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COMMONWEALTH OF MASSACHUSETTS
DEPARTMENT OF THE TRIAL COURT

MIDDLESEX, SS. **SUPERIOR COURT DEPARTMENT**

OCTAVIANA REMIGIO,	**CIVIL ACTION NO.:**
Plaintiff	26-1042
v.	
COVIDIEN LP; and SOFRADIM CORP.,	
Defendants	

COMPLAINT

NOW COMES, Plaintiff in this action and files this Complaint and Jury Demand against Defendants COVIDIEN, LP and SOFRADIM CORP (collectively referred to as "Defendants").

PARTIES

1. Plaintiff **OCTAVIANA REMIGIO**, a resident of the state of New York, was implanted with Defendant's ProGrip mesh product (hereinafter, "Mesh Device") for repair of an umbilical hernia, the use for which the product was sold and intended. Following implantation, the mesh failed.

2. Defendant COVIDIEN, LP is a Delaware limited partnership with its principal place of business at 15 Hampshire Street, Mansfield, Bristol County, Massachusetts, and offices in Bedford and Waltham, Middlesex County, Massachusetts. All acts and omissions of Covidien, LP as described herein including but not limited to those resulting in the design, manufacture, marketing, labeling, distribution, sale and placement of its hernia mesh products at issue in the instant suit into Middlesex County, were done by its agents, servants, employees and/or owners,

acting in the course and scope of their representative agencies, services, employments and/or ownership. At all times material hereto, Covidien, LP did business in Massachusetts.

3. Defendant SOFRADIM CORP. ("Sofradim") is a company with its principal place of business in Mansfield, Bristol County, Massachusetts and offices in Wrentham, Norfolk County, Massachusetts. All acts and omissions of Sofradim Corp. as described herein were done by its agents, servants, employees and/or owners, acting in the course and scope of their respective agencies, services, employments and/or ownership.

4. The above-named entities are hereinafter referenced collectively as "Defendants."

5. Defendants are individually, jointly and severally liable to Plaintiff for damages suffered by Plaintiff arising from the Defendants' design, manufacture, marketing, labeling, distribution, sale and placement of its hernia mesh products, including their line of Mesh Devices, effectuated directly and indirectly through their respective agents, servants, employees and/or owners, all acting within the course and scope of their representative agencies, services, employments and/or ownership.

6. At all relevant times herein, Defendants were engaged in the design, manufacture, production, testing, study, research, training, inspection, labeling, marketing, advertising, sales, promotion, and/or distribution of the Products. Defendants do business throughout the United States, and at all relevant times hereto, marketed, promoted, warranted, and/or sold their products in the Commonwealth of Massachusetts.

7. Prior to its acquisition by Covidien, Sofradim was a wholly-owned, joint stock sole proprietorship of Floreane Medical Implants, S.A., a French corporation.

8. Sofradim and its parent and affiliates were acquired by Covidien or its predecessor and are now wholly owned by Covidien. Since its acquisition by Covidien, Sofradim has been a

business unit or division of Covidien. Since its acquisition by Covidien, Sofradim has been referred to as the "Trevoux Plant" of Covidien and is considered a manufacturing facility for the surgical devices business unit of Covidien. Sofradim is registered with the U.S. Food and Drug Administration ("FDA") as an "establishment," which is the functional equivalent of a manufacturing facility or production plant. Covidien or its corporate affiliates are listed with the FDA as the "owner/operator" of Sofradim, which makes Covidien "directly responsible for the activities" of Sofradim. Since the acquisition of Sofradim by Covidien, the officers, managers and employees of Sofradim have been employees of Covidien.

9. Defendants had a legal duty to ensure the safety and effectiveness of their Mesh Devices prior to marketing and selling those products for permanent implantation in Plaintiff. Prior to marketing and selling the Mesh Devices, Defendants were required to weigh the reasonably knowable risks against the benefits of the device's design and to consider all information that may bear on the safety and efficacy of the design, including the gravity, severity, likelihood, and avoidance of the dangers associated with that design. In addition to making these assessments, the Defendants were required to weigh the benefits against the knowable risks to ensure that the risks do not outweigh the benefits and to mitigate any known or knowable risks through providing adequate warnings and instructions and adequately communicating those warnings and instructions to device users. Defendants had an obligation not to release a product that posed greater risks or more frequent, more severe or longer lasting risks, than other devices sold for the same use. Because implantation of Defendants' Mesh Devices is an elective procedure intended to treat non-life threatening conditions and creates the potential for serious, life-altering complications such as those experienced by Plaintiff, the risks of the Mesh Devices outweigh any purported benefits, both generally and specifically with respect to the Plaintiff in

this case.

10. At all relevant times herein, Defendants were engaged in the design, manufacture, production, testing, study, research, training, inspection, labeling, marketing, advertising, sales, promotion, and/or distribution of the Mesh Devices. Defendants at all relevant times hereto, marketed, promoted, warranted, and/or sold their products in the Commonwealth of Massachusetts and throughout the United States.

JURISDICTION

11. The Superior Court, Middlesex County has jurisdiction and venue over this matter and this action is not subject to federal jurisdiction or removal to federal court under the provisions of 28 U.S.C. § 1332.

12. Defendants have stipulated to the personal jurisdiction of this Court.

13. This Court has jurisdiction over the Defendants because they have offices and/or regularly solicited and transacted business in the Commonwealth of Massachusetts and County of Middlesex.

14. This Court also has personal jurisdiction over Defendants because Defendants are licensed to do business in Massachusetts, because they conduct a substantial amount of business in Massachusetts, because their offices are located in Middlesex County, Massachusetts and/or because they maintain registered agents for service of process in Massachusetts.

15. At all times relevant hereto, Defendants were engaged in the business of developing, manufacturing, publishing information, marketing, distributing, promoting and/or selling, either directly or indirectly, through third parties, as successor in interest, or other related

entities, hernia mesh products in the Commonwealth of Massachusetts and in interstate commerce, for which each derived significant and regular income.

FACTS COMMON TO ALL COUNTS

16. Defendants designed, manufactured, sold, and/or distributed the Mesh Devices for use in the treatment and repair of hernias, including those Mesh Devices implanted in Plaintiff.

17. Defendants were jointly responsible for the research, design, development, testing, manufacture, production, marketing, promotion, distribution and sale of Mesh Devices, including providing the warnings and instructions and physician training concerning their products.

18. The Mesh Devices were cleared for marketing pursuant to the FDA's premarket notification process, which is also referred to as the "510(k)" process. Medical devices that enter the market through the 510(k) process are not "approved" by the FDA and devices are not formally reviewed for safety or efficacy by the FDA under the 510(k) process. Under the 510(k) process, the FDA does not evaluate the product's safety or effectiveness. The Mesh devices have never been formally reviewed for safety or efficacy by the FDA. The Mesh devices have never been determined to be safe or effective by the FDA. The Mesh devices have never been through the FDA's more rigorous Premarket Approval Process and thus have never been "approved" by the FDA.

19. The polymer used in the ProGrip devices at issue in this Complaint is polyethylene terephthalate, more commonly referred to as polyester (and is also referred to as polyethylene, "PE," "PET" and/or "Dacron").

20. The polyester polymer used in the ProGrip design is more brittle and significantly more susceptible to fatigue fracture, breakage, fragmentation and other mechanical failures than alternative polymers, including but not limited to polyvinylidene fluoride (PVDF). Peer-reviewed,

published literature prior to the introduction of Parietex Composite in the U.S. concluded that "Polyester mesh should no longer be used for incisional hernia repair." Leber, et al. *Long-term complications associated with prosthetic repair of incisional hernias.* **Arch Sorg.** 1998; 133(4):378-82. Subsequent literature observed that "the use of PET in hernia surgery is at least questionable in respect to the obligate long-term degradation of this polymer," Klosterhalfen, et al., *Polymers in hernia repair - common polyester vs. polypropylene surgical meshes.* **J. Materials Science** 35:4769-4776 (2000), that "[i]t has also been reported that patients with polyethylene mesh implants have higher incidences of wound-healing complications, fistula and seroma formation and higher incidences of hernia recurrence as compared to polypropylene meshes" and that "due to the loss of stability and the reported mesh-related complications, polyethylene meshes nowadays do not seem fully suitable for a permanent reinforcement of the abdominal wall." Schumpelick, et al. *Light weight meshes in incisional hernia repair.* **J. Minim Access Surgery.** 2006;2(3):117-23.

21. The polyester material used in the ProGrip mesh is susceptible to degradation by hydrolysis, oxidation and/or enzymatic degradation. *See, e.g.,* Smith, et al. *The enzymatic degradation of polymers in vivo.* **J Biomed Mater Res** 1987; 21: 991-1003 (demonstrating degradation of polyester by certain enzymes); Riepe, et al. *Long-term in vivo alterations of polyester vascular grafts in humans.* **Eur J Vase Endovasc Sorg.** 1997;13(6):540-8 (Study of explanted polyester implant devices demonstrating in vivo hydrolytic degradation with scission of macromolecular chains and loss of strength); King, et al. *Microstructural changes in polyester biotextiles during implantation in humans.* **Journal of Textile and Apparel, Technology and Management.** 2001;1(3):l-8 (demonstrating biodegradation and loss of mechanical strength of polyester implants); Schumpelick, *supra* ("One problem of polyethylene meshes is their

degradation, which leads to a reduced mechanical stability after 10 years."); Robinson, et al. *Major mesh-related complications following hernia repair: events reported to the Food and Drug Administration.* **Sorg Endosc.** 2005; 19(12): 1556-60 ("Incorporated PET can be degraded hydrolytically, resulting in an increased brittleness of the polymer with loss of the mechanical features."); Voskerician, et al. *Effect of biomaterial design criteria on the performance of surgical meshes for abdominal hernia repair: a pre-clinical evaluation in a chronic rat model.* **J Mater Sci Mater Med.** 2010;21(6):1989-95 ("While materials such as PP and PTFE will not undergo hydrolytic degradation, PET, a polyester, will. Further, PET is also susceptible to oxidative degradation due to its ester groups, enhanced by a supplementary degradation mechanism common to all polymers, the direct oxidation by the host. The latter degradation mechanism is the result of host generated molecular species culminating with a foreign body reaction characterized by a continuous process of frustrated phagocytosis by the foreign body giant cells."); Klosterhalfen, et al., *Pathology of traditional surgical nets for hernia repair after long-term implantation in humans.* **Der Chirurg** 2000:71:53-51 (microscopic examination of fragmented and fractured Mersilene (multifilament polyester) mesh after explantation showed pronounced splitting and degradation of polyester fibers). The ultrathin individual polyester fibers that make up the ProGrip mesh are unreasonably susceptible to degradation. The gamma irradiation sterilization of the ProGrip produces free radicals that contribute to degradation before implant.

22. The polyester material used in the ProGrip devices incites inflammation and heightened foreign body response, which increases the risks of post-operative complications. Jin, et al., *Human peritoneal membrane controls adhesion formation and host tissue response following intra-abdominal placement in a porcine model.* **J. Sur. Res.** 2009;156(2):297-304 (noting polyester-collagen composite had higher foreign body reaction than other materials);

Zinther, et al. *Shrinkage of intraperitoneal onlay mesh in sheep: coated polyester mesh versus covered polypropylene mesh.* **Hernia.** 201O;14(6):611-615 (noting statistically significant increase in shrinkage rate for Parietex versus covered polypropylene mesh and further noting histology showed "marked inflammatory reaction with giant cells adjacent to the polyester filaments, which was absent in the polypropylene specimens"); Orenstein, et al. *Comparative analysis of histopathologic effects of synthetic meshes based on material, weight, and pore size in mice.* **J Sorg Res.** 2012;176(2):423-9 ("[P]olyester-based meshes appear to create a local hostile environment with marked foreign body reaction and chronic inflammatory response" and"[o]f the five synthetic meshes implanted, the polyester-based mesh was the greatest inducer of inflammation and appeared to impose severe chronic foreign body reaction."); Nguyen, et al., *Influence of a new monofilament polyester mesh on inflammation and matrix remodeling.* **J. Invest. Sorg.** 2012;25(5):330-9 (noting heightened inflammatory response with multifilament polyester material both at molecular level and histologically and recognizing the potential clinical implantations "as there is a higher associated risk for postoperative complications and delayed wound healing in the setting of a persistent and prolonged inflammatory response after mesh implantation."); van't Riet, et al. *Prevention of adhesion to prosthetic mesh: comparison of different barriers using an incisional hernia model.* **Ann Sorg.** 2003;237(1):123-128 ("in the group with Parietex mesh, a more severe inflammatory reaction was found, with the presence of many admixed inflammatory cells and microabscesses (grade 3 on the inflammation grading scale)."); Voskerician, *supra* (observing host tissue response elevated and arrested in a chronic inflammatory phase in the presence of Parietex).

23. The polyester polymer used in the ProGrip design is significantly more susceptible to loss of mechanical strength over time than alternative materials. Robinson, et al. *Major mesh-*

related complications following hernia repair: events reported to the Food and Drug Administration. **Sorg Endosc.** 2005; 19(12): 1556-60 ("A significant disadvantage of polyester is loss of mechanical strength over time... , which may lead to hernia recurrence. Polyester is not commonly implanted in the United States, and its continued use for incisional hernia repair has been questioned.").

24. The ultrathin individual fibers that make up the ProGrip mesh are unreasonably susceptible to damage from surgical instruments, such as sutures, trocars and fixation devices. The damage to individual fibers from sutures, fixation devices or other instruments can result in the mechanical failure of the ProGrip mesh.

25. The ultrathin individual fibers that make up the ProGrip mesh are unreasonably susceptible to breakage and fragmentation, particularly at the edges of the mesh. Once the broken mesh fibers migrate within the body, the small fragments become difficult, if not impossible, for doctors to find to remove.

26. The fragmentation or flaking off of particles of the ultrathin fibers exacerbates inflammation and prolonged and excessive foreign body reaction. This chronic and excessive inflammatory and foreign body reaction, in tum, exacerbates the degradation of the ultrathin mesh fibers in a vicious cycle. The degradation and fragmentation of the fibers within the ProGrip mesh can lead to the total loss of functionality of the mesh.

27. Defendants' ProGrip line of products utilizes bio-resorbable polymers called Poly(lactic) acid ("PLA") and Polyglycolic acid ("PGA") in the hooks covering the parietal surface of the mesh. As an alternative to suturing or tacking a hernia mesh during an implantation surgery, Defendants added thousands of resorbable polylactic microgrips (PLA Microgrips) to the polyester or polypropylene meshes, creating the ProGrip (PLA Microgrip Device).

28. Both PLA, PGA, and their respective degradation products are known to induce a profound inflammatory response in soft tissue.

29. Defendants had knowledge that prolonged inflammation from degradation of PLA and PGA in their ProGrip products contributes to inflammatory insult to the body's dorsal root ganglion ("DRG"), which can lead to severe, treatment-resistant chronic pain syndromes in patients.

30. Defendants' PLA Microgrip Devices were defectively designed and/or manufactured and were not reasonably safe for their intended use in hernia repair. Further, the risks of the design outweighed any potential benefits associated with the design.

31. When implanted in the body, the PLA Microgrips incite a profound inflammatory response and significantly lowers the local pH, resulting in pain, delayed wound healing, tissue contraction, mesh deformation, and a higher risk of recurrence due to formation of immature collagen.

32. The PLA Microgrips are hydrophilic and therefore attract fluids to the mesh, increasing the risk of seroma and infection.

33. Removal of a PLA Microgrip Device requires removing large amounts of underlying tissue, causing grave bodily harm, while increasing the complexity of future hernia repairs and the risk that future repairs fail.

34. In 2018, the HerniaSurge Group published International Guidelines for Groin Hernia Management, which advised: "The incidence of erosion seems higher with plug versus flat mesh. It is suggested not to use plug repair techniques." These guidelines have been endorsed worldwide by hernia mesh societies.

35. Defendants provided no warning about the risks/increased risks specifically

associated with the unique design of the PLA Microgrip, including the fact that the PLA Microgrips would further increase the inflammation response, and could increase the risk and severity of chronic pain and infection, and that the PLA Microgrips could prevent full removal of the device and resolution of symptoms.

36. Without conducting any studies on humans, Defendants' claim that the "combination of mesh and microgripping technology provides immediate tension-free fixation that offers surgical efficiencies and patient advantages." This claim is false, or at very least highly misleading, as Defendants' PLA Microgrip Devices shrink and contract over time, creating significant amounts of tension, which causes chronic debilitating pain and increases the risk of hernia recurrence.

37. Defendant's market the PLA Microgrip Devices to surgeons as being able to be positioned and fixated in less than 60 seconds. However, Defendants were silent on the extreme difficultly and even impossibility of removing their PLA Microgrip Devices when complications arise.

38. Defendants promote their PLA Microgrip Devices as resulting in less pain, because a PLA Microgrip Device "eliminates the pain associated with traditional tack fixation." This is an obvious statement, as Defendants' PLA Microgrip Devices do not require tacking. However, this statement is highly misleading, because the Defendants' PLA Microgrip Devices increase the risk of long-term debilitating pain when compared to available feasible alternatives.

39. The Instructions for Use of Defendants' PLA Microgrip Devices note that "this device should be used with the understanding that infection may require removal of the mesh." However, the PLA Microgrips prevent the Device from being fully removable, resulting in chronic and systemic infections.

40. The Instructions for Use of Defendants' PLA Microgrip Devices do not indicate how to properly remove Defendant's PLA Microgrip Devices.

41. The Instructions for Use of Defendant's PLA Microgrip Devices warn that the possible complications associated with the use of PLA Microgrip Devices are those "typically associated with surgically implantable materials." However, Defendants' PLA Microgrip Devices are the only hernia mesh devices on the market utilizing PLA Microgrips, which greatly increase the risk of inflammation, chronic pain, infection, seroma, mesh deformation, and not being able to fully remove the device when compared with other surgically implantable materials.

42. Defendants' claim their PLA Microgrip Devices provide a reduced foreign material reaction and improved biocompatibility compared to other materials. Defendants' claim is false, or at very least highly misleading, as their PLA Microgrip Devices induce a severe foreign material reaction and are not biocompatible, which results in severe complications, injuries, and device degradation.

43. As a result of the defective design and/or manufacture of the PLA Microgrip Devices, as well as Defendants' failure to adequately warn and instruct implanting physicians on the defects and risks associated with PLA Microgrip Devices, Plaintiff suffered, and many continue to suffer, from significant personal injury. These injuries include but are not limited to:

a. Adhesions;
b. Infections;
c. Seroma;
d. Fistula Formation;
e. Bowel Complications and Obstructions;
f. Erosion;
g. Organ Perforation;
h. Organ Removal;
i. Injuries to nearby organs, blood vessels, tissues and nerves;
j. Chronic Pain;
k. Hernia Recurrence;
l. Chronic Inflammatory and Fibrotic Reaction;

m. Loss of Compliance;
n. Increased scar tissue;
o. Formation of a tumor like mass or meshoma;
p. Granulomatous Response;
q. Allergic Reaction;
r. Rejection of the Hernia Mesh;
s. Improper Wound Healing;
t. Foreign Body Response;
u. Bowel Strangulation;
v. Immature Collagen Formation; and
w. Death

44. Moreover, removal of a PLA Microgrip Device requires the excision of greater amounts of tissue leading to longer surgical time and complexity, delayed healing and pain and suffering, and increases the complexity of future hernia repairs and the risk that future repairs may fail resulting in more surgical procedures.

FACTS SPECIFIC TO PLAINTIFF

45. Plaintiff was implanted with the following product manufactured by Defendants: a ProGrip device, Cat# TEM1509G, Lot# SQL0821X.

46. Plaintiff's respective implanting surgeons implanted the referenced products in accordance with the applicable medical standard of care and Defendants' directions for use.

47. The Mesh Devices implanted into Plaintiff were in the same or substantially similar condition as they were when they left the possession of Defendants, and in the condition intended by and expected by the Defendants.

48. Plaintiff's injuries and damages set forth herein were the direct and proximate result of the unreasonably dangerous and defective design of the Defendants' Mesh Devices as described in this Complaint.

49. As a direct and proximate result of the defective design of the Mesh Device, and Defendants' failure to warn and other tortious conduct alleged herein, Plaintiff suffered a variety of complications.

COUNT I
Defective Design – Strict Liability

50. Plaintiff hereby incorporates by reference each and every paragraph set forth in this Complaint as if fully set forth here in their entirety.

51. The polyester material used in the ProGrip design is dangerous and defective, and is unreasonably susceptible to chronic and severe inflammation, embrittlement, fragmentation, hydrolytic, oxidative and/or enzymatic degradation, tissue necrosis and loss of mechanical strength overtime.

52. Given its brittle polymer structure and its susceptibility to degradation, the mesh used in the ProGrip devices was insufficient in strength to withstand the internal forces of the abdomen after implantation over time, which made the device susceptible to tearing, rupture and/or deformation.

53. The appropriate treatment for complications associated with ProGrip products involves additional invasive surgery to remove the mesh from the body, and to repair the damage caused by the failed ProGrip device, thus eliminating any purported benefit that the product was intended to provide to the patient.

54. At each of the times the ProGrip product was implanted in Plaintiff, there were safer feasible alternative designs for hernia mesh products that would have reduced the likelihood, severity, frequency and duration of the injuries Plaintiff suffered. Among the safer feasible alternative design features is a biocompatible polymer monofilament, which has been incorporated in other hernia mesh designs. One such safer feasible alternative design feature was the use of a non-hydrophilic, less brittle and more pliable polymer, such as polyvinylidene fluoride (PVDF). Defendants themselves designed, manufactured and sold products utilizing PVDF components. Mesh with larger pores and less dense material than the dense, heavyweight multifilament design

of ProGrip were also safer design alternatives, which have been incorporated in several mesh designs that have been marketed and sold by Defendants and by other surgical mesh manufacturers.

55. At the time their Mesh Devices were implanted in Plaintiff, the Devices were defectively designed. There was an unreasonable risk that a Device would not perform safely and effectively for the purposes for which it was intended. Defendants failed to design against such dangers, and failed to provide adequate warnings and instructions concerning the risks.

56. Defendants' Mesh Devices were defectively designed when supplied, sold, distributed and/or otherwise placed into the stream of commerce and when they were implanted in Plaintiff.

57. Defendants expected and intended the Mesh Devices to reach users like Plaintiff in the condition in which the Devices were sold.

58. The implantation of Mesh Devices into Plaintiff was medically reasonable, and was the type of use Defendants intended and foresaw when they designed, manufactured and sold the Devices.

59. The risks of all Mesh Devices' designs significantly outweigh any benefits allegedly associated with the designs.

60. The appropriate treatment for complications associated with any Mesh Device involves additional invasive surgery to remove the implanted mesh and to repair the damage caused by the failed Device, thus eliminating any purported benefit that the product was intended to provide.

61. When the Mesh Devices were implanted in Plaintiff, there existed safer alternative designs for hernia mesh products, which were economically and technologically

feasible at the time the Devices left Defendants' control. In all reasonable probability, those alternative designs would have reduced the likelihood, severity, frequency, and duration of the injuries Plaintiff suffered, without substantially impairing the utility of the hernia mesh products.

62. The Mesh Devices implanted in Plaintiff failed to reasonably perform as intended and resulted in complications. These complications can necessitate further surgery to repair the injuries caused by the defective Devices, and to repair the very issue the Devices were intended to repair. Thus, the Devices provided no benefit to Plaintiff.

63. Defendants' Mesh Devices failed consumer safety expectations, as they did not perform as safely, when used in an intended or reasonably foreseeable manner, as an ordinary consumer would have expected.

64. Defendants' Mesh Devices injured Plaintiff.

65. Defendants are strictly liable to Plaintiff for designing defective products.

66. As a direct and proximate result of Defendants' defectively designed Mesh Devices, Plaintiff has been injured and undergone medical treatment, and/or will likely undergo future medical treatment. They also sustained severe and permanent physical and mental pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort and consortium, economic loss, and damages, including medical expenses, lost income, other damages (and in some cases death).

67. As a direct and proximate result of the defective and unreasonably dangerous condition of the products, Plaintiff experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo future medical treatment and procedures, has suffered financial or economic loss, including but not limited to, obligations for medical services and expenses, lost income, and other damages.

68. The Mesh Devices were defectively designed when supplied, sold, distributed and/or otherwise placed into the stream of commerce and when they were implanted in Plaintiff.

69. Defendants expected and intended the Mesh Devices product to reach users such as Plaintiff in the condition in which the products were sold.

70. The implantations of Mesh Devices were each a use that Defendants intended and foresaw when it designed, manufactured and sold the products.

71. The risks of the Mesh Devices' designs significantly outweigh any benefits that Defendants contend could be associated with the product's design. As described above, the, hydrophilic mesh design cause and exacerbates infection, fistula formation and abscess, catalyzes hydrolytic and/or enzymatic degradation, is unreasonably susceptible to fragmentation, is unreasonably susceptible to adhesion to, erosion of and serosal damage to internal viscera and organs, and prevents adequate tissue incorporation, leading to, *inter alia*, biofilm formation, encapsulation, chronic and excessive inflammatory response, mesh deformation, scarification and contraction, and failure/recurrence.

72. The polyester material used in the PET Mesh design is dangerous and defective, and is unreasonably susceptible to chronic and severe inflammation, embrittlement, fragmentation, hydrolytic, oxidative and/or enzymatic degradation, tissue necrosis and loss of mechanical strength over time.

73. Given its brittle polymer structure and its susceptibility to degradation, the mesh used in the PET devices was insufficient in strength to withstand the internal forces of the abdomen after implantation over time, which made the device susceptible to tearing, rupture and/or deformation.

74. As a direct and proximate result of the defective and unreasonably dangerous condition of the products, Plaintiff experienced significant mental and physical pain and suffering, have sustained permanent injury, have undergone medical treatment and will likely undergo future medical treatment and procedures, have suffered financial or economic loss, including but not limited to, obligations for medical services and expenses, lost income, and other damages.

COUNT II
Failure to Warn

75. Plaintiff hereby incorporate by reference each and every paragraph set forth in this Complaint as if fully set forth here in their entirety.

76. Defendants failed to adequately instruct or warn Plaintiff or her physicians about the necessity for invasive surgical intervention in the event of complications, or how to properly treat such complications when they occurred.

77. Defendants Covidien and Sofradim were manufacturers, distributors, and/or retailers of Mesh Devices.

78. Their Devices are inherently dangerous.

79. The use of any of Defendants' Mesh Devices in a reasonably foreseeable manner involves a substantial danger that a user would not readily recognize.

80. Defendants knew or should have known of these dangers, given the generally recognized and prevailing scientific knowledge available at the time of the manufacture and distribution of their Mesh Devices.

81. Defendants failed to provide adequate warning of the dangers created by the reasonably foreseeable use of their Devices.

82. At the time the Devices were implanted in Plaintiff, Defendants' warnings and instructions for them were inadequate and defective. As described herein, there was an

unreasonable risk that any Device would not perform safely and effectively for the purposes for which it was intended. Defendants failed to design and/or manufacture against such dangers and failed to provide adequate warnings and instructions concerning these risks.

83. Defendants failed to properly and adequately warn and instruct Plaintiff and her health care providers concerning the risks of the ProGrip, given Plaintiff's conditions and need for that information.

84. Defendants also failed to properly and adequately warn and instruct Plaintiff and her health care providers concerning the inadequate research and testing of the ProGrip, and the complete lack of a safe, effective procedure for removal of the ProGrip.

85. Defendants expected and intended the ProGrip to reach Plaintiff, her health care providers, and other consumers in the condition in which their products were sold.

86. Plaintiff and her health care providers were unaware of the defects and dangers of ProGrip; and were further unaware of the frequency, severity, and duration of the defects and risks associated with ProGrip.

87. Defendants' Instructions for Use for the ProGrip expressly understated, misstated, or concealed the risks Defendants knew or should have known were associated specifically with ProGrip, as described in this Complaint.

88. Defendants' Instructions for Use for the ProGrip failed to adequately warn Plaintiff or her health care providers of numerous risks Defendants knew or should have known were associated with the ProGrip, including but not limited to, the following:

a. The hydrophilic polyester material is heavier and denser than alternative designs, which increases the foreign body load and creates or contributes to an intense inflammatory and chronic foreign body response resulting in an adverse tissue reaction and inadequate tissue incorporation, leading to scarification, adhesion and recurrence.
b. The hydrophilic polyester material has a significantly higher surface area

and lower porosity and attracts and retains bodily fluids, which increases the foreign body load and creates or contributes to an intense inflammatory and chronic foreign body response resulting in an adverse tissue reaction and inadequate tissue incorporation, leading to scarification, adhesion and recurrence.

c. The hydrophilic polyester material attracts and retains bodily fluids, which leads to infection, abscess formation and other complications.

d. The hydrophilic polyester design provides a breeding ground for bacteria in which the bacteria cannot be eliminated by the body's immune response, which allows infection to proliferate, leading to serious infection, fistula formation and abscess and causing biofilm formation that inhibits the body's immune response and impedes proper tissue ingrowth.

e. The hydrophilic polyester becomes brittle and is unreasonably susceptible to fatigue fracture, breakage, fragmentation and other mechanical failures than alternative materials.

f. The hydrophilic polyester is unreasonably susceptible to hydrolytic, oxidative and/or enzymatic degradation.

g. The hydrophilic polyester attracts and retains bodily fluids, resulting in excessive swelling of the mesh, further decreasing the pore size and porosity of the mesh and impairing adequate tissue ingrowth.

h. The products were insufficient to withstand normal abdominal forces, which resulted in recurrent hernia formation and/or rupture and deformation of the mesh itself.

i. The hydrophilic polyester design of ProGrip products potentiates infection, causes fistula formation and abscesses and leads to biofilm formation.

j. The hydrophilic polyester design leads to an intense inflammatory and chronic foreign body response, preventing adequate tissue incorporation.

k. The hydrophilic polyester design is susceptible to hydrolytic, oxidative and/or enzymatic degradation.

l. The hydrophilic polyester material becomes brittle and loses mechanical strength and stability.

m. The ProGrip would significantly swell due to the hydrophilic nature of the mesh construct.

n. The hydrophilic polyester material is unreasonably susceptible to damage from sutures and instrumentation, and is unreasonably susceptible to breakage or rupture in vivo.

o. The risks of chronic pain, inflammation, inadequate tissue incorporation, tissue necrosis, immunologic response, dehiscence, biofilm formation, encapsulation, rejection, migration, scarification, shrinkage/contraction, degradation, deformation, intestinal obstruction, hernia incarceration or strangulation, abscess formation, fistula formation, bowel adhesion, bowel erosion, serosal damage to viscera and internal organs, or rupture/fracture of the mesh.

p. The unusually high rate of infection, fistula formation and abscess associated with the hydrophilic polyester mesh.

q. The risk of chronic inflammation associated with the ProGrip products.

r. The need for corrective surgery to adjust, remove or revise the ProGrip products in the event of complications.
s. The need to completely remove the ProGrip products in the event of infection, fistula or abscess, which in many cases may be difficult or impossible due to the design of the product.
t. The frequency, severity and duration of complications and risks associated with the ProGrip products, particularly those risks known to be associated specifically with the hydrophilic polyester material, such as infection, fistula and abscess formation, biofilm formation, chronic inflammatory response, tissue necrosis, lack of incorporation, adhesion to internal organs and viscera, erosion of internal organs, and serosal damage.
u. The defective features of the ProGrip design described hereinabove.
v. The ProGrip products expose patients to more risks and different risks than those associated with products with safer feasible alternative designs.
w. The risks associated with the ProGrip devices are more frequent, severe, longer lasting, and more difficult to treat than those associated with products with safer feasible alternative designs.
x. ProGrip products are less effective than feasible, available alternatives.
y. ProGrip put patients at a greater risk of requiring additional surgery than feasible, available alternatives.
z. Use of ProGrip products make any future abdominal surgery on the patient much more complex and dangerous than feasible, available alternatives, particularly in the event of infection, abscess or fistula formation or adhesion to or erosion of internal organs.
aa. The difficulty in removing ProGrip products after injury, including the fragmented shards of the ultrathin multifilament fibers, which increased risk of future injuries.
bb. Removal of the ProGrip due to complications may significantly impair the patients' quality of life and may not result in complete resolution of their injuries.

89. Defendants failed to adequately train or warn Plaintiff or her health care providers about the necessity for surgical intervention in the event of complications, or how to properly treat such complications associated with the ProGrip when they occurred.

90. Defendants failed to adequately warn Plaintiff, her health care providers, and the general public, that the necessary surgical removal of a ProGrip in the event of complications would leave the hernia unrepaired, and would necessitate a further attempt to repair the same hernia that the failed ProGrip was intended to treat.

91. With respect to Defendants' warnings about complications associated with the

ProGrip, they provided inadequate or no information regarding the complications, frequency, severity, and duration, even though the complications were more frequent and more severe, and lasted longer than those associated with safer feasible alternative hernia repair treatments.

92. If Plaintiff or her health care providers had been properly warned of the defects and dangers of ProGrip, and of the frequency, severity and duration of the risks associated with the ProGrip, Plaintiff would not have consented to allow the ProGrip to be implanted, nor would her health care providers have implanted them.

93. Defendants are strictly liable in tort to Plaintiff for their wrongful conduct, including their failure to warn or provide adequate instructions regarding ProGrip.

94. As a direct and proximate result of Defendants' inadequate and defective warnings and instructions, Plaintiff has been injured and undergone medical treatment, and will likely undergo future medical treatment. She has also sustained severe and permanent physical and mental pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort and consortium, economic loss, and damages, including medical expenses, lost income, and other damages.

95. Plaintiff's injuries were a reasonably foreseeable result of Defendants' failure to provide adequate warnings and instructions.

96. Plaintiff is entitled to recover compensatory, non-compensatory, punitive, and all other damages available under law for injuries sustained as a result of Defendants' failure to provide adequate warnings and instructions on the risks and dangers associated with the Mesh Devices.

1. As a result of Defendants' failure to warn or to provide adequate warnings, Plaintiff and her health care providers were unaware, and could not have known or learned through

reasonable diligence, that Plaintiff had been exposed to the risks alleged in this Complaint; and that those risks were the direct and proximate result of Defendants' wrongful acts and/or omissions.

97. At the time the Mesh Devices were implanted in Plaintiff, the warnings and instructions provided by Defendants for the Mesh Devices were inadequate and defective. As described above, there was an unreasonable risk that the products would not perform safely and effectively for the purposes for which they were intended, and Defendants failed to design and/or manufacture against such dangers and failed to provide adequate warnings and instructions concerning these risks.

2. The Defendants failed to properly and adequately warn and instruct the Plaintiff and her health care providers as to the risks of the ProGrip.

3. The Defendants 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 ProGrip.

4. The Defendants failed to properly and adequately warn and instruct the Plaintiff or her health care providers regarding the lack of a safe, effective procedure for removal of the ProGrip in the event of complications or device failure.

98. Defendants expected and intended the ProGrip to reach users such as Plaintiff in the condition in which the products were sold.

5. Plaintiff and her physicians were unaware of the defects and dangers of ProGrip, and were unaware of the frequency, severity and duration of the defects and risks associated with the ProGrip.

6. The Defendants' Instructions for Use provided with the ProGrip expressly understates and misstates the risks known to be associated with the ProGrip by, *e.g.*, stating that

the "contraindications" for Mesh Devices are the "usual contraindications for the use of wall reinforcements," and that the complications associated with ProGrip are the same as other "complications arising from wall construction with mesh" or those "typically associated with surgically implanted materials." Defendants provided no warning to Plaintiff or her physicians about the increased risks associated with the design of the ProGrip, including those identified herein.

7. The Defendants' Instructions for Use for the ProGrip failed to adequately warn Plaintiff or her physicians of numerous risks which Defendants knew or should have known were associated with the ProGrip, including but not limited to the risks of the product's inhibition of tissue incorporation, chronic pain, inflammation, fistula formation, abscess formation, biofilm formation, immunologic response, dehiscence, encapsulation, rejection, migration, scarification, shrinkage/contraction, degradation, fragmentation, deformation, adhesion to internal organs and viscera, erosion through tissue and viscera, serosal damage, tissue necrosis, intestinal obstruction, hernia incarceration or strangulation, or rupture/fracture of the mesh.

8. Defendants failed to adequately instruct or warn Plaintiff or her physicians that in the event of infection, the ProGrip must be removed in their entirety, which may be difficult or impossible due to the design of the product.

9. Defendants failed to adequately instruct or warn Plaintiff or her physicians about the necessity for invasive surgical intervention in the event of complications, or how to properly treat such complications when they occurred.

10. Defendants failed to adequately warn Plaintiff or her physicians that the necessary surgical removal of the ProGrip in the event of complications would leave the hernia unrepaired,

and would necessitate further medical treatment to attempt to repair the same hernia that the failed product was intended to treat.

11. Defendants failed to adequately warn or instruct Plaintiff or her physicians that the surgery required to remove the ProGrip in the event of complications would obviate any purported benefit associated with implantation, and would involve additional, significant risks to the patient.

99. With respect to the complications that were listed in the Defendants' product insert warnings, Defendants provided no information or warning regarding the frequency, severity and duration of those complications, even though the complications associated with ProGrip were more frequent, more severe and lasted longer than those with safer feasible alternative hernia repair treatments.

12. If Plaintiff and/or her physicians had been properly warned of the defects and dangers of ProGrip, and of the frequency, severity and duration of the risks associated with ProGrip, Plaintiff would not have consented to allow ProGrip to be implanted.

100. Defendants failed to adequately communicate the warnings of the risks associated with ProGrip to Plaintiff's physicians.

101. The Defendants are strictly liable in tort to the Plaintiff for their wrongful conduct described herein.

102. As a direct and proximate result of the inadequate and defective warnings and instructions, Plaintiff has been injured, sustained severe and permanent mental and physical pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort and consortium, economic loss and damages including, but not limited to medical expenses, lost income, and other damages.

13. Defendants are equitably estopped from asserting a learned intermediary defense due to Defendants' fraudulent concealment, through affirmative misrepresentations and omissions, of the risks and defects associated with the Mesh Devices, including the severity, duration and frequency of risks and complications. Defendants affirmatively withheld and/or misrepresented facts concerning the safety of the Mesh Devices, including but not limited to adverse data and information from studies and testing conducted with respect to Mesh Devices that showed the risks and dangers associated with Mesh Devices were unreasonable, which were intentionally withheld from Plaintiff and her physicians. As a result of Defendants' misrepresentations and concealment, Plaintiff and her physicians were unaware, and could not have known or have learned through reasonable diligence that Plaintiff had been exposed to the risks alleged herein and that those risks were the direct and proximate result of the wrongful acts and/or omissions of the Defendants.

COUNT III
Negligence

103. Plaintiff hereby incorporates by reference each and every paragraph set forth in this Complaint as if fully set forth here in their entirety.

104. In addition to the acts and omissions described in this Complaint, Defendants, by and through their authorized divisions, subsidiaries, agents, servants and/or employees, acted with carelessness, recklessness, negligence, gross negligence and/or willful, wanton, outrageous and reckless disregard for human life and safety in manufacturing, designing, labeling, creating instructions and warnings, marketing, distributing, supplying, selling and/or placing into the stream of commerce the ProGrip, including but not limited to the following:

a. failing to use due care in design and/or manufacture of the ProGrip so as to avoid the aforementioned risks to Plaintiff and others;
b. failing to conduct adequate testing, including pre-clinical and clinical testing and post-marketing surveillance to determine the safety of ProGrip;
c. failing to recognize the significance of their own and other testing, and information regarding ProGrip, which testing and information evidenced

such products are dangerous and potentially harmful when implanted in humans;

d. failing to respond promptly and appropriately to their own and other testing, and information regarding ProGrip; and failing to promptly and adequately warn of the injuries as described in this Complaint;

e. failing to promptly, adequately and appropriately recommend monitoring of patients implanted with ProGrip, in light of the Devices' dangers and potential harm to humans;

f. failing to properly, appropriately and adequately monitor the post-market performance of ProGrip;

g. aggressively promoting, marketing, advertising and/or selling ProGrip despite their knowledge and experience of its dangers and risks;

h. failing to use reasonable and prudent care in their statements of the efficacy, safety and risks of implanting ProGrip, which were knowingly false and misleading, in order to influence patients' health care providers to implant ProGrip;

i. failing to accompany ProGripwith proper and adequate warnings regarding all possible adverse effects and risks associated with the implantation of ProGrip;

j. failing to disclose to Plaintiff and her health care providers their full knowledge and experience regarding the potential risks and harm associated with the implantation of ProGrip;

k. failing to disclose to Plaintiff and her health care providers in an appropriate and timely manner, facts relative to the potential risks and harm associated with the implantation of ProGrip;

l. failing to warn Plaintiff and her health care providers of the severity and duration of such adverse effects;

m. failing to warn Plaintiff and her health care providers directly or indirectly, whether orally or in writing, before actively encouraging the sale of ProGrip, about the increased risk associated with ProGrip;

n. placing and/or permitting the placement of ProGrip into the stream of commerce without adequate warnings that their implantation is harmful to humans and/or without proper warnings of ProGrip's risks;

o. failing to respond or react promptly and appropriately to reports that ProGrip caused harm to patients;

p. disregarding government and/or industry studies, information, documentation and recommendations, consumer complaints and reports or other information regarding the hazards of implantation of ProGrip and their potential harm to humans;

q. under-reporting, underestimating or downplaying the serious dangers and risks of ProGrip;

r. failing to exercise reasonable care in informing health care providers implanting ProGrip about Defendants' own knowledge regarding the potential risks and harm associated with the implantation of ProGrip;

s. failing to adequately warn Plaintiff and her health care providers of the known or reasonably foreseeable danger that Plaintiff would suffer serious

injuries or death after being implanted with ProGrip;

t. promoting ProGrip in advertisements, websites and other modes of communication aimed at creating or increasing the rate and frequency of implantation of ProGrip, without regard to the dangers and risks associated with their implantation;
u. failing to conduct or respond to post-marketing surveillance of complications and injuries associated with the implantation of ProGrip;
v. failing to use due care under the circumstances; and
w. other acts or omissions constituting negligence and carelessness, as may appear during the course of discovery or at the trial of this matter.

105. Defendants had a duty to individuals, including the Plaintiff, to use reasonable and ordinary care in designing, testing, inspecting, manufacturing, packaging, labeling, marketing, distributing, training, and preparing written instructions and warnings for the ProGrip, as well as in the instruction and training of physicians to implant the ProGrip and/or to properly treat complications associated with the ProGrip.

14. Defendants knew, or in the exercise of reasonable care should have known, that ProGrip was defectively and unreasonably designed, was unreasonably dangerous and likely to injure patients in whom ProGrip was implanted. Defendants knew or should have known that Plaintiff and her physicians were unaware of the dangers and defects inherent in ProGrip.

106. Defendants breached their duty of care and were negligent as described herein in the design, manufacture, labeling, warning, instruction, training, selling, marketing and distribution of ProGrip.

107. Defendants breached their duty of care by:

a. Failing to design the ProGrip so as to avoid an unreasonable risk of harm to the patients in whom the product was implanted, including the Plaintiff.
b. Failing to use reasonable care in the testing and study of the ProGrip so as to avoid an unreasonable risk of harm to patients in whom the ProGrip product was implanted, including the Plaintiff.
c. Withholding adverse information regarding the ProGrip within their knowledge, including but not limited to information from testing or study of ProGrip and/or devices with similar design features and adverse event reporting demonstrating unacceptable risks, and thereby preventing

Plaintiff and his physicians from understanding the risks associated with the ProGrip.

d. Failing to adequately instruct, train or warn physicians regarding the use of the ProGrip, the risks associated therewith, including the frequency, severity and duration of such risks, and the appropriate treatment for complications associated with ProGrip.

e. Negligently or carelessly designing, marketing, labeling, testing, packaging and/or selling the ProGrip; and/or

f. Negligently or carelessly failing to properly instruct and train physicians in the implantation and/or removal of ProGrip and in the appropriate treatment of complications associated with ProGrip.

108. The reasons that Defendants' negligence caused the Mesh Devices to be unreasonably dangerous and defective include those described herein.

15. Defendants also negligently failed to warn or instruct Plaintiff or her physicians regarding the risks and defects associated with ProGrip, and failed to adequately communicate such warnings and instructions to Plaintiff or her physicians, including those described herein, which include but are not limited to:

16. The Defendants failed to adequately warn Plaintiff or her physicians that the design elements of ProGrip potentiate infection, cause fistula formation and abscesses and lead to biofilm formation.

17. The Defendants failed to adequately warn Plaintiff or her physicians that the design elements of ProGrip leads to an intense inflammatory and chronic foreign body response, preventing adequate tissue incorporation.

18. The Defendants failed to adequately warn Plaintiff or her physicians that the design elements of ProGrip are susceptible to hydrolytic, oxidative and/or enzymatic degradation.

19. The Defendants failed to adequately warn Plaintiff or her physicians that the ProGrip become brittle and lose mechanical strength and stability.

a. The Defendants expressly understated the risks known to be associated specifically with ProGrip, instead stating that the risks were the same as any other implantable material. The design elements of the ProGrip as stated herein cause or increase the risks of numerous complications, including infection, tissue necrosis, fistula and abscess formation, biofilm formation, prevention of adequate incorporation, increased inflammatory reaction and foreign body response, serosal damage, adhesion to internal organs and viscera, and erosion into internal organs and viscera.

20. The Defendants failed to adequately warn Plaintiff or her physicians of numerous risks which Defendants knew or should have known were associated with ProGrip, including but not limited to the risks of chronic pain, inflammation, inadequate tissue incorporation, tissue necrosis,

immunologic response, dehiscence, biofilm formation, encapsulation, rejection, migration, scarification, shrinkage/contraction, degradation, deformation, intestinal obstruction, hernia incarceration or strangulation, abscess formation, fistula formation, bowel adhesion, bowel erosion, serosal damage to viscera and internal organs, or rupture/fracture of the mesh.

21. The Defendants failed to adequately warn Plaintiff or her physicians of the risk of chronic inflammation associated with the ProGrip.
22. The Defendants failed to adequately warn Plaintiff or her physicians of the need for corrective surgery to adjust, remove or revise the ProGrip in the event of complications.
23. The Defendants failed to adequately warn Plaintiff or her physicians of the need to completely remove the ProGrip in the event of infection, fistula or abscess, which in many cases may be difficult or impossible due to the design of the product.
24. The Defendants failed to adequately warn Plaintiff or her physicians of the defective features of the ProGrip design described hereinabove.
25. The Defendants failed to adequately warn Plaintiff or her physicians that the ProGrip exposes patients to more risks and different risks than those associated with products with safer feasible alternative designs.
26. The Defendants failed to adequately warn Plaintiff or her physicians that the risks associated with the ProGrip are more frequent, severe, longer lasting, and more difficult to treat than those associated with products with safer feasible alternative designs.
27. The Defendants failed to adequately warn Plaintiff or her physicians that ProGrip is less effective than feasible, available alternatives.
28. The Defendants failed to adequately warn Plaintiff or her physicians that the ProGrip puts patients at a greater risk of requiring additional surgery than feasible, available alternatives.
29. The Defendants failed to adequately warn Plaintiff or her physicians that use of the ProGrip makes any future abdominal surgery on the patient much more complex and dangerous than feasible, available alternatives, particularly in the event of infection, abscess or fistula formation or adhesion to or erosion of internal organs.
30. The Defendants failed to adequately warn Plaintiff or her physicians of the difficulty in removing ProGrip after injury.
31. The Defendants failed to adequately warn Plaintiff or her physicians that removal of the ProGrip due to complications may significantly impair the patients' quality of life and may not result in complete resolution of their injuries.
32. The Defendants failed to adequately warn Plaintiff or her physicians of the risks listed above in Count II of this Complaint.

109. Defendants knew or should have known that its failure to exercise ordinary care under the circumstances in the manufacture, design, packaging, labeling, warnings, instructions,

sale, marketing, distribution and training of physicians to implant the ProGrip products and/or to treat resulting complications would cause foreseeable harm, injuries, and damages to individuals implanted with ProGrip products, including the Plaintiff.

110. Defendants knew, or in the exercise of reasonable care should have known, that the ProGrip products were defectively and unreasonably designed and were unreasonably dangerous and likely to injure patients in whom they are implanted. Defendants knew or should have known that Plaintiff or her physicians were unaware of the dangers and defects inherent in the ProGrip products.

111. Defendants' Mesh Devices caused Plaintiff to suffer injuries.

112. As a direct and proximate result of Defendants' negligence in designing, testing, inspecting, manufacturing, packaging, labeling, marketing, distributing, training and preparing written instructions and warnings for ProGrip products, and Defendants' negligence in failing to adequately communicate warnings and instructions for ProGrip products, Plaintiff has been injured, sustained severe and permanent physical and mental pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort and consortium, economic loss, and damages including, but not limited to medical expenses, lost income, and other damages.

113. Defendants owed a duty to Plaintiff to exercise reasonable care when designing, manufacturing, producing, marketing, labeling, packaging and selling Defendants' ProGrip, and when creating instructions and warnings for it.

114. Defendants did not exercise reasonable care when designing, manufacturing, producing, labeling, packaging, marketing, selling, creating, and explaining the instructions or warnings for the ProGrip.

115. Plaintiff suffered injuries as a result of Defendants' failure to exercise reasonable

care in designing, manufacturing, producing, marketing, labeling, packaging and selling, and creating instructions or warnings for the Mesh Devices.

116. Defendants' negligence proximately caused the damages and injuries to Plaintiff.

Count IV
Punitive Damages

117. Plaintiff hereby incorporates by reference each and every paragraph set forth in this Complaint as if fully copied and set forth herein in their entirety.

118. Defendants failed to adequately test and study the Mesh Devices to determine and ensure that the products were safe and effective prior to releasing the products for sale for permanent human implantation, and Defendants continued to manufacture and sell Mesh Devices after obtaining knowledge and information that the products was defective and unreasonably unsafe. The limited testing and study that was undertaken by Defendants prior to release and after release of the Mesh devices, including but not limited to animal studies and human clinical studies, revealed to Defendants that the risks associated with the Mesh Devices were unreasonably frequent and severe and outweighed any purported benefits of the product. The adverse results of those tests and studies were intentionally concealed, or else were misrepresented, by Defendants in order to continue to profit from sales of Mesh Devices. Defendants were aware of the probable consequences of implantation of the dangerous and defective Mesh Devices, such as those suffered by Plaintiff. Defendants willfully and recklessly failed to avoid those consequences, and in doing so, Defendants acted intentionally, maliciously and recklessly with regard to the safety of those persons who might foreseeably have been harmed by the Mesh Devices, including Plaintiff, justifying the imposition of punitive damages.

119. At all times relevant hereto, Defendants knew or should have known that the Defendants' Mesh Devices were inherently dangerous with respect to the risks of serious

complications, including but not limited to serious infections and failures, pain and suffering, loss of life's enjoyment, remedial surgeries and treatments, as well as other severe and personal injuries which are chronic or permanent in nature.

120. At all times material hereto, Defendants attempted to misrepresent and did misrepresent facts concerning the safety of the Defendants' Mesh devices, including but not limited to adverse data and information from studies and testing conducted with respect to Mesh Devices that showed the risks and dangers associated therewith were unreasonable.

33. Defendants' misrepresentations included knowingly withholding material information from the medical community and the public, including Plaintiff or her treating physicians, concerning the safety and efficacy of the Defendants' Mesh Devices.

121. At all times material hereto, Defendants knew and intentionally and/or recklessly disregarded the fact that the Defendants' Mesh devices cause severe and potentially permanent complications with greater frequency than safer alternative devices or treatments and that necessitate different medical treatment.

122. At all times material hereto, Defendants intentionally misstated and misrepresented data and continue to misrepresent data so as to minimize the true and accurate risk of injuries and complications caused by the Mesh devices, including but not limited to data regarding the frequency, severity and duration of those risks and complications.

123. Notwithstanding their knowledge, Defendants continued to market the Defendants' Mesh Devices to consumers without disclosing the true risk of side effects and complications, or the frequency, severity and duration of those risks.

124. Defendants knew of Mesh Device devices' defective and unreasonably dangerous nature, but continued to manufacture, produce, assemble, market, distribute, and sell the devices

so as to maximize sales and profits at the expense of the health and safety of the public, including Plaintiff, in conscious and/or reckless disregard of the foreseeable harm caused by the Mesh devices.

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

Wherefore, Plaintiff respectfully requests judgment in her favor and against Defendants for such amount sufficient to punish, penalize and deter Defendants' conduct and any other amounts or relief as may be fair and reasonable under the circumstances.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment against Defendants, individually, jointly and severally, as follows:

a. for general and compensatory damages in an amount to be proven at the time of trial;

b. for special damages in an amount to be proven at the time of trial;

c. for statutory damages as set forth above, in an amount to be proven at the time of trial;

d. for exemplary and punitive damages in an amount to be proven at the time of trial, and sufficient to punish Defendants or to deter Defendants and others from repeating the injurious conduct alleged herein;

e. for pre-judgment and post-judgment interest on the above general and special damages;

f. for costs of this suit and attorneys' fees; and

g. all other relief that this Court deems necessary, proper and just.

JURY TRIAL DEMANDED

Plaintiff hereby demands a trial by jury on all issues so triable.

Dated: April 17, 2026

Respectfully submitted,

PLAINTIFF,
By their attorneys,
JMS LAW LTD.

By /s/Jill M. Santiago _
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