well as authorized to and doing substantial business in this district.

11. At all times material hereto, Coloplast developed, designed, manufactured, labeled, packaged, distributed, marketed, supplied, advertised, sold and otherwise engaged in all activities that are part and parcel of the sale and distribution of the Pelvic Mesh Products at issue in this matter. By said activities, Coloplast's Pelvic Mesh Products, including but not limited to the Aris, are placed into the stream of commerce throughout the United States, including within the State of Texas.

12. Coloplast is subject to personal jurisdiction in the U.S. District Court for Texas Northern District Court as Coloplast systematically and continually conducts business in this District, and Coloplast conducts business throughout the United States, including in Texas.

FACTUAL ALLEGATIONS
COLOPLAST PELVIC ORGAN PROLAPSE PRODUCTS BACKGROUND

13. At all relevant times, ABISS was in the business of developing, designing, manufacturing, labeling, packaging, distributing, marketing, supplying, advertising, selling and otherwise engaging in all activities that are part and parcel of the sale and distribution Pelvic Mesh Product medical devices for the treatment of medical conditions in the female pelvic, primarily pelvic organ prolapse and stress urinary incontinence.

14. Coloplast develops, designs, manufactures, labels, packages, distributes, markets, supplies, advertises, sells and otherwise engages in all activities that are part and parcel of the sale and distribution Pelvic Mesh Product medical devices for the treatment of medical conditions in the female pelvic, primarily pelvic organ prolapse and stress urinary incontinence.

15. At all relevant times, transvaginal meshes were used to treat pelvic organ prolapse and stress urinary incontinence.

16. A pelvic organ prolapse occurs when a pelvic organ, such as a bladder, drops ("prolapses") from its normal position and pushes against the wall of the vagina. Prolapses 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. Stress urinary incontinence is a type of incontinence caused by leakage of urine during moments of physical stress. It affects 20-40% of all women.

17. Surgical mesh, including transvaginal mesh, is a medical device that is generally used to repair weakened or damaged tissue. It is made from porous absorbable or non-absorbable synthetic material and 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 transvaginal meshes are comprised of non-absorbable synthetic polypropylene. Upon information and belief, the Pelvic Mesh Products are comprised of a synthetic, petroleum-based mesh.

18. Coloplast's Pelvic Mesh Products were derived from polypropylene mesh products, and were and are utilized in the treatment of medical conditions in the female pelvis, primarily pelvic organ prolapse and stress urinary incontinence.

19. In 1996, the FDA cleared the first mesh product for use in the treatment of stress urinary incontinence (SUI). These products include transvaginal mesh, including the Aris Transobturator Tape System manufactured, marketed and distributed by Coloplast. These products are approved by the FDA under the abbreviated 510(k) approval process.

20. 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." ABISS' FDA registration lists its proprietary device as "Mentor Aris Trans-Obturator Tape and Surgical Kit."

21. 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 trademark.

22. ABISS is registered with the FDA, Registration Number 3004756681, as the manufacturer of "Mentor Aris Trans-Obturator Tape and Surgical Kit" and listed Elizabeth A. Boots, Coloplast U.S., Vice President, Quality Assurance, as its United States Agent. ABISS is also the assignee of a United States Patent Application for an invention entitled "Implant for the Treatment of Cystocele and Rectocele" "for the treatment of cystocele, rectocele and/or prolapse of the vaginal dome…" United States Patent Application WO/2004/091442 and 2005/0278037 A1.

23. Coloplast'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…."

24. Coloplast'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 described Coloplast'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."

25. Coloplast develops, designs, manufactures, labels, packages, distributes, markets, supplies, advertises, sells and otherwise engages in all activities that are part and parcel of the sale and distribution medical devices, including medical devices implanted to treat certain women, like Plaintiff, for pelvic organ prolapse and stress urinary incontinence such as the Coloplast Aris (hereinafter "Products"). The Pelvic Mesh Product known as Aris Transobturator System as well as any as yet unidentified pelvic mesh products designed and sold for similar purposes, inclusive of the instruments and procedures for implantation, are collectively referenced herein as Coloplast's Pelvic Mesh Products or the Pelvic Mesh Products.

26. Plaintiff Linda Channell was implanted with Coloplast Pelvic Mesh Products developed, designed, manufactured, marketed, packaged, labeled, distributed, supplied, advertised, sold and placed in the stream of commerce by Coloplast. Due to defective design, defective manufacturing, defective marketing, failure to warn and negligence by Coloplast, the Products have caused Plaintiff severe and permanent bodily injuries and significant mental and physical pain and suffering, as well as economic losses.

27. Coloplast's Pelvic Mesh Products, including the Pelvic Mesh Products specifically used for Plaintiff, have been and continue to be marketed to the medical community

and to patients as safe, effective, reliable medical devices implanted by safe and effective, minimally invasive surgical techniques for the treatment of medical conditions, primarily pelvic organ prolapse and stress urinary incontinence. Coloplast markets the Pelvic Mesh Products, including the Products specifically used for Plaintiff, as safer and more effective when compared to 1) the traditional products and procedures for treatment of pelvic organ prolapse and stress urinary incontinence and 2) other competing pelvic mesh and sling products.

28. Coloplast made public statements in the form of written product descriptions, product labels, promotional materials, marketing materials and other materials that asserted that implanting the Pelvic Mesh Products in patients was safe and would not cause harm to patients, like Plaintiff. Coloplast has also marketed and sold its Pelvic Mesh Products to the medical community at large and patients through carefully planned, multifaceted marketing campaigns and strategies. These campaigns and strategies include, but are not limited to direct to consumer advertising, aggressive marketing to health care providers at medical conferences, hospitals, private offices and include the provision of valuable consideration and benefits to health care providers. Also utilized are documents, brochures, websites, telephone information lines, and training offering exaggerated and misleading expectations as to the safety and utility of the Coloplast's Pelvic Mesh Products.

29. Contrary to Coloplast's representations and marketing to the medical community and to the patients themselves, Coloplast's Pelvic Mesh Products have high failure, injury, and complication rates, fail to perform as intended, require frequent and often debilitating re-operations, and have caused severe and irreversible injuries, conditions, and damage to the Plaintiffs. These defects include, but are not limited to:

a. The material is not inert and therefore reacts to human tissues and/or other naturally occurring human bodily contents adversely affecting patient health.

b. The mesh material harbors infections that adversely affect human tissues and patient heath.

c. The Pelvic Mesh Products migrate from the location of their implantation, adversely affecting tissues and patient health.

d. The mesh material abrades tissues adversely affecting patient health.

e. The Pelvic Mesh Products regularly fail to perform the purpose of their implantation such that the patient requires removal of the device and repeated treatment and surgery.

f. Due to their various defects, the Pelvic Mesh Products regularly cause significant injury to patients such that the Pelvic Mesh Products must be removed, resulting in additional surgery.

g. The Pelvic Mesh Products become embedded in human tissue over time such that if it needs to be removed due to its various defects, the removal causes damage to the organs and tissues, adversely affecting patient health.

h. The Pelvic Mesh Products are defective in shape, composition, weight, physical, chemical and mechanical properties and is inappropriately engineered for use in the female pelvis.

i. The Pelvic Mesh Products erode into other pelvic organs, tissue, muscle, nerves, and bone adversely affecting tissues and patient health.

30. Because of their numerous defects, the Pelvic Mesh Products create an unreasonable risk of injury and other adverse health consequences for patients, including, but not

necessarily limited to, mesh erosion, extrusion/protrusion, chronic pain, mesh contraction, infection, abscesses, fistula, inflammation, scar tissue, organ perforation, dyspareunia, bleeding, neuropathic, and other acute and chronic nerve damage and pain, pudendal nerve damage, vaginal scarring, vaginal shrinkage, pelvic floor damage, pelvic pain, urinary and fecal problems, prolapse of organs, and in many cases forcing the need for intensive 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, and injuries to the woman's intimate partner.

31. Coloplast made, participated in and/or contributed to filings with the Food and Drug Administration in conjunction with the clearance process and other filing requirements for Coloplast's Pelvic Mesh Products.

32. Upon information and belief, Coloplast sent to the FDA a 510(k) submission for its Pelvic Mesh Products.

33. Upon information and belief, Coloplast was in control of designing, assembling, manufacturing, marketing, testing, distributing, packaging, labeling, processing, supplying, marketing, advertising, promoting, selling and issuing of product warnings and related information with respect to its Pelvic Mesh Products.

34. Coloplast has consistently underreported and withheld information about the propensity of its Pelvic Mesh Products to fail and cause injury and complications, and have misrepresented the efficacy and safety of the Products, through various means and media, actively and intentionally misleading the FDA, the medical community, patients and the public at large.

35. Coloplast has known and continues to know that its disclosures to the FDA were and are incomplete and misleading; and that its Pelvic Mesh Products were and are causing numerous patients severe injuries and complications. Coloplast suppressed this information, and failed to accurately and completely disseminate or share this and other critical information with the FDA, health care providers, or the patients. As a result, Coloplast actively and intentionally misled and continue to mislead the public, including the medical community, health care providers and patients, into believing that its Pelvic Mesh Products were and are safe, effective, and would not cause harm to patients. These statements were made with the intent that medical professionals and members of the public would rely upon them, with the intent that members of the public would pay for the Pelvic Mesh Products and that the Pelvic Mesh Products would be implanted in patients. When Coloplast made these statements, Coloplast knew or should have known that the statements were inaccurate.

36. Coloplast has at all times provided incomplete, insufficient, and misleading training and information to physicians, in order to increase the number of physicians utilizing the Coloplast's Pelvic Mesh Products, and thus increase the sales of the Pelvic Mesh Products, and also leading to the dissemination of inadequate and misleading information to patients, including Plaintiffs.

37. Coloplast was at all times material hereto subject to the laws of the United States of America, including provisions relating to the FDA, and the rules and regulations thereof, in conjunction with the clearance process, labeling and other marketing activities that pertain to the its Pelvic Mesh Products.

38. Coloplast failed to perform or rely on proper and adequate testing and research in order to determine the safety and effectiveness of its Pelvic Mesh Products.

39. Coloplast failed to perform or rely on proper and adequate testing and research in order to determine and evaluate the risks and benefits of the its Pelvic Mesh Products.

40. Coloplast failed to design and establish a safe, effective procedure for removal of its Pelvic Mesh Products; therefore, in the event of a failure, injury, or complication it is impossible to easily and safely remove Coloplast's Pelvic Mesh Products.

41. Feasible and suitable alternative designs as well as suitable alternative procedures and instruments for implantation and treatment of stress urinary incontinence, pelvic organ prolapse, and similar other conditions have existed at all times relevant as compared to the Coloplast's Pelvic Mesh Products.

42. Coloplast's Pelvic Mesh Products were at all times utilized and implanted in a manner foreseeable to Coloplast.

43. The Pelvic Mesh Products implanted into the Plaintiff were in the same or substantially similar condition as they were when they left the possession of Coloplast, and in the condition directed by Coloplast.

44. The injuries, conditions and complications suffered due to Coloplast's Pelvic Mesh Products include but are not limited to mesh erosion, extrusion/protrusion, chronic pain, mesh contraction, infection, abscesses, fistula, inflammation, scar tissue, organ perforation, dyspareunia, bleeding, neuropathic, and other acute and chronic nerve damage and pain, pudendal nerve damage, vaginal scarring, vaginal shrinkage, pelvic floor damage, pelvic pain, urinary and fecal problems, prolapse of organs, and in many cases forcing the need for intensive 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, and injuries to the woman's intimate partner.

45. Despite Coloplast's knowledge of these catastrophic injuries, conditions, and complications caused by their Pelvic Mesh Products, Coloplast has, and continues to manufacture, market and sell the Pelvic Mesh Products, while continuing to fail to adequately warn, label, instruct, and disseminate information with regard to Coloplast's Pelvic Mesh Products, both prior to and after the marketing and sale of the Pelvic Mesh Products.

46. Prior to the time that the Pelvic Mesh Products were implanted into Plaintiff, Coloplast was aware of numerous defects in the Pelvic Mesh Products, including, but not limited to, the defects and unreasonable risks identified above. Based thereon, Coloplast knew or should have known that the Pelvic Mesh Products caused an unreasonably high rate of complications, such as mesh erosion, extrusion/protrusion, chronic pain, mesh contraction, infection, abscesses, fistula, inflammation, scar tissue, organ perforation, dyspareunia, bleeding, neuropathic, and other acute and chronic nerve damage and pain, pudendal nerve damage, vaginal scarring, vaginal shrinkage, pelvic floor damage, pelvic pain, urinary and fecal problems, and prolapse of organs in women implanted with the Pelvic Mesh Products. Despite being aware of the numerous defects and unreasonable risks in its products, Coloplast developed, designed, manufactured, labeled, packaged, distributed, marketed, supplied, advertised, sold and otherwise engaged in all activities that are part and parcel of the sale and distribution of the Pelvic Mesh Products with the intent that it would be implanted in patients. Coloplast was aware that implanting the Pelvic Mesh Products in patients was likely to cause injury and harm to the patients into whom the Pelvic Mesh Products were implanted. Alternatively, Coloplast failed to

exercise reasonable care in determining the risks and potential adverse consequences of implanting the Products into patients.

47. Even though Coloplast has known or should have known that the Pelvic Mesh Products created a foreseeable, unreasonable risk of harm to those women into whom they were implanted, Coloplast continued to market the Pelvic Mesh Products in the United States. Coloplast has sold thousands of Pelvic Mesh Products in the United States alone.

48. Coloplast has failed to provide adequate warning or information about the risks that the Pelvic Mesh Products cause an unreasonably high rate of complications, including mesh erosion, extrusion/protrusion, chronic pain, mesh contraction, infection, abscesses, fistula, inflammation, scar tissue, organ perforation, dyspareunia, bleeding, neuropathic, and other acute and chronic nerve damage and pain, pudendal nerve damage, vaginal scarring, vaginal shrinkage, pelvic floor damage, pelvic pain, urinary and fecal problems, and prolapse of organs to physicians who implanted the Pelvic Mesh Products, or to women implanted with the Pelvic Mesh Products.

CASE SPECIFIC ALLEGATIONS

49. On or about October 7, 2008, at East Texas Medical Center Athens, Plaintiff's physician implanted Coloplast Pelvic Mesh Products, that being the Coloplast Aris System, to treat stress urinary incontinence.

50. Prior to Plaintiff's surgery, her treating physician, as well as Plaintiff, was exposed to the aforementioned advertising and marketing campaign directed by Coloplast.

51. Plaintiff and her physician, either through direct promotional contact with Coloplast Sales Representatives, Lab Faculty, through word-of-mouth with other health care providers, and/or through promotional materials, received the information Coloplast intended

Plaintiff and her physician to receive and view, to wit: that the Pelvic Mesh Products were safe and effective for use in the treatment of pelvic organ prolapse and stress urinary incontinence.

52. Plaintiff began experiencing severe and debilitating pain, mesh erosion, and exposure/extrusion/protrusion some time after implant.

53. Plaintiff returned to her physicians several times due to complications and problems attributed to Coloplast's Pelvic Mesh Products.

54. As a direct and proximate result of the use of the Coloplast Pelvic Mesh Products, Plaintiff suffered, and continues to suffer, serious bodily injury and harm including removal of the Coloplast Pelvic Mesh Products on March 28, 2011. The removal of Coloplast's Pelvic Mesh Products resulted in a hospitalization as well as related complications. It was not until recently that Plaintiff learned the Coloplast Pelvic Mesh Products were defective and the cause of her pain, suffering, and complications.

55. As a direct and proximate result of the use of the Coloplast Pelvic Mesh Products, that being the Coloplast Aris System, Plaintiff incurred, and continues to incur, medical expenses to treat her injuries and condition.

56. As a direct and proximate result of the use of the Coloplast Pelvic Mesh Products, that being the Coloplast Aris System, Plaintiff continues to receive medical treatment and is anticipated to undergo further surgeries to remove more mesh.

COUNT I
PRODUCT LIABILITY ACT – DEFECTIVE MANUFACTURE AND DESIGN

57. Plaintiff hereby incorporates by reference and reavers each and every allegation contained in the foregoing paragraphs of this Complaint as if fully set forth herein and further states and alleges as follows:

58. One or more of the defects in the Pelvic Mesh Products are the result of improper or incorrect manufacturing processes that result in the Pelvic Mesh Products as manufactured deviating from its intended design. The defects caused by improper or incorrect manufacturing rendered the Pelvic Mesh Products unreasonably dangerous, deficient, and defective to consumers and to Plaintiff. The defects in the Pelvic Mesh Products implanted in Plaintiff existed from their manufacture; therefore the defects were present when they left the possession and control of Coloplast. The Pelvic Mesh Products were used by Plaintiff in a reasonably foreseeable and intended manner.

59. Coloplast's Pelvic Mesh Products were "defective", unfit, unsafe, inherently dangerous and "unreasonably dangerous" for their intended and reasonably foreseeable uses. These Pelvic Mesh Products were in said condition when they entered the stream of commerce and were received by Plaintiff. The Pelvic Mesh Products do not meet or perform to the expectations of patients and their health care providers. Coloplast's Pelvic Mesh Products were dangerous to an extent beyond that which would be contemplated by the ordinary consumer.

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

61. Coloplast has intentionally and recklessly designed, manufactured, marketed, labeled, sold and distributed the Pelvic Mesh Products with wanton and willful disregard for the rights and health of the Plaintiffs and others, and with malice, placing their economic interest above the health and safety of the Plaintiff and others.

62. The Pelvic Mesh Products used by Plaintiff's physician were not substantially changed, modified, or altered at any time in any manner whatsoever prior to use. The subject Pelvic Mesh Products reached the Plaintiff in such a condition that was unreasonably dangerous to her. The Coloplast Pelvic Mesh Products were used in the manner for which it was intended, that is, for treatment of pelvic organ prolapse and/or stress urinary incontinence. This use resulted in injury to Plaintiff.

63. At no time did Plaintiff have reason to believe that Pelvic Mesh Products were in a condition not suitable for its proper and intended use among patients.

64. Plaintiff was not able to discover, nor could she have discovered through the exercise of reasonable care, the defect of the Pelvic Mesh Products. Further, in no way could Plaintiff have known that Coloplast had manufactured the Pelvic Mesh Products in such a way as to increase the risk of harm or injury to the recipients of the implant.

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

COUNT II
PRODUCT LIABILITY ACT - FAILURE TO WARN

66. Plaintiff hereby incorporates by reference and reavers each and every allegation contained in the foregoing paragraphs of this Complaint as if fully set forth herein and further states and alleges as follows:

67. The Pelvic Mesh Products were defective by reason of failure of Coloplast to provide adequate warnings or instructions.

68. Coloplast failed to properly and adequately warn and instruct the Plaintiff and her health care providers as to the proper candidates, if any, and the safest and most effective methods of implantation and use of Coloplast's Pelvic Mesh Products.

69. Coloplast failed to properly and adequately warn and instruct the Plaintiff and her health care providers as to the risks and benefits of Coloplast's Pelvic Mesh Products, given the Plaintiff's condition and need for information.

70. Coloplast failed to properly and adequately warn and instruct the Plaintiff and her health care providers with regard to the inadequate research and testing of the Pelvic Mesh Products, and the complete lack of a safe, effective procedure for removal of the Pelvic Mesh Products.

71. Coloplast failed to provide such adequate warning or instruction that a manufacturer exercising reasonable care would have provided to physicians who implanted the Pelvic Mesh Products or to those women who had been implanted with the Pelvic Mesh Products, concerning the following risks, given their condition and need for information. Coloplast had actual or constructive knowledge of the following risks at the time the Pelvic Mesh Products left Coloplast's control and was being marketed:

a. The high failure rate of the Pelvic Mesh Products;

b. The high rate of infections and abscesses caused by the Pelvic Mesh Products;

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

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

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

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

72. After receiving notice of numerous bodily injuries resulting from the Pelvic Mesh Products, Coloplast failed to provide such post-marketing or post-sale warnings or instructions that a manufacturer exercising reasonable care should have provided to physicians who implanted the Pelvic Mesh Products or those women who had been implanted with the Pelvic Mesh Products that the products were causing an unreasonably high rate of complications such as mesh erosion, extrusion/protrusion, chronic pain, mesh contraction, infection, abscesses, fistula, inflammation, scar tissue, organ perforation, dyspareunia, bleeding, neuropathic, and other acute and chronic nerve damage and pain, pudendal nerve damage, vaginal scarring, vaginal shrinkage, pelvic floor damage, pelvic pain, urinary and fecal problems, and prolapse of organs. Furthermore Coloplast failed to provide post-marketing or post-sale warnings to instructions concerning the necessity to remove the Pelvic Mesh Products from the patient's body in the event of the product failure or other complications.

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

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

75. Coloplast is strictly liable in tort to the Plaintiff for their wrongful conduct pursuant to the common law.

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

COUNT III
NEGLIGENCE

77. Plaintiff hereby incorporates by reference and reavers each and every allegation contained in the foregoing paragraphs of this Complaint as if fully set forth herein and further states and alleges as follows:

78. At all times relevant herein, Coloplast had a duty to exercise reasonable and ordinary care in the development, design, manufacture, label, packaging, instructions, warnings, sale, distribution, marketing, supply, advertisement, selling and other activities that are part and parcel of the sale and distribution of the Pelvic Mesh Products, including a duty to ensure that the Pelvic Mesh Products did not pose a significantly increased risk of bodily injury to its users.

79. Coloplast had a duty to exercise reasonable care in the advertising and sale of the Pelvic Mesh Products, including a duty to warn and instruct Plaintiff and other consumers, of the dangers associated with the use of the Pelvic Mesh Products that were known or should have been known to Coloplast at the time of the sale of the Pelvic Mesh Products to the Plaintiff.

80. Coloplast had a duty to exercise reasonable and ordinary care in the recruitment and training of physicians to implant the Pelvic Mesh Products.

81. Coloplast knew or should have known Plaintiff could foreseeably suffer injury as a result of Coloplast's failure to exercise ordinary care as described above.

82. Coloplast failed to warn the general public, including Plaintiff, of the risk of serious harm.

83. Coloplast breached their duty to Plaintiff by failing to exercise due care under the circumstances.

84. Coloplast failed to exercise ordinary and reasonable care in the development, design, manufacture, label, packaging, instructions, warnings, sale, distribution, marketing, supply, advertisement, selling and other activities that are part and parcel of the sale and distribution of the Pelvic Mesh Products. Coloplast was negligent in that they failed to provide adequate warnings and instructions to Plaintiff or to her physician regarding the Pelvic Mesh Products. Coloplast further breached their duty of care in the recruitment and training of physicians to implant the Pelvic Mesh Products.

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

COUNT IV
BREACH OF EXPRESS WARRANTY

86. Plaintiff hereby incorporates by reference and reavers each and every allegation contained in the foregoing paragraphs of this Complaint as if fully set forth herein and further states and alleges as follows:

87. At all relevant and material times, Coloplast developed, designed, manufactured, labeled, packaged, distributed, marketed, supplied, advertised, sold and otherwise engaged in all activities that are part and parcel of the sale and distribution of their product, the Pelvic Mesh Products, representing the quality and effectiveness to health care professionals, the FDA, Plaintiff and the public in such a way as to induce its purchase or use, thereby making an express warranty that the Coloplast Pelvic Mesh Products would conform to the representations. More specifically, Coloplast represented that the Pelvic Mesh Products were safe and effective, that it was safe and effective for use by individuals such as Plaintiff, and/or that it was safe and effective to treat Plaintiff's conditions.

88. At all relevant times, Coloplast intended that the Coloplast Pelvic Mesh Products be used in the manner that Plaintiff used and Coloplast expressly warranted that each product was safe and fit for use by consumers, that it was of merchantable quality, that its side effects were minimal, and that it was adequately tested and fit for its intended use.

89. At all relevant times, Coloplast was aware that consumers, including Plaintiff, would use the Coloplast Pelvic Mesh Products; which is to say that Plaintiff was a foreseeable user of the Coloplast Pelvic Mesh Products.

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

91. The Coloplast Pelvic Mesh Products were expected to reach and did in fact reach consumers, including Plaintiff and her implanting physician, without substantial change in the condition in which it was manufactured and sold by Coloplast.

92. At all relevant times, Plaintiff and/or her implanting physicians used the Coloplast Pelvic Mesh Products for the purpose and in the manner intended by Coloplast.

93. The representations, as set forth above, contained or constituted affirmations of fact or promises made by the seller to the buyer which related to the good and become part of the basis of the bargain creating an express warranty that the good shall conform to the affirmations of fact or promises.

94. The Coloplast Pelvic Mesh Products did not conform to the representations made by Coloplast. Defendants breached various express warranties with respect to the Pelvic Mesh Products including the following particulars:

a. Coloplast represented to Plaintiff and her physicians and healthcare providers through its labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that the Coloplast Pelvic Mesh Products were safe and effective, when in reality Coloplast fraudulently withheld and concealed information about the substantial risks of serious injury and/or death associated with using the Pelvic Mesh Products;

b. Coloplast represented to Plaintiff and her physicians and healthcare providers that the Coloplast Pelvic Mesh Products were as safe, and/or safer than other alternative procedures and devices and fraudulently concealed information, which demonstrated that the Pelvic Mesh Products were not safer than alternatives available on the market; and

c. Coloplast represented to Plaintiff and her physicians and healthcare providers that the Coloplast Pelvic Mesh Products were more efficacious than other alternative medications and fraudulently concealed information, regarding the true efficacy of the Pelvic Mesh Products.

95. In reliance upon Coloplast's express warranty, Plaintiff was implanted with the Coloplast Pelvic Mesh Products as prescribed and directed, and therefore, in the foreseeable manner normally intended, recommended, promoted and marketed by Coloplast.

96. At the time of making such express warranties, Coloplast knew or should have known that the Coloplast Pelvic Mesh Products do not conform to these express representations because the Coloplast Pelvic Mesh Products were not safe and have numerous serious side effects, many of which Coloplast did not accurately warn about, thus making the Coloplast Pelvic Mesh Products unreasonable unsafe for their intended purpose.

97. Members of the medical community, including physicians and other healthcare professionals, as well as Plaintiff and the public, relied upon the representations and warranties of Coloplast in connection with the use recommendation, description, and/or dispensing of the Coloplast Pelvic Mesh Products.

98. Plaintiff and Plaintiff's physician, by the use of reasonable care, could not have discovered the breached warranty and realized its danger.

99. Coloplast breached their express warranties to Plaintiff in that Coloplast's Pelvic Mesh Products were not of merchantable quality, safe and fit for their intended uses, nor were they adequately tested. The breach of the warranty was a substantial factor in bringing about Plaintiff's injuries.

100. The Pelvic Mesh Products implanted in Plaintiff failed to function as intended and as represented by Coloplast because they did not relieve the symptoms or otherwise alleviate the medical products they were intended to cure. Instead, the Pelvic Mesh Products caused Plaintiff to suffer severe and debilitating pain, mesh erosion, exposure/extrusion/protrusion, infections, bleeding, dyspareunia, bladder problems and bowel problems and other severe adverse health consequences. Because the Pelvic Mesh Products failed to conform to representations and were not suitable for the purpose for which they were used, Coloplast has breached its expressed warranties.

101. As a direct and proximate result of Coloplast's wrongful conduct, including Coloplast's breach of expressed warranty, Plaintiff has sustained and will continue to sustain severe and debilitating injuries, serious bodily injury, mental and physical pain and suffering and has incurred economic loss.

COUNT V
BREACH OF IMPLIED WARRANTY

102. Plaintiff hereby incorporates by reference and reavers each and every allegation contained in the foregoing paragraphs of this Complaint as if fully set forth herein and further states and alleges as follows:

103. At all relevant and material times, Defendants manufactured, distributed, advertised, promoted and sold the Coloplast Pelvic Mesh Products.

104. At all relevant times, Coloplast intended that the Coloplast Pelvic Mesh Products be implanted for the purposes and in the manner that Plaintiff or Plaintiff's implanting physicians in fact used them and Coloplast impliedly warranted each product to be of merchantable quality, safe and fit for such use, and was not adequately tested.

105. Coloplast was aware that consumers, including Plaintiff or Plaintiff's physicians, would implant Coloplast's Pelvic Mesh Products in the manner directed by the instructions for use; which is to say that Plaintiff was a foreseeable user of Coloplast's Pelvic Mesh Products.

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

107. The Coloplast Pelvic Mesh Products were expected to reach and did in fact reach consumers, including Plaintiff or Plaintiff's physicians, without substantial change in the condition in which they manufactured and sold Coloplast Pelvic Mesh Products.

108. Coloplast breached various implied warranties with respect to the Coloplast Pelvic Mesh Products, including the following particulars:

a. Coloplast represented through their labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters and regulatory submissions that the Coloplast Pelvic Mesh Products were safe and fraudulently withheld and concealed information about the substantial risks of serious injury and/or death associated with using the Pelvic Mesh Products;

b. Coloplast represented that the Coloplast Pelvic Mesh Products were safe, and/or safer than other alternative devices or procedures and fraudulently concealed information, which demonstrated that the Coloplast Pelvic Mesh Products were not as safe or safer than alternatives available on the market; and

c. Coloplast represented that the Coloplast Pelvic Mesh Products were more efficacious than other alternative medications and fraudulently concealed information regarding the true efficacy.

109. In reliance upon Coloplast's implied warranty, Plaintiff used the Pelvic Mesh Products as prescribed and in the foreseeable manner normally intended, recommended, promoted and marketed by Coloplast.

110. Coloplast breached their implied warranty to Plaintiff in that the Coloplast Pelvic Mesh Products were not of merchantable quality, safe and fit for its intended use, or adequately tested, in violation of Common Law principles.

111. As a direct and proximate result of Coloplast's wrongful conduct, including Coloplast's breach of implied warranty, Plaintiff has sustained and will continue to sustain severe and debilitating injuries, serious bodily injury, mental and physical pain and suffering and has incurred economic loss.

COUNT VI
COMMON LAW FRAUD

112. Plaintiff hereby incorporates by reference and reavers each and every allegation contained in the foregoing paragraphs of this Complaint as if fully set forth herein and further states and alleges as follows:

113. Coloplast falsely and fraudulently have represented and continue to represent to the Plaintiff, medical and healthcare community, the FDA and the public that Pelvic Mesh Products had been tested and were found to be safe and effective.

114. The representations made by Coloplast were, in fact, false. When Coloplast made their representations, Coloplast knew and/or had reason to know that those representations were false, and Coloplast willfully, wantonly, and recklessly disregarded the inaccuracies in their representations and the dangers and health risks to users of the Pelvic Mesh Products.

115. These representations were made by Coloplast with the intent of defrauding and deceiving the medical and healthcare community, Plaintiff and the public, and also inducing the

medical and healthcare community, Plaintiff and the public, to recommend, prescribe, dispense, and purchase the Pelvic Mesh Products for use as a means of treatment for stress urinary incontinence and/or pelvic organ prolapse, all of which evinced a callous, reckless, willful and depraved indifference to the health, safety and welfare of Plaintiff.

116. In representations to Plaintiff and/or to Plaintiff's healthcare providers, Coloplast fraudulently concealed and intentionally omitted the following material information:

a. That Coloplast's Pelvic Mesh Products were not as safe as other products and procedures available to treat stress urinary incontinence and/or pelvic organ prolapse;

b. That the risk of adverse events with the Coloplast Pelvic Mesh Products was higher than with other products and procedures available to treat stress urinary incontinence and/or pelvic organ prolapse;

c. Coloplast's Pelvic Mesh Products were not adequately tested;

d. That the limited clinical testing revealed that Coloplast's Pelvic Mesh products had a higher risk of adverse effects, in addition to, and above and beyond those associated with other products and procedures available to treat stress urinary incontinence and/or pelvic organ prolapse;

e. That Coloplast deliberately failed to follow up on the adverse results from clinical studies and formal and informal reports from physicians and other healthcare providers and buried and/or misrepresented those findings;

f. That Coloplast was aware of dangers in the Coloplast Pelvic Mesh Products in addition to and above and beyond those associated with other products and

procedures available to treat stress urinary incontinence and/or pelvic organ prolapse;

g. That Coloplast's Pelvic Mesh Products were defective, and that they caused dangerous and adverse side effects, including but not limited to higher incidence of erosion and failure, at a much more significant rate than other products and procedures available to treat stress urinary incontinence and/or pelvic organ prolapse;

h. That patients needed to be monitored more regularly than usual while using the Coloplast Pelvic Mesh Products and that in the event the Pelvic Mesh Product needed to be removed that the procedures to remove them had a very high failure rate and/or needed to be performed repeatedly;

i. That the Coloplast Pelvic Mesh Products were manufactured negligently;

j. That the Coloplast Pelvic Mesh Products were manufactured defectively;

k. That the Coloplast Pelvic Mesh Products were designed negligently and designed defectively.

117. Coloplast was under a duty to disclose to Plaintiff and her physicians, the defective nature of the Coloplast Pelvic Mesh Products, including, but not limited to, the heightened risks of mesh erosion, extrusion/protrusion, chronic pain, mesh contraction, infection, abscesses, fistula, inflammation, scar tissue, organ perforation, dyspareunia, bleeding, neuropathic, and other acute and chronic nerve damage and pain, pudendal nerve damage, vaginal scarring, vaginal shrinkage, pelvic floor damage, pelvic pain, urinary and fecal problems, prolapse of organs and other permanent injuries.

118. Coloplast had sole access to material facts concerning the defective nature of the Pelvic Mesh Products and their propensity to cause serious and dangerous side effects and hence, cause dangerous injuries and damage to persons who used Coloplast's Pelvic Mesh Products.

119. Coloplast's concealment and omissions of material fact concerning the safety of the Pelvic Mesh products were made purposefully, willfully, wantonly, and/or recklessly to mislead, to cause Plaintiff's physicians and healthcare providers to purchase, prescribe, and/or dispense the Coloplast Pelvic Mesh Products; and/or to mislead Plaintiff into reliance and cause Plaintiff to use the Coloplast Pelvic Mesh Products.

120. At the time these representations were made by Coloplast, and at the time Plaintiff use Coloplast's Pelvic Mesh Products, Plaintiff was unaware of the falsehood of these representations, and reasonably believed them to be true.

121. Coloplast knew and had reason to know that the Coloplast Pelvic Mesh Products could and would cause severe and grievous personal injury to the users of Coloplast's Pelvic Mesh Products, and that they were inherently dangerous in a manner that exceeded any purported, inaccurate, or otherwise downplayed warnings.

122. In reliance upon these false representations, Plaintiff was induced to, and did use Coloplast's Pelvic Mesh Products, thereby sustaining severe and permanent personal injuries and damages. Coloplast knew or had reason to know that Plaintiff and her physicians and other healthcare providers had no way to determine the truth behind Coloplast's concealment and omissions, and that these included material omissions of facts surrounding the use of the Coloplast Pelvic Mesh Products, as described in detail herein.

123. Plaintiff reasonably relied on revealed "facts" which foreseeably and purposefully suppressed and concealed facts that were critical to understanding the real dangers inherent in the use of the Coloplast Pelvic Mesh Products.

124. Having knowledge based upon Coloplast's research and testing, or lack thereof, Coloplast blatantly and intentionally distributed false information, including but not limited to assuring Plaintiff, the public and Plaintiff's healthcare providers and physicians, that Coloplast's Pelvic Mesh Products were safe for use as a means of providing relief from stress urinary incontinence and/or pelvic organ prolapse and were as safe or safer than other products and/or procedures available and on the market. As a result of Coloplast's research and testing, or lack thereof, Coloplast intentionally omitted, concealed and suppressed certain results of testing and research to healthcare professionals, Plaintiff and the public at large.

125. Coloplast had a duty when disseminating information to the public to disseminate truthful information; and a parallel duty not to deceive the public, Plaintiff, Plaintiff's healthcare providers and physicians, and the United States Food and Drug Administration ("FDA").

126. The information distributed to the public, the medical and healthcare community, the FDA, and Plaintiff, by Coloplast included, but was not limited to websites, information presented at medical and professional meetings, information disseminated by sales representatives to physicians and other medical care providers, reports, press releases, advertising campaigns, television commercials, print advertisements, billboards, and other commercial media containing material representations, which were false and misleading, and contained omissions and concealment of the truth about the dangers of the use of the Coloplast Pelvic Mesh Products.

127. Coloplast intentionally made material misrepresentations to the medical community and public, including Plaintiff, regarding the safety of the Coloplast Pelvic Mesh Products specifically that the Pelvic Mesh Products did not have dangerous and/or serious adverse health safety concerns, and that the Coloplast Pelvic Mesh Products were as safe or safer than other means of treating stress urinary incontinence and/or pelvic organ prolapse.

128. Coloplast intentionally failed to inform the public, including Plaintiff, of the high failure rate including erosion, the difficulty or impossibility of removing the mesh, and the risk of permanent injury.

129. Coloplast chose to over-promote the purported safety, efficacy and benefits of the Coloplast Pelvic Mesh Products instead.

130. Coloplast's intent and purpose in making these misrepresentations was to deceive and defraud the public, the medical and healthcare community, and the Plaintiff; to gain the confidence of the public, the medical and healthcare community, and the Plaintiff; to falsely assure them of the quality and fitness for use of the Pelvic Mesh Products; and induce the public, the medical and healthcare community, and the Plaintiff to request, recommend, prescribe, dispense, purchase and continue to use Coloplast's Pelvic Mesh Products.

131. Coloplast made claims and representations in its documents submitted to the FDA and its reports to the public and to healthcare professionals and in advertisements that Coloplast's Pelvic Mesh Products had innovative beneficial properties and did not present serious health risks.

132. These representations, and others made by Coloplast, were false when made and/or were made with the pretense of actual knowledge when such knowledge did not actually exist, and were made recklessly and without regard to the true facts.

133. These representations, and others made by Coloplast, were made with the intention of deceiving and defrauding public, the medical and healthcare community, and the Plaintiff, and were made in order to induce Plaintiff, and her healthcare professionals, to rely on misrepresentations, and caused Plaintiff to purchase, rely, use and request the Coloplast Pelvic Mesh Products and their healthcare professionals to dispense, recommend or prescribe the Coloplast Pelvic Mesh Products.

134. Coloplast recklessly and/or intentionally falsely represented the dangerous and serious health and safety concerns inherent in the use of the Coloplast Pelvic Mesh Products to the public at large, for the purpose of influencing the sales of products know to be dangerous and defective, and/or not as safe as other alternatives.

135. Coloplast willfully and intentionally failed to disclose the truth, failed to disclose material facts and made false representations, for the purpose of deceiving and lulling Plaintiff, as well as her healthcare professionals, into a false sense of security, so that Plaintiff and her healthcare provider would rely on Coloplast's representations, and Plaintiff would request and purchase the Coloplast Pelvic Mesh Products, and that her healthcare providers would dispense, prescribe and recommend the Coloplast Pelvic Mesh Products.

136. Coloplast utilized direct-to-consumer advertising to market, promote and advertise the Coloplast Pelvic Mesh Products.

137. At the time the representations were made, Plaintiff and her healthcare providers did not know the truth about the dangers and serious health and/or safety risks inherent in the use of the Coloplast Pelvic Mesh products. Plaintiff did not discover the true facts about the dangers and serious health and/or safety risks, nor did Plaintiff discover Coloplast's false representations,

nor would Plaintiff with reasonable diligence have discovered the true facts or Coloplast's misrepresentations.

138. Had Plaintiff know the true facts about the dangers and serious health and/or safety risks of the Coloplast Pelvic Mesh Products, Plaintiff would not have purchased, used or relied on Coloplast's Pelvic Mesh Products.

139. Coloplast's wrongful conduct constitutes fraud and deceit, and was committed and perpetrated willfully, wantonly, and/or purposefully on Plaintiff.

140. As a direct and proximate result of Coloplast's wrongful conduct, including Coloplast's fraud, Plaintiff has sustained and will continue to sustain severe and debilitating injuries, serious bodily injury, mental and physical pain and suffering and has incurred economic loss.

COUNT VII
CONSTRUCTIVE FRAUD

141. Plaintiff hereby incorporates by reference and reavers each and every allegation contained in the foregoing paragraphs of this Complaint as if fully set forth herein and further states and alleges as follows:

142. Coloplast is in a unique position of knowledge concerning the quality, safety and efficacy of Coloplast's Pelvic Mesh Products, which knowledge is not possessed by Plaintiff or their physicians, and Coloplast thereby holds a position of superiority over Plaintiffs and their physicians.

143. Despite their unique and superior knowledge regarding the defective nature of Coloplast's Pelvic Mesh Products, Coloplast continues 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 to the intended use of Coloplast's Pelvic Mesh Products, as compared to other products and forms of treatment.

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

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

146. Coloplast's representations about safety and efficacy are false, and Coloplast knew the representations were false when made, or in the alternative made such representations recklessly without any knowledge of the truth and as a positive assertion. Coloplast made such false representations about safety and efficacy through its written materials and speakers, including their advertisements, trainers, lab faculty, leave behinds, publications, regulatory submissions and other written and oral materials.

147. Upon information and belief, Coloplast's misrepresentations were designed, and made with the intention, to induce physicians and Plaintiff to prescribe, dispense, recommend and/or purchase the Coloplast Pelvic Mesh Products. Plaintiffs and the medical community have relied upon Coloplast's material misrepresentations.

148. Coloplast took unconscionable advantage of their dominant position of knowledge with regard to Plaintiffs and the medical providers and engaged in constructive fraud in their relationship with Plaintiffs and the medical providers. Plaintiffs reasonably and justifiably relied on Coloplast's misrepresentations.

149. As a direct and proximate result of Coloplast's wrongful conduct, including Coloplast's constructive fraud, Plaintiff has sustained and will continue to sustain severe and debilitating injuries, serious bodily injury, mental and physical pain and suffering and has incurred economic loss in addition to loss of consortium.

COUNT VIII
NEGLIGENT MISREPRESENTATION

150. Plaintiff hereby incorporates by reference and reavers each and every allegation contained in the foregoing paragraphs of this Complaint as if fully set forth herein and further states and alleges as follows:

151. Coloplast, a for profit company, had a duty to accurately and truthfully represent to the medical and healthcare community, Plaintiff and the public, that the Pelvic Mesh Products had not been adequately tested and found to be safe and effective for the treatment of urinary incontinence and pelvic organ prolapse. The representations made by Coloplast, in fact, were false.

152. Coloplast failed to exercise ordinary care in the representations concerning the Pelvic Mesh Products while Coloplast was involved in their development, design, manufacture, label, package, distribution, marketing, testing, supply, advertisement, selling, quality assurance, quality control and otherwise engaged in all activities that are part and parcel of the sale and distribution in interstate commerce, because Coloplast negligently misrepresented the Pelvic Mesh Products' high risk of unreasonable, dangerous, adverse side effects.

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

154. As a foreseeable, direct and proximate result of the negligent misrepresentation of Coloplast as set forth herein, Coloplast 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 it created a high risk, and/or higher than acceptable risk, and/or higher than reported and represented risk, of adverse side effects, including mesh erosion, extrusion/protrusion, chronic pain, mesh contraction, infection, abscesses, fistula, inflammation, scar tissue, organ perforation, dyspareunia, bleeding, neuropathic, and other acute and chronic nerve damage and pain, pudendal nerve damage, vaginal scarring, vaginal shrinkage, pelvic floor damage, pelvic pain, urinary and fecal problems, prolapse of organs, and in many cases forcing the need for intensive 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, injuries to the woman's intimate partner and other severe and personal injuries, which are permanent and lasting in nature.

155. Coloplast took unconscionable advantage of their dominant position of knowledge with regard to Plaintiff and the medical providers and engaged in negligent misrepresentations in their relationship with Plaintiff and the medical providers. Plaintiff reasonably and justifiably relied on Coloplast's misrepresentations.

156. As a direct and proximate result of Coloplast's wrongful conduct, including Coloplast's negligent misrepresentation, Plaintiff has sustained and will continue to sustain severe and debilitating injuries, serious bodily injury, mental and physical pain and suffering and has incurred economic loss.

COUNT IX
PUNITIVE DAMAGES

157. Plaintiff hereby incorporates by reference and reavers each and every allegation contained in the foregoing paragraphs of this Complaint as if fully set forth herein and further states and alleges as follows:

158. At all times relevant hereto, Coloplast knew or should have known that the Coloplast Pelvic Mesh Products were inherently more dangerous with respect to the risks of erosion, 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 product, as well as other severe and personal injuries which are permanent and lasting in nature.

159. At all times material hereto, Coloplast attempted to misrepresent and did misrepresent facts concerning the safety of the Coloplast Pelvic Mesh Products.

160. At the time Coloplast designed, manufactured, marketed, labeled, packaged, and sold the dangerous and defective Pelvic Mesh Products and failed to adequately warn Plaintiff of the dangerous and defective nature of the Pelvic Mesh Products and thereby caused Plaintiff's injuries, Coloplast knew, or in the exercise of the appropriate degree care should have known, that its conduct created an extreme degree of risk of serious injury to others and thereby showed complete and reckless indifference to, and conscious disregard for the safety of others, including Plaintiffs, and such conduct warrants the imposition of punitive damages under all applicable legal standards.

161. Coloplast's misrepresentations included knowingly withholding material information from the medical community and the public, including Plaintiff, concerning the safety and efficacy of the Coloplast Pelvic Mesh Products.

162. At all times material hereto, Defendants knew and recklessly disregarded the fact that the Coloplast Pelvic Mesh Products cause debilitating and potentially lethal side effects with greater frequency than safer alternative methods, products and/or procedures and/or treatments.

163. At all times material hereto, Coloplast knew and recklessly disregarded the fact that the Coloplast Pelvic Mesh Products cause debilitating and potentially lethal side effects with greater frequency than safer alternative products and/or methods of treatment and recklessly failed to advise the FDA of same.

164. At all times material hereto, Coloplast intentionally misstated and misrepresented data and continue to misrepresent data so as to minimize the risk the risk of injuries caused by the Coloplast Pelvic Mesh Products.

165. Notwithstanding the foregoing, Coloplast continues to aggressively market the Coloplast Pelvic Mesh Products to consumers, without disclosing the true risk of side effects where there were safer alternatives.

166. Coloplast knew of the Coloplast Pelvic Mesh Products' defective and unreasonable dangerous nature, but continues to manufacture, produce, assemble, market, distribute, and sell the Coloplast Pelvic Mesh Products so as to maximize sales and profits at the expense of the health and safety of the public, including Plaintiff, in conscious and/or negligent disregard of the foreseeable harm caused by the Coloplast Pelvic Mesh Products.

167. Coloplast continues to intentionally and/or recklessly and/or grossly negligently fail to disclose to the public, including Plaintiff, the serious side effects of the Coloplast Pelvic Mesh Products in order to ensure continued and increased sales.

168. Coloplast intentionally, recklessly, and/or grossly negligent failure to disclose information deprived Plaintiffs of necessary information to enable them to weigh the true risks of using the Coloplast Pelvic Mesh Products against their benefits.

169. As a direct and proximate result of Coloplast's wrongful conduct, including the acts and omissions listed above, Plaintiff has sustained and will continue to sustain severe and debilitating injuries, serious bodily injury, mental and physical pain and suffering and has incurred economic loss.

WHEREFORE, Plaintiff prays for relief against Defendants Analytic Biosurgical Solutions, Coloplast A/S, Coloplast Corporation, Coloplast Manufacturing, US, LLC and Mentor Worldwide, LLC, jointly and severally, as follows:

a) Compensatory damages, in excess of the amount required for federal diversity jurisdiction, and in an amount to totally compensate Plaintiffs for all of their injuries and damages, both past, present and future;

b) Special damages, in excess of the amount required for federal diversity jurisdiction and in an amount to fully compensate Plaintiff for all of their injuries and damages, both past and present, including but not limited to, past and future medical expenses, lost income, loss of earning capacity, permanent disability, and pain and suffering;

c) Restitution and disgorgement of profits;

d) Punitive damages;

e) Attorneys' fees, expenses, and costs of this suit;

f) Pre-judgment and post-judgment interest in the maximum amount allowed by law; and

g) Such other relief, monetary or equitable, as this Court deems necessary, just and proper

JURY DEMAND

Plaintiffs specifically demand a trial by jury of all claims asserted in this Complaint.

Dated: June 18, 2012

Respectfully submitted,

/s G. Sean Jez
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