UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
ORLANDO DIVISION

SHELBY MARIE REBANDO, BRAD JAMES REBANDO, CASSONDRA CAPUTO, DANIELLE DEBRA HANSE, BRIAN JAMES HANSE, NAKEIA WEBBE, and CURTNEY WEBBE *Plaintiffs* v. COOPERSURGICAL , INC., THE COOPER COMPANIES, INC., FEMCARE, LTD. – UK SUBSIDIARY OF UTAH MEDICAL PRODUCTS, INC., and UTAH MEDICAL PRODUCTS, INC. *Defendants*	)	Case No.

PLAINTIFFS' COMPLAINT AND JURY DEMAND

NOW COMES Plaintiffs, Shelby and Brad Rebando, Cassondra Caputo, Danielle and Brian Hanse, and Nakeia and Curtney Webbe (hereinafter "Plaintiff(s)" and/or "Mrs. Cuputo" and/or "Mrs. Hanse" and/or "Mrs. Rebando" and/or "Mrs. Webbe") by and through their counsel, Griffin Purnell LLC, and for their cause of action against Defendants CooperSurgical, Inc., The Cooper Companies, Inc., Femcare, Ltd. – UK subsidiary of Utah Medical Products, Inc., and Utah Medical Products, Inc. (collectively hereinafter "Defendants"), all jointly

and severally, as the companies and/or successors in interest to the companies that designed, developed, manufactured, tested, labeled, packaged, distributed, marketed and/or sold the Filshie Clip medical device that was surgically used in Plaintiffs and others throughout the United States and the world. Accordingly, Plaintiffs allege and state to the Court as follows:

I. INTRODUCTION

1. Plaintiffs bring this civil action to recover damages within the jurisdictional limits of this Court including all (1) General Damages; (2) Special Damages; and (3) Punitive Damages as well as all other damages allowable under Florida law as a result of the use, design, manufacture, surveillance, sale, marketing, advertising, promotion, labeling, packaging, and distribution of Filshie Clips.

2. Plaintiffs bring claims fully set forth below asserting: (1) design defect; (2) manufacturing defect; (3) strict liability; (4) negligence; (5) gross negligence; and (6) punitive damages.

3. This claim arises from Mrs. Caputo's, Mrs. Hanse's, Mrs. Rebando's and Mrs. Webbe's Filshie Clip tubal ligation procedures which, because of Defendants' actions and omissions, resulted in a series of damages.

II. PARTIES

4. Plaintiff Cassondra Caputo resides in Lake City, Florida and is subject to the jurisdiction of this Court, and is deemed to be a resident and citizen of the State of Florida for purposes of venue and jurisdiction.

5. Plaintiffs Shelby and Brady Rebando reside in Howey In The Hills, Florida, and are subject to the jurisdiction of this Court, and are deemed to be residents and citizens of the State of Florida for purposes of venue and jurisdiction.

6. Plaintiffs Danielle and Brian Hanse reside in Hernando Beach, Florida, and are subject to the jurisdiction of this Court, and are deemed to be residents and citizens of the State of Florida for purposes of venue and jurisdiction.

7. Plaintiff Nakeia Webbe resides in Jacksonville, Florida and Plaintiff Curtney Webbe resides in Basseterre, Saint Kitts and Nevis, and are subject to the jurisdiction of this Court, and are deemed to be residents and citizens of the State of Florida and Saint Kitts and Nevis for purposes of venue and jurisdiction.

8. Defendant, The Cooper Companies, Inc. ("Cooper Companies") is a Delaware corporation with its principal place of business located at 6101 Bollinger Canyon Road, in San Ramon, California. For diversity of citizenship purposes, Defendant Cooper Companies, Inc. is a citizen of both Delaware and California. Cooper Companies, Inc. may be served with process by serving its registered agent at 6140 Stoneridge Mall Road, Suite 590, Pleasanton, CA 94588.

9. Defendant CooperSurgical, Inc. ("CooperSurgical") is a Delaware corporation with its principal place of business located at 95 Corporate Drive in Trumbull, Connecticut. CooperSurgical may be served with process by serving its registered agent at CooperSurgical, Inc., 95 Corporate Drive, Trumbull, CT 06611.

10. Defendant Femcare, Ltd. is a UK subsidiary of Utah Medical Products, Inc. with its principal place of business located at 32 Premier Way, Romsey, Hampshire SO51 9DQ, United Kingdom. Femcare, Ltd. – UK Subsidiary of Utah Medical Products, Inc. may be served with process by serving its registered agent Karen Elizabeth Glasbey, Femcare UK, 32 Premier Way, Romsey, Hampshire, United Kingdom SO519DQ.

11. Defendant Utah Medical Products, Inc. is the parent company of Femcare, Ltd. with its principal place of business located at 7043 South 300 West, Midvale, Utah 84047-1048 and may be served with process by serving its registered agent Ben Shirley at 7043 South 300 West, Midvale, UT 84047.

12. CooperSurgical is a subsidiary of Defendant Cooper Companies, Inc. Defendant CooperSurgical is a citizen of both Delaware and Connecticut for diversity of citizenship purposes.

13. Femcare, Ltd. is a UK subsidiary of Utah Medical Products, Inc., and a citizen of England for diversity of citizenship purposes. Utah Medical Products, Inc. is a citizen of Utah for diversity of citizenship purposes.

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

III. JURISDICTION & VENUE

15. This Court has subject matter original jurisdiction through diversity of citizenship pursuant to 28 U.S.C. §1332(a) because the Plaintiffs are citizens of Florida and Saint Kitts and Nevis, the named Defendants are citizens of different states and the amount in controversy exceeds the sum of value of $75,000.00, exclusive of interest and costs.

16. This Court has specific jurisdiction over these Defendants because they purposefully availed themselves of the privilege of conducting business in the State of Florida and established minimum contacts sufficient to confer jurisdiction over these Defendants, and the assumption of jurisdiction over Defendants will not offend traditional notions of fair play and substantial justice and is consistent with constitutional requirements of due process.

17. CooperSurgical, Femcare, Ltd., and Utah Medical Products sell their products and intend that they be used by medical professionals treating patients in Florida.

18. At all times relevant hereto and alleged herein, the Defendants conducted and continue to regularly conduct substantial business within the State

of Florida which included and continues to include, the research, safety surveillance, manufacture, sale, distribution and/or marketing of Filshie Clips which are distributed through the stream of interstate and intrastate commerce in the State of Florida, and within the Middle District of Florida.

19. Venue is proper in this District pursuant to 28 U.S.C. § 1391(b) and 18 U.S.C. §1965 (a) because a substantial part of the events or omissions giving rise to the claim occurred in this District and each Defendant transacts business affairs and conducts activity that gave rise to the claim of relief in this District.

IV. FACTUAL BACKGROUND

a. *Plaintiffs Bring this Action Because Filshie Clips Injured them after migration.*

20. Plaintiffs in this action seek compensation for injuries they sustained in connection from the use of Filshie Clips, a medical device used in tubal ligations.

21. This action is brought by Plaintiffs who were implanted with a female birth control device known as a Filshie Clip. In short, this device is intended to cause bilateral occlusion (blockage) of the fallopian tubes by applying a clip onto the fallopian tubes which then anchors and elicits tissue growth, theoretically causing a closure of the tubes. However, in reality, the clips migrate from the tubes wreaking havoc on the female body.

b. What is a Filshie Clip and How is it Supposed to Work?

22. Filshie Clips are part of the "Filshie Clip system" for laparoscopic tubal ligation which involves applying a titanium clip with silicone rubber lining around each of the fallopian tubes.

23. The Filshie Clip works by exerting continued pressure on the fallopian tube, causing avascularization for the 3 to 5 mm area it encompasses. The silicone continues this pressure even after necrosis starts and the fallopian tube decreases in size. Fibrosis then occurs, and the clip is peritonealized if all goes as planned.

24. Defendants' disposable delivery system consists of an applicator which allows insertion into the women's body to allow the clip to be snapped onto the fallopian tube.

25. A women's choice of birth control is a deeply personal decision, particularly when choosing a long-acting form of birth control like a tubal ligation which should permanently alter a women's body.

c. Background on Filshie Clips and the FDA Process.

26. Femcare, the manufacturer of the Filshie Clip, obtained Conditional Premarket Approval (PMA) by the Food and Drug Administration (FDA). The Defendants' failure to conform with the FDA requirements prescribed in the PMA and violations of relevant state and federal law form the basis of this lawsuit.

27. Class III medical devices are those that either "present a potential unreasonable risk of illness or injury or are for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health." 21 U.S.C. § 360(c)(1)(c).

28. Because Filshie Clips are classified as a Class III medical device the FDA evaluated Filshie Clips' safety and effectiveness prior to granting the product Conditional PMA in 1996.

29. At that time, the FDA authorized its commercial distribution. Such approval was contingent upon the FDA's finding that there was "a reasonable assurance" of the device's safety and effectiveness. *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008).

30. However, the PMA imposed certain conditions on Femcare's sale of the product, including certain labeling requirements and restrictions on false or misleading advertising.

31. The Medical Device Amendments of 1976, 21 U.S.C. § 360(c) *et seq*. (the "MDA"),

expressly preempt certain state law requirements, stating that:

> Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement –

> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter. 21 U.S.C. § 360k(a).

32. In *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008), the United States Supreme Court set forth a two-step analysis for determining whether a claim is expressly preempted pursuant to the statute. 552 U.S. at 321-22.

33. First, the court must ascertain whether the federal government has established requirements applicable to the medical device at issue. *Id*. at 321. The Supreme Court concluded that any Class III device that receives premarket approval, which is specific to individual devices, satisfies this first prong of the § 360k(a) test.

34. Second, the court must determine whether the state common law claims relate to safety and effectiveness and impose requirements that are "different from, or in addition to" those imposed by federal law. *Riegel*, 552 U.S. at 321-22 (quoting 21 U.S.C. § 360k(a)(1)).

35. Here, the express preemption provision "does not [, however,] prevent a State from providing a damages remedy for claims premised on a violation of

FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements." *Riege*l, 552 U.S. at 330.

d. Plaintiffs' Claims are Not Preempted by Federal Law Because They Do Not Impose Additional Requirements on the Defendants.

36. Personal injury claims caused by a medical device were not swept away on the day the MDA was enacted in 1976.

37. The PMA process does not establish that a medical device manufacturer and/or distributor are entirely immune from liability.

38. § 360k(a) does not preempt state-law claims against a medical device manufacturer based on duties that parallel federal requirements because such claims do not impose requirements that are "different from, or in addition to" those imposed by federal law.

39. State tort law provides a right of action to a person who is injured when a device manufacturer's noncompliance with federal reporting standards results in a failure to warn of the risks of using a device and causes injury to a patient.

e. CooperSurgical, Femcare, Ltd., and Utah Medical Products Design and Promote Defective Filshie Clips.

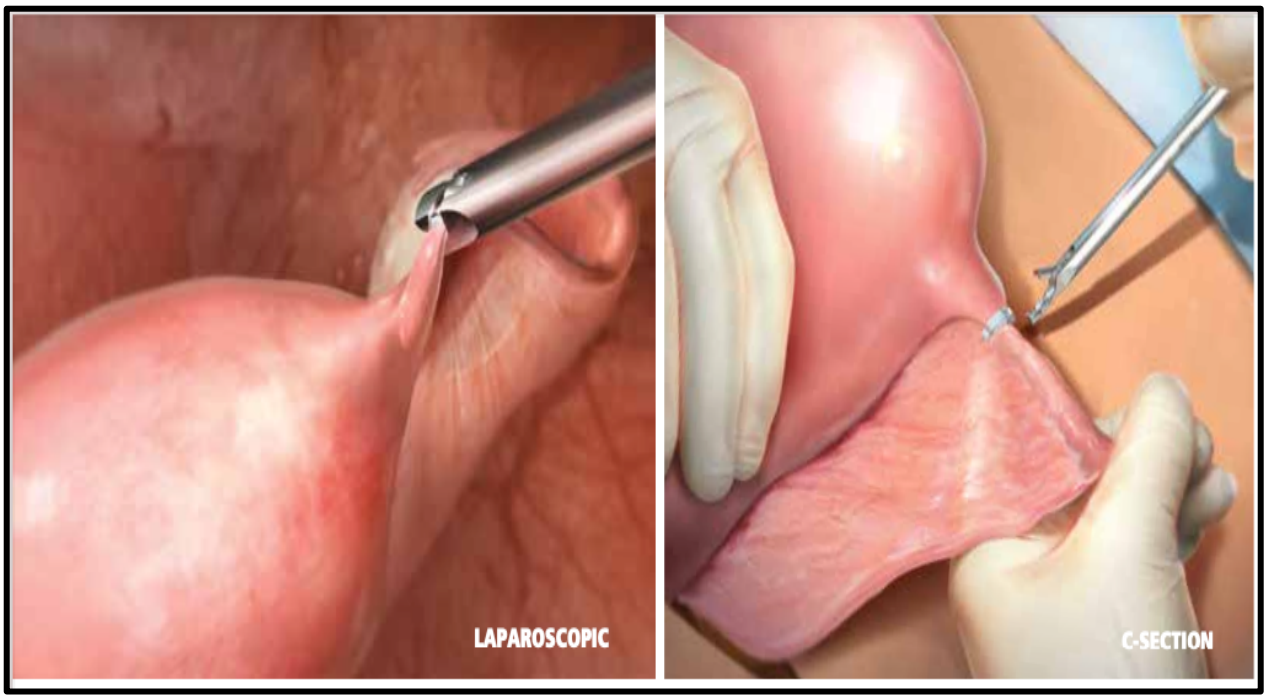
40. Defendants, CooperSurgical, Femcare, Ltd., and Utah Medical Products, singularly and in combination, designed, manufactured, sold and

distributed Filshie Clips and related equipment utilized in Plaintiffs' tubal ligations.

41. For years, Defendants intentionally manufactured, sold and distributed Filshie Clips to the public as a quick, easy, and simple form of sterilization. Defendants told women they could use Filshie Clips to effectively prevent pregnancy while the product was in place and that the product was safe. Defendants' representations were false.

42. Created by Marcus Filshie in the late 1970s, more than 12 million women worldwide have undergone tubal ligation with the Filshie Clip method.

43. As stated above, the Filshie Clip works by exerting continued pressure on the fallopian tube, causing avascularization for the 3 to 5 mm area it encompasses. The silicone continues this pressure even after necrosis starts and the fallopian tube decreases in size. Fibrosis then occurs, and the clip is peritonealized. The clips are placed perpendicular to the isthmic portion of the tube, so that it completely encompasses the tube, and the lower edge of the jaw can be seen in the mesosalpinx.



[1]

44. The Filshie Clip System was manufactured and promoted prior to 1996 in Europe and elsewhere. In 1996, the Filshie Clip System received PMA from the FDA, after information was submitted regarding, among other things, the safety and efficacy of the system.

45. Subsequently, the Filshie Clip System was marketed and sold throughout the United States, including the State of Florida.

f. CooperSurgical, Femcare, Ltd., and Utah Medical Products Failed to Inform Patients of the Risks Associated with Filshie Clips.

[1] Medical drawing of Filshie Clips being applied in a laparoscopic and c-section procedure provided by CooperSurgical in their surgical products catalog.

46. It should go without saying that it is of the utmost importance that women know all risks associated with a particular type of birth control given that a woman's choice of birth control can have long-term consequences on her health.

47. Filshie Clips pose significant health risk, and the product has subjected untold thousands of women to significant injuries. These injuries stem from the simple fact that Filshie Clips have a propensity to migrate after being placed on the fallopian tubes. Migration of the clips following a normal application is estimated to occur over 25% of the time. The pathophysiology is related to the speed at which peritoneal-like tissue forms over the clip anchoring it to the fallopian tube.[2]

48. The migration of the clip often requires surgical intervention to remove the Filshie Clips from the woman's body. Defendants neither warned nor adequately informed Plaintiffs nor their healthcare providers how frequently these migrations occur or the severity and permanency of the potential injuries even though Defendants had received adverse reports and knew or should have known Filshie Clips had a significant propensity to migrate.

49. Women and their doctors depend on Defendants, the manufacturers and distributors of products like Filshie Clips, to be forthcoming about the safety and risks of Filshie Clips. This reliance on Defendants was warranted. The

[2] G. Marcus Filshie, *Female sterilization: medico legal aspects,* Reviews in Gynaecological Practice; Vol.1 Summer 2001.

regulatory scheme that governs Filshie Clips is premised on a system whereby the manufacturer is responsible for reporting relevant safety information to the public.

50. The onus is on the manufacturer to come forward with any safety risks because the public and the U.S. Food and Drug Administration ("FDA") would otherwise have no insight of adverse events.

51. The Plaintiffs have suffered as a result of Defendants' failure to report adverse events involving the Filshie Clip. That failure violated requirements imposed by the FDA.

52. As shown below in the excerpt from the Defendants' PMA application, during the premarket approval process, it was reported to the FDA that the Filshie Clip System had a migration incidence of .13%.

ADVERSE EFFECTS

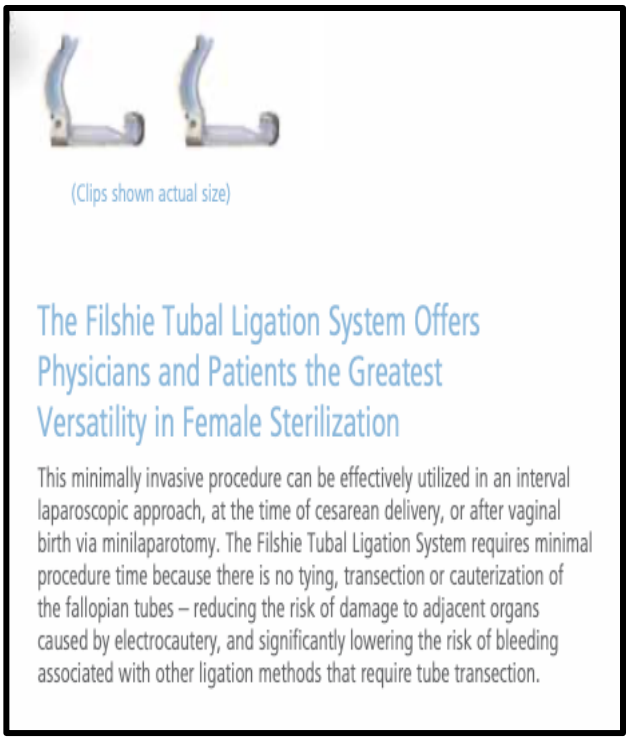
The following adverse effects have been reported with the use of the Filshie Clip (see Table 1).

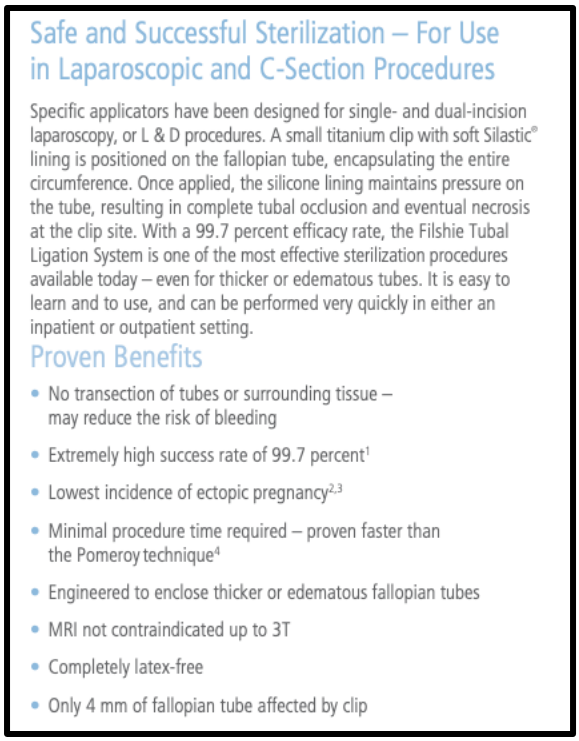
pregnancy (0.46%); ectopic pregnancy (0.016%); clip migration or expulsion (0.13%); misapplication to ovarian ligament, broad ligament, omentum, bowel, tubal serosa, cornual or broad ligament (0.05%); pain and cramping (35.7%);

53. However, the risk of clip migration was significantly higher and continued to increase from year to year since the initial PMA. Despite these increases, Defendants failed to address the Filshie Clips safety issues, even though adverse event reports did or should have alerted them to a product defect causing the device to cause injuries.

54. Rather than inform of the risks, CooperSurgical, Femcare, Ltd., and Utah Medical Products tout the benefits of the Filshie Clip version of the bilateral tubal ligation procedure over other available procedures. As noted in the press release regarding the Femcare, Ltd. purchase, the Filshie Clip System was claimed to be "safer than electrocautery and the newer hysteroscopic devices" without mention of the risk of migration associated with the clips.

> In summary, the Filshie Clip is as effective as the newest occlusive devices and much more effective than the more traditional sterilization approaches, is as easy or easier to place as any of the traditional techniques and easier than the newer hysteroscopic devices, is safer than electrocautery and the newer hysteroscopic devices when placed by less than well-trained and skilled clinicians, and has a substantially higher probability of reversibility when compared to all of the other approaches for women who later decide they may like to get pregnant.





55. Defendants had a duty to act as reasonable manufacturers and distributors of medical devices. They had a duty to continually monitor their product, including, but not limited to, its design, manufacturing, performance, safety profile, and labeling. They had a duty to continually test their product and ensure it was safe and would perform as intended. Yet Defendants breached their duties and, as a result, Plaintiffs were injured.

56. The knowledge Defendants have regarding the migration issues involved with the Filshie Clip Systems not only triggers responsibility under Florida law for product liability, they also imposed parallel duties on the Defendants pursuant to the Food, Drug, and Cosmetic Act (FDCA) to accurately report and update the FDA of the same. These duties, both under Florida product liability law and the FDCA, are substantially similar. The Florida product liability law does not impose a higher standard than the FDCA.

57. If Defendants had timely disclosed the propensity and severity of risks associated with use of the Filshie Clips, Plaintiffs' injuries could have been avoided. Instead, Defendants did nothing, and for that, Plaintiffs here seek redress both to compensate them for their losses and to strongly deter future, similar misconduct.

g. Mrs. Hanse's experience with the Filshie Clips - Plaintiff is Implanted with Filshie Clips in her Tubal Ligation.

58. In March 2011, Mrs. Hanse underwent a tubal ligation procedure.

59. The tubal ligation procedure used Filshie Clips.

60. Plaintiff was provided with a Disclosure and Consent for medical and surgical procedures which included generic risks and hazards associated with the procedure. Plaintiff was not told the Filshie Clip system was being used for her procedure, more specifically she was not advised of the potential risk of migration and the appurtenant damages that could be caused by the Filshie Clips.

61. The only risks mentioned were associated with the ligation procedure itself.

62. At the time, and upon information and belief to date, the product information sheet supplied to her healthcare providers made no mention of the actual rate of migration known of the Filshie Clips.

63. Plaintiff suffered several adverse symptoms related to the clip migration. These included but are not limited to severe pelvic pain, stomach pain, sexual discomfort, unusually painful menstrual cycles, severe dermatologic rashes, and ovarian pain.

64. Plaintiff underwent a uterine oblation in 2012, in an effort to ease her pain, to no avail – the pain continued. She was informed by her medical providers that she would simply have to live with the pain because they could not determine what was causing it.

h. Mrs. Hanse Discovers The Cause of Her Suffering.

65. In June 2018, during the course of a hip x-ray, the Filshie Clips were located. The clips were not where they were supposed to be – they had migrated.

66. The Filshie Clips had migrated from their original placement.

67. Plaintiff was informed the Filshie Clips remained in her body and were displaced.

68. Plaintiff underwent an exploratory surgery to find and remove the migrated clips. During the surgery, it was uncovered that one of the clips had migrated and was lodged in Mrs. Hanse's omentum. The clip was removed. The other clip remained on the fallopian tube but was so damaged and corroded that it had to be surgically removed as well.

i. Mrs. Rebando's experience with the Filshie Clips - Plaintiff is Implanted with Filshie Clips in her Tubal Ligation.

69. In February 2017, Mrs. Rebando underwent a tubal ligation procedure.

70. The tubal ligation procedure used Filshie Clips.

71. Plaintiff was provided with a Disclosure and Consent for medical and surgical procedures which included generic risks and hazards associated with the procedure. No mention was made of the risk of migration and the appurtenant damages that could be caused by the Filshie Clips. The only risks mentioned were associated with the ligation procedure itself.

72. At the time, and upon information and belief to date, the product information sheet supplied to her healthcare providers made no mention of the actual rate of migration known of the Filshie Clips.

73. Plaintiff suffered several adverse symptoms related to the clip migration. These included but are not limited to hot flashes, night sweats, severe pelvic pain, stabbing stomach pain, sexual discomfort, unusually painful menstrual cycles, and ovarian pain.

j. Mrs. Rebando Discovers The Cause of Her Suffering.

74. Upon x-rays and CT scans it was determined that the Filshie Clips were not where they were supposed to be – they had migrated. They were found to be floating in Plaintiff's abdomen.

75. The Filshie Clips had migrated from their original placement.

76. Plaintiff was informed the Filshie Clips remained in her body and were displaced.

k. Mrs. Webbe's experience with the Filshie Clips - Plaintiff is Implanted with Filshie Clips in her Tubal Ligation.

77. In March 2011, Mrs. Webbe underwent a tubal ligation procedure.

78. The tubal ligation procedure used four Filshie Clips.

79. Plaintiff was provided with a Disclosure and Consent for medical and surgical procedures which included generic risks and hazards associated with the procedure. No mention was made of the risk of migration and the appurtenant

damages that could be caused by the Filshie Clips. The only risks mentioned were associated with the ligation procedure itself.

80. At the time, and upon information and belief to date, the product information sheet supplied to her healthcare providers made no mention of the actual rate of migration known of the Filshie Clips.

81. Plaintiff suffered several adverse symptoms related to the clip migration. These included but are not limited to severe pelvic pain, stabbing stomach pain, sexual discomfort, and constant numbing pain in her abdomen.

l. Mrs. Webbe Discovers The Cause of Her Suffering.

82. During surgery for possible cysts in May 2021, it was determined that the Filshie Clips were not where they were supposed to be – they had migrated. The clips had migrated and had affixed itself to Plaintiff's uterus. Two more clips were removed in November 2021.

83. Mrs. Webbe also has to live with the specter of a clip remaining displaced in her body.

84. The Filshie Clips had migrated from their original placement.

85. Plaintiff was informed that one Filshie Clip still remained in her body and was displaced.

86. The design, manufacture and warnings of the CooperSurgical, Femcare, Ltd. and Utah Medical Products devices at issue in this case exhibited

several defects that violated common-sense consumer expectations, as well as the expectations of the medical professionals involved in gynecological care.

87. The Filshie Clips, which were warranted, marketed, and purported to be permanently in place on the fallopian tubes, were defective.

88. Evidence of the Filshie Clips propensity to migrate was available to Defendants and should have been relayed to the physicians and/or Plaintiffs by way of warning on the product packaging or other dissemination of the information.

89. To date, Defendants have failed to adequately warn of these dangers, and certainly hadn't done so at the time Plaintiffs consented to the Filshie Clip method of sterilization.

90. As a result of the design, manufacture, and marketing defects of the Filshie Clips, Plaintiffs (and a large number of the women in the world who had submitted to their use) have experienced significant pain, suffering, and surgeries they otherwise would not have had they chosen one of the other methods of sterilization available to women.

m. Mrs. Caputo's experience with the Filshie Clips - Plaintiff is Implanted with Filshie Clips in her Tubal Ligation.

91. In 2011, Mrs. Caputo underwent a tubal ligation procedure.

92. The tubal ligation procedure used four Filshie Clips.

93. Plaintiff was provided with a Disclosure and Consent for medical and surgical procedures which included generic risks and hazards associated with the procedure. No mention was made of the risk of migration and the appurtenant damages that could be caused by the Filshie Clips. The only risks mentioned were associated with the ligation procedure itself.

94. At the time, and upon information and belief to date, the product information sheet supplied to her healthcare providers made no mention of the actual rate of migration known of the Filshie Clips.

95. Plaintiff suffered several adverse symptoms related to the clip migration. These included but are not limited to severe pelvic pain, sexual discomfort and pain, urinary tract dysfunction.

n. Mrs. Caputo Discovers The Cause of Her Suffering.

96. In January of 2022, Radiology uncovered that fact that her clips had migrated, it was determined that the Filshie Clips were not where they were supposed to be – they had migrated.

97. Mrs. Caputo has to live with the specter of a clip remaining displaced in her body.

98. The Filshie Clips had migrated from their original placement.

99. Plaintiff was informed that the Filshie Clips still remained in her body and were displaced.

100. Plaintiff has sustained and will continue to sustain damages including mental and physical injuries manifesting as migraines and chronic pain. She is unable to work due to this chronic pain.

101. The design, manufacture and warnings of the CooperSurgical, Femcare, Ltd. and Utah Medical Products devices at issue in this case exhibited several defects that violated common-sense consumer expectations, as well as the expectations of the medical professionals involved in gynecological care.

102. The Filshie Clips, which were warranted, marketed, and purported to be permanently in place on the fallopian tubes, were defective.

103. Evidence of the Filshie Clips propensity to migrate was available to Defendants and should have been relayed to the physicians and/or Plaintiffs by way of warning on the product packaging or other dissemination of the information.

104. To date, Defendants have failed to adequately warn of these dangers, and certainly hadn't done so at the time Plaintiffs consented to the Filshie Clip method of sterilization.

105. As a result of the design, manufacture, and marketing defects of the Filshie Clips, Plaintiffs (and a large number of the women in the world who had submitted to their use) have experienced significant pain, suffering, and surgeries

they otherwise would not have had they chosen one of the other methods of sterilization available to women.

V. THE DISCOVERY RULE APPLIES TO THIS MATTER

106. All of the allegations contained in the previous paragraphs are realleged herein.

107. 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 the Plaintiffs had been injured, the cause of the injury and the tortious nature of the wrongdoing that caused the injury.

108. Despite diligent investigation by Plaintiffs of the cause of their injuries, the nature of Plaintiffs' injuries and damages and their relation to Filshie Clips and Defendants' wrongful conduct was not discovered and could not have been discovered, until a date within the applicable statute of limitations.

109. Therefore, under appropriate application of the discovery rule, Plaintiffs' suit was filed within the applicable statutory limitations period.

110. Any applicable statutes of limitations have been tolled by the knowing and active concealment and denial of material facts known by the Defendants when they had a duty to disclose those facts.

111. The Defendants' purposeful and fraudulent acts of concealment have kept Plaintiffs ignorant of vital information essential to the pursuit of Plaintiffs' claims, without any fault or lack of diligence on Plaintiffs' part.

112. Defendants are estopped from relying on the statute of limitations defense because Defendants failed to timely disclose, among other things, facts evidencing the defective and unreasonably dangerous nature of their Filshie Clips.

VI. CAUSES OF ACTION

COUNT 1: ALL DEFENDANTS – PRODUCTS LIABILITY – DESIGN DEFECT

113. All of the allegations contained in the previous paragraphs are realleged herein.

114. The Filshie Clips are inherently dangerous and defective, unfit and unsafe for their intended use and reasonably foreseeable uses and do not meet or perform to the expectations of patients and their health care providers. These defects were not known to be unsafe by the ordinary consumer who consumes the product with the ordinary knowledge common to the community.

115. The Filshie Clips reached their intended consumer without substantial change in the condition in which they were in when they left Defendants' possession.

116. The Filshie Clips were defective in design because they failed to perform as safely as persons who ordinarily use the products would have expected at the time of use.

117. The Filshie Clips used in Plaintiffs were defective in design, because Filshie Clips' risk of harm exceed their claimed benefits. Namely, the Filshie Clip System as designed allows for migration from the implantation site which increases the risk of injury from the foreign body (the clips themselves) as they float freely.

118. The design was approved by the FDA without the benefit of the knowledge that Filshie Clips had a greater than .13% risk of migration. The incidence of migration is reported at 25%, a significant increase from the .13% currently reflected in the product information sheets. This information was available to the designer, manufacturer, and distributor at the time of the PMA. Further, the increased incidence of migration reported since 1996 was not reported to the FDA; a continued duty and requirement after obtaining the PMA. Such failure allowed for the defective design to remain the same.

119. Plaintiffs and their healthcare providers used the Filshie Clips in a manner that was reasonably foreseeable to the Defendants. In fact, they were used precisely as called for in their design.

120. Neither Plaintiffs nor their healthcare providers could have, by the exercise of reasonable care, discovered the Filshie Clips' defective conditions or perceived their unreasonable dangers prior to use. To the extent the product information sheet did report the risk of migration, it was clearly understated and unlikely to inform a reasonable consumer/patient or their healthcare providers of the risk of harm.

121. As a result of the foregoing design defects, the Filshie Clips created risks to the health and safety of Plaintiffs that were 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 Filshie Clips.

122. Defendants have intentionally and recklessly designed the Filshie Clips with wanton and willful disregard for the rights and health of the Plaintiffs and others, and with malice, placing their economic interests above the health and safety of the Plaintiffs and others.

123. As a proximate result of the Defendants' design of the Filshie Clips, Plaintiffs have been injured catastrophically, and sustained severe and permanent pain, suffering, disability, and impairment, loss of enjoyment of life, loss of care, comfort, and economic damages.

124. As a result of Defendants' conduct, Plaintiffs have been damaged and continue to sustain damages in an amount to be determined by a jury but in an amount exceeding $75,000.00, as a direct and proximate result of the Defendants' conduct.

COUNT 2: ALL DEFENDANTS – PRODUCTS LIABILITY – MANUFACTURING DEFECT

125. All of the allegations contained in the previous paragraphs are realleged herein.

126. Defendants designed, set specifications, manufactured, prepared, compounded, assembled, processed, marketed, labeled, performed medical vigilance, distributed and sold the Filshie Clips that were used on Plaintiff.

127. The Filshie Clips used in Plaintiffs contained a condition or conditions, which Defendants did not intend, at the time the Filshie Clips left Defendants' control and possession.

128. Plaintiffs and Plaintiffs' health care providers used the device in a manner consistent with and reasonably foreseeable to Defendants.

129. As a result of this condition or these conditions, the product failed to perform as safely as the ordinary consumer would expect, causing injury, when used in a reasonably foreseeable manner.

130. The Filshie Clips were defectively and/or improperly manufactured, rendering them defective and unreasonably dangerous and hazardous to Plaintiffs.

131. Defendants had a duty to prevent defective and/or improper manufacturing defects. This duty parallels the FDCA's requirement for truthfully and completely reporting incidents of adverse events, and if necessary, obtaining approval for changes in the design, manufacture, and warnings/marketing approved by the FDA.

132. Defendants have intentionally and recklessly manufactured Filshie Clips with wanton and willful disregard for the rights and health of the Plaintiffs and others, and with malice, placing their economic interests above the health and safety of the Plaintiffs and others.

133. As a proximate result of the Defendants' manufacture of Filshie Clips, Plaintiffs have been injured catastrophically, and sustained severe and permanent pain, suffering, disability, and impairment, loss of enjoyment of life, loss of care, comfort, and economic damages.

134. As a result of Defendants' conduct, Plaintiffs have been damaged and continue to sustain damages in an amount to be determined by a jury but in an amount exceeding $75,000.00, as a direct and proximate result of the Defendants' conduct.

COUNT 3: ALL DEFENDANTS – PRODUCT LIABILITY – FAILURE TO WARN

135. All of the allegations contained in the previous paragraphs are realleged herein.

136. Defendants designed, set specifications, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed and sold the Filshie Clips, including the ones used on Plaintiffs, in stream of commerce and in the course of same, directly advertised and marketed the device to consumers or persons responsible for consumers.

137. At the time Defendants designed, set specifications, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed and sold the Filshie Clips in the stream of commerce, Defendants knew or should have known that the device presented an unreasonable danger to users of the product when put to its intended and reasonably anticipated use.

138. Specifically, Defendants knew or should have known that the Filshie Clips posed an unreasonable risk of migration from the implantation site, resulting in significant injuries.

139. Defendants had a duty to warn of the risk of harm associated with the use of the device and to provide adequate warnings concerning the risk the device could migrate, even if used properly. This duty parallels the FDCA's requirement for truthfully and completely reporting incidents of adverse events, and if necessary, obtaining approval for changes in the design, manufacture, and warnings/marketing approved by the FDA.

140. The Defendants had a continuing duty to warn Plaintiffs, Plaintiffs' physicians, and/or the medical community of the potential for migration of the Filshie Clips under the FDCA and parallel this state's product liability laws.

141. Defendants failed to properly and adequately warn and instruct the Plaintiffs and their health care providers with regard to the inadequate research and testing of the Filshie Clips, and the complete lack of a safe, effective procedure for preventing migration. Rather, Defendants affirmatively advertised the safety of the Filshie Clip system vis a vis the alternative methods of bilateral tubal ligation, effectively downplaying even the de minimis risk of migration or expulsion reported to the FDA for approval of the device.

142. The risks associated with the Filshie Clips are of such a nature that health care providers and users could not have recognized the potential harm. The risks are further of the kind that a reasonable patient would consider when giving consent for the use of the Filshie Clip method of tubal ligation over other safer alternative procedures for achieving the same result.

143. The Filshie Clips were defective and unreasonably dangerous at the time of their release into the stream of commerce due to the inadequate warnings, labeling and/or instructions accompanying the product, including but not limited to, the potential for migration from intended location after placement on the fallopian tubes.

144. The Filshie Clips, when used in Plaintiffs, were in the same condition as when they were manufactured, inspected, marketed, labeled, promoted, distributed and sold by the Defendants.

145. The Defendants intentionally, recklessly, and maliciously misrepresented the safety, risks, and benefits in order to advance their own financial interests, with wanton and willful disregard for the rights and health of the Plaintiffs.

146. As a proximate result of the Defendants' design, manufacture, marketing, sale and/or distribution of the Filshie Clips, Plaintiffs have been injured catastrophically, and sustained severe and permanent pain, suffering, disability, and impairment, loss of enjoyment of life, loss of reproductive health, comfort, and economic damages.

147. As a result of Defendants' conduct, Plaintiffs have been damaged and continue to sustain damages in an amount to be determined by a jury but in an amount exceeding $75,000.00, as a direct and proximate result of the Defendant's conduct.

COUNT 4: ALL DEFENDANTS – STRICT LIABILITY

148. All of the allegations contained in the previous paragraphs are realleged herein.

149. Filshie Clips are inherently dangerous and defective, unfit and unsafe for their intended use and reasonably foreseeable uses and do not meet or perform to the expectations of patients and their health care providers.

150. Filshie Clips were expected to, and did, reach their intended consumer without substantial change in the condition in which they were in when they left Defendants' possession.

151. The Filshie Clips that were used in Plaintiffs were defective in design because they failed to perform as safely as persons who ordinarily use the products would have expected at time of use.

152. The Filshie Clips used in Plaintiffs were defective in design, in that the Filshie Clips' risks of harm exceeded its claimed benefits.

153. Plaintiffs and their healthcare providers used the Filshie Clips in a manner that was reasonably foreseeable to the Defendants. Neither Plaintiffs nor her healthcare providers could have, by the exercise of reasonable care, discovered the Filshie Clips defective conditions or perceived its unreasonable dangers prior to their implantation of the device.

154. Defendants failed to warn regarding the defects, namely likelihood of risk of migration of the Filshie Clips. Defendants had a duty to warn of these defects and failed to obtain the requisite approval to update their FDA such that they accurately reported the risk of migration. This duty parallels the FDCA's

requirement for truthfully and completely reporting incidents of adverse events, and if necessary, obtaining approval for changes in the design, manufacture, and warnings/marketing approved by the FDA.

155. As a result of the foregoing design, manufacturing, and marketing defects, the Filshie Clips created risks to the health and safety of its users that were 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 Filshie Clips.

156. The Defendants intentionally, recklessly, and maliciously misrepresented the safety, risks, and benefits in order to advance their own financial interests, with wanton and willful disregard for the rights and health of the Plaintiffs.

157. As a proximate result of the Defendants' design, manufacture, marketing, sale and/or distribution of the Filshie Clips, Plaintiffs have been injured catastrophically, and sustained severe and permanent pain, suffering, disability, and impairment, loss of enjoyment of life, loss of reproductive health, comfort, and economic damages.

158. As a result of Defendants' conduct, Plaintiffs have been damaged and continue to sustain damages in an amount to be determined by a jury but in an

amount exceeding $75,000.00, as a direct and proximate result of the Defendant's conduct.

COUNT 5: ALL DEFENDANTS – NEGLIGENCE

159. All of the allegations contained in the previous paragraphs are realleged herein.

160. At times relevant, Defendants were in the business of designing, developing, setting specifications, manufacturing, marketing, selling and/or distributing Filshie Clips, including the clips that were used on Plaintiffs.

161. Defendants had a duty to exercise reasonable and ordinary care in the manufacture, design, labeling, instructions, warnings, sale, marketing, safety surveillance and distribution of Filshie Clips so as to avoid exposing others to foreseeable and unreasonable risks of harm.

162. Defendants breached their duty of care to the Plaintiffs and their physicians, in the manufacture, design, labeling, warnings, instructions, sale, marketing, safety surveillance, and distribution of Filshie Clips.

163. Defendants had a duty to warn Plaintiffs, Plaintiffs' physician, and/or the medical community of the potential for migration.

164. Defendants knew or reasonably should have known that Filshie Clips are dangerous or likely to be dangerous when used in their intended or reasonably foreseeable manner.

165. At the time of the manufacture and sale of the Filshie Clips, Defendants knew or should have known that Filshie Clips were designed and manufactured in such a manner so as to present an unreasonable risk of migration when placed on the fallopian tubes.

166. At the time of the manufacturer and sale of the Filshie Clips, Defendants knew or should have known that Filshie Clips were designed and manufactured to have unreasonable and insufficient capacity to avoid migrating from the fallopian tubes.

167. At the time of the manufacture and sale of the Filshie Clips, Defendants knew or should have known that using Filshie Clips for its intended use or in a reasonably foreseeable manner created a significant risk of a patient suffering severe injuries, including but not limited to additional surgeries and/or medical procedures in order to remove the migrated Filshie Clips, or penetration or damage to organs, such as the bowel, by the Filshie Clips.

168. Defendants knew or reasonably should have known that the consumers of the Filshie Clips would not realize the danger associated with using the device for its intended use and/or in a reasonably foreseeable manner.

169. Defendants breached their duty to exercise reasonable and prudent care in the development, testing, design, manufacture, inspection, marketing,

labeling, promotion, distribution and sale of the Filshie Clips in, among others, the following ways:

(a) Designing and distributing a product in which they knew or should have known that the likelihood and severity of potential harm from the product exceeded the burden of taking measures to reduce or avoid harm;

(b) Designing and distributing a product in which they knew or should have known that the likelihood and severity of potential harm from the product exceeded the likelihood of potential harm from other devices or procedures available for the same purpose;

(c) Failing to use reasonable care in manufacturing the product and producing a product that differed from their design or specifications;

(d) Failing to use reasonable care to warn or instruct Plaintiff, Plaintiff's healthcare providers or the general health care community about Filshie Clip's substantially dangerous condition or about facts making the product likely to be dangerous, including pre-and post-sale;

(e) Failing to perform reasonable pre-and post-market testing of the Filshie Clips to determine whether or not the product was safe for its intended use;

(f) Failing to provide adequate instructions, guidelines, and safety precautions, to those persons to whom it was reasonably foreseeable would recommend, use, implant and remove the Filshie Clips;

(g) Advertising, marketing and recommending the use of the Filshie Clips, while concealing and failing to disclose or warn of the dangers known by the Defendants to be connected with and inherent in the use of the Filshie Clips;

(h) Representing that Filshie Clips were safe for their intended use when in fact, Defendants knew and should have known the product was not safe for its intended purpose;

(i) Continuing manufacture and sale of Filshie Clips with the knowledge that they were dangerous and not reasonably safe, and failing to comply with FDA manufacturing regulations;

(j) Failing to use reasonable and prudent care in the design, research, manufacture, and development of Filshie Clips so as to avoid the risk of serious harm associated with the use of the Filshie Clips;

(k) Failing to establish an adequate quality assurance program used in the manufacturing of the Filshie Clips;

(l) Failing to establish and maintain an adequate post-marketing surveillance program for Filshie Clips;

(m) Failing to adequately and correctly report safety information related to the Filshie Clip product resulting in inadequate warnings; and

(n) Failing to provide adequate and continuous warnings about the inherent danger of migration with Filshie Clips after they had been placed on the fallopian tubes.

170. This duty parallels the FDCA's requirement for truthfully and completely reporting incidents of adverse events, and if necessary, obtaining approval for changes in the design, manufacture, and warnings/marketing approved by the FDA.

171. A reasonable manufacturer, distributor, and/or seller under the same or similar circumstances would not have engaged in the aforementioned acts and omissions.

172. As a proximate result of the Defendants' design, manufacture, marketing, sale and/or distribution of the Filshie Clips, Plaintiffs have been injured catastrophically, and sustained severe and permanent pain, suffering, disability,

and impairment, loss of enjoyment of life, loss of reproductive health, comfort, and economic damages.

173. As a result of Defendants' conduct, Plaintiffs have been damaged and continue to sustain damages in an amount to be determined by a jury but in an amount exceeding $75,000.00, as a direct and proximate result of the Defendant's conduct.

COUNT 6: ALL DEFENDANTS – VIOLATION OF CONSUMER PROTECTION LAWS

174. All of the allegations contained in the previous paragraphs are realleged herein.

175. Plaintiffs purchased and used the Filshie Clips primarily for personal use thereby suffering ascertainable losses as a result of the Defendants' actions in violation of the consumer protection laws.

176. Had the Defendants not engaged in the deceptive conduct described herein, Plaintiffs and their physicians would not have purchased and/or paid for the Filshie Clips and would not have incurred related medical costs and injury.

177. The Defendants engaged in wrongful conduct while at the same time obtaining, under false pretenses, moneys from Plaintiffs for the Filshie Clips that were surgically placed into them, and that would not have been paid for had the Defendants not engaged in unfair and deceptive conduct.

178. Defendants' deceptive acts or practices that were precluded by law include the following:

(a) Representing that goods or services have characteristics, ingredients, uses, benefits or quantities that they do not have;

(b) Advertising goods or services with the intent not to sell them as advertised; and

(c) Engaging in fraudulent or deceptive conduct that creates a likelihood of confusion and/or misunderstanding.

179. Plaintiffs were injured by the cumulative and indivisible nature of the Defendants' conduct. The cumulative effect of the Defendants' conduct directed at patients, physicians and consumers, including the Plaintiffs and their physicians, was to create demand for and promote the sale of the Filshie Clips. Each aspect of the Defendants' conduct combined to artificially create sales of the Filshie Clips.

180. The 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 Filshie Clips. This duty parallels the FDCA's requirement for truthfully and completely reporting incidents of adverse events, and if necessary, obtaining approval for changes in the design, manufacture, and warnings/marketing approved by the FDA.

181. Had the Defendants not engaged in the deceptive conduct described above, Plaintiffs would not have consented to the method of bilateral tubal ligation,

purchased and/or paid for the Filshie Clips, and would not have incurred related medical costs.

182. The Defendants' deceptive, unconscionable, or fraudulent representations and material omissions to patients, physicians and consumers, including Plaintiffs and their physicians, constituted unfair and deceptive acts and trade practices in violation of the state and Federal consumer protection statutes.

183. The Defendants' actions, as complained of herein, constitute unfair competition or unfair, unconscionable, deceptive or fraudulent acts, or trade practices in violation of state and Federal consumer protection statutes, including but not limited to the Deceptive Trade Practices- Consumer Protection Act.

184. The Defendants have engaged in unfair competition or unfair or deceptive acts or trade practices or have made false representations in violation under the statute listed above to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising, the 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.

185. The Defendants violated the statutes that were enacted to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising, by knowingly and falsely representing that

the Filshie Clips were fit to be used for the purpose for which they were intended, when in fact they were defective and dangerous, and by other acts alleged herein. These representations were made in uniform promotional materials and product labeling.

186. The actions and omissions of the 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.

187. The Defendants had actual knowledge of the defective and dangerous condition of the Filshie Clips and failed to take any action to cure such defective and dangerous conditions.

188. Plaintiffs and their implanting physicians and surgeons relied upon the Defendants' misrepresentations and omissions in determining which product and/or procedure to undergo and/or perform.

189. The Defendants' deceptive, unconscionable or fraudulent representations and material omissions to patients, physicians and consumers, constitute unfair and deceptive acts and practices.

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

191. As a proximate result of the Defendants' design, manufacture, marketing, sale and/or distribution of the Filshie Clips, Plaintiffs have been injured catastrophically, and sustained severe and permanent pain, suffering, disability, and impairment, loss of enjoyment of life, loss of reproductive health, comfort, and economic damages.

192. As a result of Defendants' conduct, Plaintiffs have been damaged and continue to sustain damages in an amount to be determined by a jury but in an amount exceeding $75,000.00, as a direct and proximate result of the Defendant's conduct.

COUNT 7: ALL DEFENDANTS – GROSS NEGLIGENCE

193. All of the allegations contained in the previous paragraphs are realleged herein.

194. The wrongs done by the 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 punitive damages, in that Defendants' conduct 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 material representations that were false, with Defendants, knowing that they were false or with reckless disregard as to the truth and as a positive assertion, with the intent that the representation is acted on by Plaintiffs.

195. Plaintiffs and their physicians relied on the representations of Defendants and suffered injury as a proximate result of this reliance.

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

197. Plaintiffs also allege that the acts and omissions of 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 punitive 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.

198. As a result of Defendants' conduct, Plaintiffs have been damaged and continue to sustain damages in an amount to be determined by a jury but in an amount exceeding $75,000.00, as a direct and proximate result of the Defendants' conduct.

COUNT 8: ALL DEFENDANTS – PUNITIVE DAMAGES

199. All of the allegations contained in the previous paragraphs are realleged herein.

200. At times material hereto, Defendants knew or should have known that their Filshie Clips, as designed, manufactured, assembled, sold and/or distributed were inherently dangerous.

201. At times material hereto, Defendants attempted to misrepresent and did misrepresent facts concerning the safety of their Filshie Clips.

202. Defendants' misrepresentations included knowingly withholding material information from the public and consumers alike, including Plaintiffs, concerning the safety of the Filshie Clips.

203. At times material hereto, Defendants knew and recklessly disregarded the fact that their Filshie Clips could cause serious, disabling, and permanent injuries to individuals such as Plaintiffs.

204. Notwithstanding the foregoing, Defendants continued to aggressively market and promote their Filshie Clips, without disclosing the risks.

205. As a proximate result of Defendants' willful, wanton, careless, reckless, conscious, and deliberate disregard for the rights and safety of their consumers, Plaintiffs suffered severe and permanent physical and emotional injuries, endured pain and suffering, and have suffered economic loss, including

incurring significant expenses for medical care and treatment, and will continue to incur such expenses in the future.

206. Defendants' aforesaid conduct was committed with knowing, conscious, careless, reckless, willful, wanton, and deliberate disregard for the rights and safety of consumers, including Plaintiffs, thereby entitling Plaintiffs to punitive damages in an amount appropriate to punish Defendants and deter them from similar conduct in the future.

207. As a result of Defendants' conduct, Plaintiffs have been damaged and continue to sustain damages in an amount to be determined by a jury but in an amount exceeding $75,000.00, as a direct and proximate result of the Defendants' conduct.

VII. RESERVATION OF RIGHTS

208. Plaintiffs reserve the right to prove the amount of damages at trial. Plaintiffs reserve the right to amend their Petition to add or remove counts upon further discovery and as their investigation continues.

VIII. JURY DEMAND

209. Pursuant to Federal Rule of Civil Procedure 38, Plaintiffs hereby request that all causes of action alleged herein be tried before a properly impaneled jury.

IX. PRAYER FOR RELIEF – DAMAGES

210. The conduct of the Defendants, as alleged hereinabove, was a direct, proximate and producing cause of the damages to Plaintiffs and of the following general and special damages including:

(a) All available compensatory damages for the described losses with respect to each cause of action;

(b) Past and future medical expenses, as well as the cost associated with past and future life care;

(c) Past and future lost wages and loss of earning capacity;

(d) Past and future emotional distress;

(e) Loss of consortium damages;

(f) Consequential damages;

(g) All available noneconomic damages, including without limitation pain, suffering, and loss of enjoyment of life;

(h) Damages to punish Defendants for proximately causing physical pain and mental anguish;

(i) Enter judgment against Defendants, jointly and severally, awarding Plaintiffs damages in an amount to be determined at trial and their costs and reasonable attorney's fees including, compensatory

damages in an amount sufficient to fairly and completely compensate her for all damages;

(j) Punitive damages;

(k) Attorney's fees;

(l) Prejudgment and post judgment interest, costs, and disbursements;

(m) Any and all other recoverable personal injury damages for Plaintiffs; and

(n) Such and further relief at law or in equity as this Court may deem just and appropriate.

WHEREFORE, PREMISES CONSIDERED, Plaintiffs demand that the Defendants be cited to appear and answer herein. Upon final judgment against the Defendants, and each of them, jointly and severally, awarding Plaintiffs damages in an amount to be determined at trial and their costs and reasonable attorney's fees including, compensatory damages in an amount sufficient to fairly and completely compensate them for all damages listed herein and such and further relief at law or in equity as this Court may deem just and appropriate.

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Respectfully submitted,

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