UNITED STATES DISTRICT COURT
DISTRICT COURT OF MASSACHUSETTS
EASTERN DIVISION

IN RE: COVIDIEN HERNIA MESH PRODUCTS LIABILITY LITIGATION NO. II **This Document Relates To:** **Case No._____** **GARRETT COOPER v. COVIDIEN, INC.; COVIDIEN LTD; COVIDIEN PLC; COVIDIEN HOLDING INC.; MEDTRONIC USA, INC.; MEDTRONIC PLC; COVIDIEN, LLC (d/b/a Covidien, LP, f/k/a Tyco Healthcare Group LP); TYCO INTERNATIONAL LTD; TYCO INTERNATIONAL GROUP S.A.; SURGICAL SOLUTIONS GROUP; UNITED STATES SURGICAL CORP., a division of Tyco Healthcare Group LP; SOFRADIM PRODUCTION SAS; AND SOFRADIM CORP.**	**MDL No. 1:22-md-03029-PBS** **JURY TRIAL DEMANDED**

COMES NOW, Plaintiff, by and through Plaintiff's undersigned attorneys, and hereby bring this Complaint for damages against Covidien, Inc., Covidien LTD, Covidien PLC, Covidien Holding Inc., Medtronic USA, Inc., Medtronic PL, Covidien, LLC (d/b/a Covidien, LP, f/k/a Tyco Healthcare Group LP), Tyco International LTD, Tyco International Group S.A., Surgical Solutions Group, United States Surgical Corp., a division of Tyco Healthcare Group LP, Sofradim Production SAS, and Sofradim Corp. (collectively "Defendants" or "Covidien"), and, in support thereof, state(s) the following:

I. PRELIMINARY STATEMENT

1. This is a medical device tort action brought on behalf of the above-named Plaintiff arising out of the failure of Defendants' hernia mesh device, the Covidien Parietex ("Parietex" or

"Hernia Mesh Device"). As a direct and proximate result, Plaintiff has suffered permanent injuries and significant pain and suffering, emotional distress, loss wages and earnings capacity, and diminished quality of life. Plaintiff respectfully seeks damages in excess of $75,000 for all damages to which Plaintiff may be legally entitled.

2. This matter is being filed in MDL 3029 in accordance with the Court's Direct Filing Order (ECF No. 35, 1:22-md-03029-PBS).

3. Absent direct filing, this case would be filed in the United States District Court, District of Massachusetts, Eastern Division.

II. PARTIES

4. At all material times, Plaintiff has been a citizen and resident of San Diego County in San Diego, California and the United States.

5. Defendant COVIDIEN, INC. ("Covidien Inc.") is a Delaware corporation with its principal place of business at 15 Hampshire Street, Mansfield, Bristol County, Massachusetts, and offices and facilities in Bedford and Waltham, Middlesex County, Massachusetts, and Boston, Suffolk County, Massachusetts. All acts and omissions of Covidien Inc. as described herein including but not limited to those resulting in the design, manufacture, marketing, labeling, distribution, sale and placement of its hernia mesh Device 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 Inc. did business in Massachusetts.

6. Defendant COVIDIEN, LTD. ("Covidien ltd.") is a Bermuda public limited company with its principal place of business in Bermuda, and offices in Bedford and Waltham, Middlesex County, Massachusetts. All acts and omissions of Covidien ltd. as described herein

including but not limited to those resulting in the design, manufacture, marketing, labeling, distribution, sale and placement of its hernia mesh Device 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 ltd. did business in Massachusetts.

7. Defendant COVIDIEN PLC ("Covidien plc") is an Irish public limited company with its principal place of business in Massachusetts at 15 Hampshire Street, Mansfield, Bristol County, Massachusetts, and offices in Bedford and Waltham, Middlesex County, Massachusetts. All acts and omissions of Covidien plc as described herein including but not limited to those resulting in the design, manufacture, marketing, labeling, distribution, sale and placement of its Hernia Mesh Device at issue, 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 plc did business in Massachusetts.

8. Defendants, COVIDIEN HOLDING INC., ("COVIDIEN") is a corporation that is incorporated under the laws of the State of Delaware. COVIDIEN has its principal place of business at 15 Hampshire Street, Mansfield, Bristol County, Massachusetts, and offices in Bedford and Waltham, Middlesex County, Massachusetts. COVIDIEN has a registered agent in Massachusetts at CT Corporation System, 155 Federal Street, Ste. 700, Boston, Massachusetts, 02110. COVIDIEN focuses its business on products in key surgical specialties, including hernia repair, laparoscopic instrumentation, embolization device, pharmaceuticals and medical supplies.

9. Defendant COVIDIEN, LLC (d/b/a Covidien LP, f/k/a Tyco Healthcare Group 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. Tyco US is registered to conduct business in Massachusetts, with a registered agent in the Commonwealth. Its General Partner is Covidien Holding Inc., formerly named Covidien, Inc. prior to September 5, 2012. All acts and omissions of Tyco US as described herein including but not limited to those resulting in the design, manufacture, marketing, labeling, distribution, sale and placement of its Hernia Mesh Device at issue here, 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, Tyco US did business in Massachusetts.

10. Defendant, TYCO INTERNATIONAL LTD. ("Tyco") (d/b/a Covidien, Inc.) is a company incorporated in Massachusetts with a registered agent in the Commonwealth with its principal place of business at 15 Hampshire Street, Mansfield, Bristol County, Massachusetts. Tyco is the parent company for Defendants TIGSA, through its subsidiaries, engaged in the healthcare business. All acts and omissions of Tyco as described herein including but not limited to those resulting in the design, manufacture, marketing, labeling, distribution, sale and placement of its hernia mesh Device 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, Tyco did business in Massachusetts.

11. Defendant TYCO INTERNATIONAL GROUP S.A., ("TIGSA") (d/b/a Covidien, Inc.) is a Delaware limited partnership with a registered agent in Delaware limited partnership with its principal place of business at 15 Hampshire Street, Mansfield, Bristol County, Massachusetts. TIGSA is a holding company and wholly owned subsidiary of Tyco that, through its subsidiaries, engaged in the healthcare business. All acts and omissions of TIGSA as described herein including

but not limited to those resulting in the design, manufacture, marketing, labeling, distribution, sale and placement of its hernia mesh Device 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, TIGSA did business in Massachusetts.

12. Defendant, SURGICAL SOLUTIONS GROUP ("Covidien Surgical") is a Delaware corporation with its principal place of business in Colorado, and is a wholly owned subsidiary of Covidien Ltd. All acts and omissions of Covidien Surgical 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. At all times material hereto, Covidien Surgical did business in Massachusetts.

13. Defendant, United States Surgical Corp. ("U.S. Surgical") is a Delaware corporation with its principal place of business in Connecticut, and is a wholly owned subsidiary of Covidien plc. U.S. Surgical is registered to do business in Massachusetts, with a registered agent in the Commonwealth. It also shares the same corporate directors as Covidien US. All acts and omissions of U.S. Surgical as described herein including but not limited to those resulting in the design, manufacture, marketing, labeling, distribution, sale and placement of its Hernia Mesh Device here, 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, U.S. Surgical did business in Massachusetts.

14. Defendant SOFRADIM PRODUCTION SAS ("Sofradim Production") is a French company with its principal place of business at 116 Avenue Du Formans, Trevoux, France, 01600. All acts and omissions of Sofradim 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.

15. 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.

16. Defendant MEDTRONIC USA INC. and MEDTRONIC plc f/k/a Medtronic Inc. & Covidien plc, (collectively referred to as "MEDTRONIC") is a corporation that is incorporated under the laws of the State of Minnesota, with offices and facilities at 12 Gill Street, Woburn, Middlesex County, Massachusetts and Boston, Suffolk County, Massachusetts. It is the corporate parent/stockholder of COVIDIEN and all of its subsidiaries and entities. All acts and omissions of Medtronic 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.

17. Medtronic, directly and/or through the actions of Covidien has at all pertinent times been responsible for the research, development, design, testing, manufacture, production, marketing, promotion, distribution and/or sale of all Mesh Device described herein.

18. 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 Device, 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.

19. 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.

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

21. 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 Device 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.

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

23. Defendants are individually, jointly and severally liable to Plaintiff for damages suffered by Plaintiff arising from the Defendants' design, manufacture, marketing, labeling, distribution, and sale of the Mesh Device at issue in the instant suit, 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.

24. Defendants had a legal duty to ensure the safety and effectiveness of their Mesh Device prior to marketing and selling those products for permanent implantation in Plaintiff. Prior to marketing and selling the Mesh Device, 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 Device sold for the same use. Because implantation of Defendants' Mesh Device 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 Device outweigh any purported benefits, both generally and specifically with respect to the Plaintiff in this case.

25. 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, 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.

26. 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 Device. Defendants at all relevant times hereto, marketed, promoted, warranted, and/or sold their products in the Commonwealth of Massachusetts and throughout the United States.

III. JURISDICTION AND VENUE

27. At all material times, Plaintiff has been a citizen and resident of San Diego County in San Diego, California and the United States.

28. This Court has subject-matter jurisdiction over this action pursuant to 28 U.S.C. § 1332(a) based on complete diversity of citizenship between Plaintiff and all Defendants. The amount in controversy exceeds $75,000.00.

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

30. The Court has jurisdiction over the Defendants who designed, developed, manufactured, produced, testing, studied, researched, inspected, labeled, marketed, advertised, sold, promoted, and/or distributed the Hernia Mesh Device(s) in and from the Commonwealth of Massachusetts.

31. 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.

32. Defendants have substantial, systematic and continuous contact with this State such that exercise of personal jurisdiction over these Defendants is appropriate.

33. Further, Defendants have purposely availed themselves to the privilege of conducting business within this State and have the requisite minimum contacts with this State such that the maintenance of this suit does not offend traditional notions of fair play and substantial justice and that Defendants should reasonably anticipate being hailed into Court here.

34. 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, the Hernia Mesh Device implanted in the Plaintiff, in the Commonwealth of Massachusetts and in interstate commerce, for which it derived significant and regular income.

35. Venue is proper in this District pursuant to 28 U.S.C. § 1391 because the events or omissions giving rise to Plaintiff's claims occurred in this District.

IV. FACTS COMMON TO ALL COUNTS

COVIDIEN HERNIA MESH DEVICE

36. The Covidien Hernia Mesh Device, the Parietex, implanted in Plaintiff's body was designed, manufactured and distributed by Covidien.

37. Defendants' Hernia Mesh Device implanted in Plaintiff was designed, patented, manufactured, labeled, marketed, sold, distributed, or otherwise placed on the market by Defendants and is a knitted polyester mesh.

38. Defendants sought and obtained FDA clearance to market their Hernia Mesh Device under Section 510(k) of the Medical Device Amendment to the Food, Drug and Cosmetics Act. Section 510(k) provides for marketing of a medical device if the device is deemed

"substantially equivalent" or "substantially similar" to other predicate Device marketed prior to May 28, 1976. The 510(k) process is not a formal review for safety or efficacy. No clinical testing or clinical study is required to gain FDA clearance under this process. Upon information and belief, no formal review for safety or efficacy was ever conducted for the Hernia Mesh Device.

39. The "510(k) tree" or predicate Device for all of Defendants polyester hernia meshes, like the Hernia Mesh Device at issue here, interlink with each other. Therefore, Defendants have represented to the FDA that all hernia mesh Device are "***substantially similar***" to one another.

40. Testing done on one polyester hernia mesh was frequently used by Defendants to avoid doing testing on its other hernia mesh devices.

41. Testing done on one polyester hernia mesh was frequently used by Defendants to market other of its polyester hernia meshes.

42. Defendants marketed and sold their polyester hernia meshes to the medical community at large and patients through carefully planned, multifaceted marketing campaigns and strategies. These campaigns and strategies include, but are not limited to, aggressive marketing to health care providers at medical conferences, hospitals, and private offices, as well as the provision of valuable benefits to health care providers. Defendants further utilized documents, patient brochures, and websites.

43. Defendants' polyester hernia meshes were cleared for marketing pursuant to the FDA's premarket notification process, which is also referred to as the "510(k)" process. Medical Device that enter the market through the 510(k) process are not "approved" by the FDA and Device 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.

44. The polyester polymer used in the design of Defendants polyester hernia meshes, like the Hernia Mesh Device at issue here, 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) and polypropylene. Peer-reviewed, published literature prior to the introduction of Defendants' PET mesh 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 Surg.** 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.

45. The polyester material used in the Defendants' 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 Vasc Endovasc Surg.** 1997;13(6):540-8 (Study of explanted polyester implant Device 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):1-8 (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*. **Surg 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 individual polyester fibers that make up the PET mesh are unreasonably susceptible to degradation. The gamma irradiation sterilization of the PET produces free radicals that contribute to degradation before implant.

46. The polyester material used in the PET Device 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**. 2010;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 Surg 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. Surg.** 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 Surg.** 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 PET mesh).

47. The polyester polymer used in the PET mesh 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*. **Surg 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.").

48. Due to the hydrophilic nature of the PET mesh, the strands of polyester attract and retain bodily fluids, resulting in excessive swelling of the mesh, further increasing the weight and density of the mesh after implant and thus the foreign body load, which increases and prolongs the inflammatory and foreign body reaction to the PET mesh.

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

PERMANENT NON-INERT POLYMER IN HERNIA MESH DEVICE: DEFECTS & RISKS

50. Defendants' Hernia Mesh Device contains a permanent, non-inert polymer, specifically polyester. Despite Defendants' claims that polyester is inert, scientific evidence shows that polyester is biologically incompatible with human tissue and incite a chronic immune response

in much of the population after implantation. The immune response promotes degradation and contracture of the mesh, as well as the surrounding tissue, and can contribute to the formation of severe adverse reactions to the Hernia Mesh Device.

51. The Hernia Mesh Device is defective due to its high rates of failure, injury, and complications, its failure to perform as intended, its requirement of frequent and often debilitating re-operations, and its cause of severe and irreversible injuries, conditions, and damage to numerous patients, including Plaintiff.

52. The specific nature of the Hernia Mesh Device's defects includes, but is not limited to, the following:

a) The use of polyester in the Device and the immune reactions resulting from such material, causes adverse reactions and injuries.

b) Adverse reactions to the polyester in the Device consist of adhesions, injuries to nearby organs, nerves, or blood vessels, and other complications, including infection, chronic pain, and hernia recurrence.

c) The Device has a propensity to degrade or fragment over time, causing a chronic inflammatory and fibrotic reaction, and resulting in continuing injury over time as the polyester acts as a chronic trigger for inflammation.

d) Upon information and belief, Defendants utilized various substandard and/or adulterated polyester in the Device.

e) The weave of the Device produces very small interstices allowing bacteria to enter and hide from white blood cells and macrophages—the host defenses designed to eliminate bacteria. The bacteria also secrete an encasing biofilm, serving to further protect them from destruction by white blood cells and macrophages. In addition, some bacteria are capable of accelerating the degradation of polyester.

f) The polyester contains numerous additive compounds, which leach from the Device and are toxic to tissue, enhancing the inflammatory reaction and the intensity of fibrosis.

g) Scanning electron microscopy has shown polyester to not be inert, with degradation leading to flaking, fissuring, and release of toxic compounds. This enhances the inflammatory and fibrotic reactions.

h) For decades, polyester was known to shrink 30-50+%.

i) Polyester is subject to oxidation by acids and other byproducts produced during the inflammatory reaction, causing degradation and loss of compliance.

j) Inadequate porosity. Mesh porosity is important for tissue ingrowth, with low porosity decreasing tissue incorporation. Porosity also affects the inflammatory and fibrotic reaction. With mechanical stress, the effective porosity is decreased.

k) After implantation in the human body, polyester is known to depolymerize, cross-link, undergo oxidative degradation by free radicals, and stress crack.

l) The Device has a tendency to unravel or fray, causing polyester fibers to protrude from the mesh, which harden after implantation, causing an increased foreign body reaction, pain, and risk of organ perforation.

m) The large surface area of polyester promotes wicking of fluids and bacteria, and is a "bacterial super highway" providing a safe haven for bacteria.

n) Common complications associated with polyester include restriction of abdominal wall mobility and local wound disturbances. Failures of polyester often include persistent and active inflammatory processes, irregular or low formation of scar tissue, immature collagen formation, and unsatisfying integration of the mesh in the regenerative tissue area.

53. Shrinkage, stiffness, and deformation of flexible meshes is affected by scar tissue. The Hernia Mesh Device has inter-filament distances and pores that are too small and close together, increasing the risk of bridging by scar tissue.

54. Defendants knew or should have known that the Hernia Mesh Device implanted in the groin will be subject to movement and bending. Polyester in the groin has a higher likelihood of folding and bunching, and the scar fills the spaces between the folds. The phenomenon was termed a "meshoma" because the mesh forms a tumor-like mass. Further, 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.

DEFENDANTS' ACTS & OMISSIONS REGARDING THEIR DEFECTIVE DEVICE

55. At all material times, Defendants were responsible for designing, manufacturing, producing, testing, studying, inspecting, labeling, marketing, advertising, selling, promoting, and distributing their Hernia Mesh Device, and providing warnings/information about the Device.

56. Defendants' Hernia Mesh Device was defectively designed and manufactured; and was also defective as marketed due to inadequate warnings, instructions, labeling and/or inadequate testing, despite Defendants' knowledge of the Device's lack of safety.

57. Defendants had independent obligations to know and timely and adequately disclose scientific and medical information about their Hernia Mesh Device; and to warn of their risks and side effects as soon as each Defendant was aware of them. Defendants did not do so.

58. Defendants also knew or should have known that their Hernia Mesh Device unreasonably exposed Plaintiff to the risk of serious harm, while conferring no benefit over available feasible and safer alternatives that did not present the same risks and adverse effects.

59. Defendants made claims regarding the benefits of implanting the Device but minimized or omitted their risks and adverse effects. Although Defendants knew or should have known that their claims were false and misleading, they failed to adequately disclose the true health consequences and the true risks and adverse effects of the Hernia Mesh Device.

60. At all material times, Defendants failed to provide sufficient warnings and instructions that would have put Plaintiff, Plaintiff was health care providers, and the general public on notice of the dangers and adverse effects caused by implantation of the Hernia Mesh Device.

61. Defendants have marketed and continue to market their Hernia Mesh Device to Plaintiff and health care providers as safe, effective and reliable, and implantable by safe and

effective, minimally invasive surgical techniques. Further, Defendants continue to market their Device as safer and more effective than available feasible alternative treatments for hernias, and other competing products. Those alternatives have existed at all material times, and have always presented less frequent and less severe risks and adverse effects than the Hernia Mesh Device.

62. The risks of the Hernia Mesh Device's design outweigh any potential benefits associated with the design. As a result of their defective design and/or manufacture, an unreasonable risk of severe adverse reactions can occur, including but not limited to: foreign body response; granulomatous response; allergic reaction; rejection; erosion; excessive and chronic inflammation; adhesions to internal organs; scarification; improper wound healing; infection; seroma; abscess; fistula; tissue damage and/or death; nerve damage; chronic pain; recurrence of hernia; and other complications.

63. Defendants omitted mention of the Device's risks, dangers, defects, and disadvantages when they advertised, promoted, marketed, sold and distributed them as safe to regulatory agencies, health care providers, Plaintiff and other consumers. But Defendants knew or should have known that the Hernia Mesh Device was not safe for its intended purposes, and that it would and did cause serious medical problems, including severe and permanent injuries and damages—and in some Plaintiff, catastrophic injuries and death.

64. Defendants have underreported information about the propensity of the Hernia Mesh Device to fail and cause injury and complications; and have made unfounded representations regarding the efficacy and safety of the Device through various means and media.

65. Defendants knew or should have known that at all material times their communications about the benefits, risks and adverse effects of the Hernia Mesh Device, including

communications in labels, advertisements and promotional materials, were materially false and misleading.

66. Defendants' nondisclosures, misleading disclosures, and misrepresentations were material and were substantial factors contributing directly to the serious injuries and damages Plaintiff have suffered.

67. Plaintiff would not have agreed to allow the implantation of the Hernia Mesh Device had Defendants disclosed the true health consequences, risks and adverse effects caused by their Hernia Mesh Device.

68. Upon information and belief, Defendants failed to conduct adequate pre-market clinical testing and research, and failed to conduct adequate post-marketing surveillance to determine the safety of the Hernia Mesh Device.

69. Upon information and belief, Defendants failed to disclose on their warning labels or elsewhere that adequate pre-market clinical testing and research, and adequate post marketing surveillance had not been done on the Hernia Mesh Device, thereby giving the false impression that the Device had been sufficiently tested.

70. Upon information and belief, Defendants designed their animal studies in a manner to make their Hernia Mesh Device appear safer than it actually performs in humans, and to appear safer than competing safer alternative designs and procedures.

71. Upon information and belief, during animal studies of the Hernia Mesh Device, Defendants' administered or directed others to administer medications to the animals that would favorably impact the study endpoints. This administration of these medications and their impact on the study endpoints were not adequately disclosed to Plaintiff, Plaintiff's physicians, or regulatory bodies.

72. Upon information and belief, Defendants are in possession of information, such as data and reports from the Americas Hernia Society Quality Collaborative (AHSQC), that Defendants' Hernia Mesh Device results in significantly higher rates of numerous severe complications when compared to competitor hernia meshes. Defendants have not made such information public or disclosed such information to the FDA. Furthermore, upon information and belief, Defendants prohibit organizations, like AHSQC from releasing such information.

73. The Hernia Mesh Device is defective due to Defendants' failure to adequately warn or instruct Plaintiff and Plaintiff's health care providers concerning at least the following subjects:

a) The Hernia Mesh Device's propensities for degradation and fragmentation.

b) The rate and manner of mesh erosion or extrusion in the Device.

c) The risk of chronic inflammation resulting from the Device.

d) The risk of chronic infections resulting from the Device.

e) The Device would be "tension free" only at the time of implantation; and would drastically contract once implanted.

f) The risk of recurrent hernias, intractable hernia pain, and other pain resulting from the Device.

g) The need for corrective or revision surgery to revise or remove the Device.

h) The severity of complications that could arise as a result of implantation of the Device.

i) The hazards associated with the Device.

j) The Device's defects described in this Complaint.

k) Treatment of hernias with the Device is no more effective than with feasible available alternatives; and exposes patients to greater risk than with feasible available alternatives.

l) Treatment of hernias with the Device makes future surgical repairs more difficult than with feasible available alternatives.

m) Use of the Device puts patients at greater risk of requiring additional surgery than use of feasible available alternatives.

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

o) The Device is cytotoxic, immunogenic, and/or non-biocompatible, causing or contributing to complications such as delayed wound healing, chronic inflammation, adhesion formation, foreign body response, rejection, infection, seroma formation, chronic pain, and others.

p) The Device significantly contracts, hardens, and deforms post-implantation.

74. The Hernia Mesh Device was at all times utilized and implanted in a manner foreseeable to Defendants: Defendants generated Instructions for Use for the Device, created implantation procedures, and allegedly trained the implanting physicians. But Defendants provided incomplete and insufficient training and information to physicians regarding the use of the Device, subsequent anatomical changes, and aftercare of patients, including Plaintiff.

75. The Hernia Mesh Device implanted in Plaintiff was in the same or substantially similar condition as when they left Defendants' possession, and in the condition directed by and expected by Defendants.

76. As a result of having the Hernia Mesh Device implanted, Plaintiff has experienced significant physical and mental pain and suffering, sustained permanent injury, undergone medical treatment and will likely undergo further medical treatment, and suffered financial or economic loss, including obligations for medical services and expenses, lost income, and other damages.

PLA MICROGRIPS: ADDED DEFECTS & RISKS

77. As an alternative to suturing or tacking a hernia mesh, Defendants added thousands of resorbable polylactic microgrips (PLA Microgrips) to polyester meshes, creating devices such as the Parietex ProGrip (PLA Microgrip Devices).[1]

[1] Defendants utilize Parietene Progrip (polypropylene) animal studies when marketing Parietex Progrip (polyester).

78. Defendants' PLA Mircrogrip 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.

79. As a result of the defective design and/or manufacture of the PLA Microgrip Devices, an unreasonable risk of severe adverse reactions can occur, including but not limited to: foreign body response; granulomatous response; allergic reaction; rejection; erosion; excessive and chronic inflammation; pain; immature collagen formation; recurrence; infection; seroma; inability to remove; and other complications.

80. 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.

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

82. 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.

DEFENDANTS' ACTS & OMISSIONS REGARDING PLA MICROGRIPS

83. 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.

84. 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.

85. 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.

86. 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.

87. The Instructions for Use of Defendants' PLA Microgrip Devices note that "this product 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.

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

89. 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 products 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.

90. 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 product degradation.

PLAINTIFF'S USE OF THE PRODUCT

91. The Hernia Mesh Device was utilized and implanted in a manner foreseeable to Defendants.

92. The Hernia Mesh Device that was implanted into Plaintiff was in the same or substantially similar condition as when it left the possession of the Defendants, and in the condition directed by the Defendants.

93. On or about April 26, 2016, Plaintiff underwent surgery for repair of a ventral hernia by Dr. Huda Zahid Anwarul at the Kaiser Permanente in Rancho Cucamonga, California. A Covidien Parietex ProGrip Self-Fixating Mesh, (Model No. TEM1208GL), was implanted to repair the hernia defect.

94. On or about April 25, 2022, Plaintiff underwent a diagnostic laparoscopy due to pain. During the procedure, the surgeon found that there was considerable scar tissue, and that the old mesh was wrapped tightly around the internal ring with tension. This surgery was performed by Dr. Mersadies Martin at Kaiser Permanente in Rancho Cucamonga, California.. Dr. Martin

removed the Hernia Mesh device.

95. Plaintiff experienced chronic debilitating pain, inflammatory responses, and other consequential physical discomfort and mental anguish as a result of the Hernia Mesh Device implantation, which impaired Plaintiff's activities of daily living.

96. At the time of the operation, Plaintiff was not informed of, and had no knowledge of the complaints, known complications and risks associated with the Hernia Mesh Device.

97. Plaintiff was never informed by the Defendants of the defective and dangerous nature of the Hernia Mesh Device.

98. At the time of the implant, neither Plaintiff nor Plaintif's physicians were aware of the defective and dangerous condition of the Hernia Mesh Device.

99. Plaintiff has suffered and will continue to suffer physical pain and suffering, as well as mental anguish and emotional distress.

100. Plaintiff has also incurred substantial medical bills and has suffered loss of other monies due to the defective hernia patch that was implanted.

ESTOPPEL AND TOLLING OF STATUTE OF LIMITATIONS

101. Defendants are estopped from relying on any statutes of limitations or repose by virtue of their acts of fraudulent concealment, which include intentional concealment from Plaintiff and/or the general public that the Mesh Products are defective, while continually marketing the products with the effects described in this Complaint.

102. Given Defendants' affirmative actions of concealment by failing to disclose this known but non-public information about the defects—information over which Defendants had exclusive control—and because Plaintiff could not reasonably have known the Mesh Products

were defective, Defendants are estopped from relying on any statutes of limitations that might otherwise be applicable to the claims asserted in this Complaint.

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

104. Further, in the existence of due diligence, Plaintiff could not have reasonably discovered the Defendants' wrongful conduct, including, but not limited to, the defective design and/or manufacturing of the products until a date within the statute of limitations. Therefore, under appropriate application of the discovery rule, Plaintiff's suit was filed well within the statutory limitations period.

V. COUNTS

COUNT I: STRICT LIABILITY - DEFECTIVE DESIGN

105. Plaintiff re-alleges and incorporates by reference every paragraph of this Complaint as if each were set forth fully and completely herein.

106. Defendants designed, manufactured, labeled, supplied, sold, distributed, marketed and/or otherwise placed into the stream of commerce the Hernia Mesh Device implanted into Plaintiff.

107. The implantation of the Hernia Mesh Device in Plaintiff's bodies was a type of use that Defendants intended and foresaw when they designed, manufactured, and sold the products.

108. At the time of the Hernia Mesh Device 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. In addition, other safer feasible alternative designs for hernia mesh products that would have reduced the likelihood, severity, frequency and duration of the injuries Plaintiff suffered include utilizing the polymer polypropylene as the permanent polymer grafting material. Still other options include fully biologic Device that use animal cells such porcine or bovine. Another alternative to the Hernia Mesh Device at issue here would be to utilize fully degradable polymers such as poly-4-hyrdoxubutyrate (P4HB) polymeric mesh, which would provide immediate short-term support, similar to a traditional nonresorbable mesh, but provide an absorbable scaffold that enables abdominal wall or inguinal floor to remodel to host tissue over a resorption time of 12-18 month post-implantation.

109. A reasonably prudent medical device manufacturer would not have placed the Hernia Mesh Device with its defective design into the stream of commerce.

110. The Defendants' Hernia Mesh Device was defectively designed when manufactured, labeled, supplied, sold, distributed and/or otherwise placed into the stream of commerce and when they were implanted in Plaintiff.

111. The Defendants' Hernia Mesh Device was unreasonably dangerous, taking into consideration the utility of said Device and the risks involved in its use. The foreseeable risks associated with the design of the Hernia Mesh Device was more dangerous than reasonably

prudent consumers such as Plaintiff and/or Plaintiff's physicians would expect when the Hernia Mesh Device is used for their normal and intended purposes.

112. The Hernia Mesh Device implanted in Plaintiff was not reasonably safe for their intended uses and were defective as described within this complaint in regard to their design. As previously stated, the Hernia Mesh Device's design defects include, but are not limited to:

a) The use of polyester in the Hernia Mesh Device and the intense chronic inflammatory that results from such material, causing adverse reactions and injuries as alleged throughout this complaint.

b) Biomechanical issues with the design of the Hernia Mesh Device, including the propensity to shrink or contract over time inside of the body, which causes the surrounding tissue to become fibrotic and contract, resulting in additional inflammation, pain, mesh deformation, recurrence, and other injuries.

c) The propensity of the Hernia Mesh Device to degrade, fragment, fray, and unravel inside the body, which causes a chronic inflammatory and fibrotic reaction, contributing to and causing the injuries described throughout this complaint.

d) Biomaterial and issues with the design of the Hernia Mesh Device, including the use of a collagen film, which:

   i. Carries a high risk of infection.

   ii. Does not prevent and/or adequately reduce adhesion formation.

   iii. Is delicate and prone to tearing and/or degrading during implantation.

   iv. Allows bare polyester to come into contact with the viscera within days of implantation.

v. Increases the risk of adverse immunological responses.

vi. Inhibits wounds healing.

e) Biomaterial and Biomechanical issues with the design of the Hernia Mesh Device, including the use of PLA in general and forming the PLA into Velcro-like hooks to adhere to the underlying tissue, which results in one of the following if the Defendants' Hernia Mesh Device fails:

i. Removal of large amounts of native tissue, resulting in a significantly larger defect than the Defendants' Hernia Mesh Device was initially utilized to repair.

ii. Inability to remove portions of Defendants' failed Hernia Mesh Device and stop the complications that the failed Hernia Mesh Device is causing.

f) Biomaterial issues with the design of the Hernia Mesh Device, including the use of hydrophilic materials, which:

i. Increase the risk of seroma formation.

ii. Increase the risk of infection.

iii. Increase the rate in which polyester degrades.

g) Biomaterial issues with the design of the Hernia Mesh Device, including the use of acidic resorbable polymers, such as PGLA and PLA, both of which:

i. Reduce the pH of the tissues in close proximity to the mesh.

ii. Incite an intense inflammatory response while resorbing.

iii. Increase the risk of adhesions and scarring.

iv. Cause tissue contraction, and subsequent mesh deformation.

v. Inhibit wound healing.

vi. Inhibit strong incorporation.

vii. Inhibit the formation of mature collagen.

viii. Inhibit reperitonealization.

ix. Increase the risk of chronic pain and infection.

113. Defendants' Hernia Mesh Device reached Plaintiff's implanting surgeons and were implanted without any substantial change in the condition in which they were supplied, distributed, sold and/or otherwise placed into the stream of commerce.

114. Defendants' Hernia Mesh Device failed to perform as safely as ordinary consumers and/or their physicians would expect when used as intended or when used in a manner reasonably foreseeable by the manufacturer, and the risks and dangers of the Hernia Mesh Device outweigh its benefits. The design defects in the Hernia Mesh Device was not known, knowable and/or reasonably visible to Plaintiff or Plaintiff's physicians, or discoverable upon any reasonable examination. The Hernia Mesh Device was used and implanted in the manner in which they were intended to be used and implanted by Defendants pursuant to the Instructions for Use and the product specifications provided by Defendants.

115. The appropriate treatment for complications associated with the Hernia Mesh Device involves additional invasive surgery to remove the mesh from the body and/or repair the damage caused by the failed mesh, thus eliminating any purported benefit that the product was intended to provide to the patient.

116. The Hernia Mesh Device implanted in Plaintiff failed to reasonably perform as intended, and had to be surgically removed and/or revised necessitating further invasive surgery to repair the injuries caused by the defective products and to repair the very issue that the products were intended to repair, and thus provided no benefit to Plaintiff.

117. The defective and unreasonably dangerous condition of the Hernia Mesh Device was the proximate cause of the damages and injuries complained of by Plaintiff.

118. As a direct and proximate result of the Hernia Mesh Device's aforementioned design defects, Plaintiff have experienced significant mental and physical pain and suffering, sustained severe and permanent injuries requiring past and future medical treatment, and resulting in disability, impairment, loss of enjoyment of life, loss of care, comfort, and have incurred financial or economic loss, including, but not limited to, obligations for medical expenses, lost income, and other damages.

119. Defendants are strictly liable to Plaintiff for designing, manufacturing, marketing, selling and/or distributing defective products.

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

COUNT II: STRICT LIABILITY - MANUFACTURING DEFECT

120. Plaintiff re-alleges and incorporates by reference every paragraph of this Complaint as if each were set forth fully and completely herein.

121. Defendants designed, manufactured, labeled, supplied, sold, distributed, marketed and/or otherwise placed into the stream of commerce the Hernia Mesh Device implanted in Plaintiff. The Hernia Mesh Device was defective in manufacture and construction when it left the hands of Defendants in that its manufacture and construction deviated from good manufacturing practices and/or manufacturing specifications as would be used and/or maintained by a reasonably prudent and careful medical device manufacturer.

122. The Hernia Mesh Device implanted in the Plaintiff was not reasonably safe for their intended uses and were defective as described throughout this complaint, as a matter of law, with respect to their manufacture, in that they deviated materially from Defendants' design and manufacturing specifications in such a manner as to pose unreasonable risks of serious bodily harm to the Plaintiff.

123. Upon information and belief, Defendants' utilized adulterated polyester in the Hernia Mesh Device.

124. Upon information and belief, Defendants' utilized an adulterated collagen film.

125. Upon information and belief, Defendants' altered their sterilization process on the Hernia Mesh Device without conducting adequate safety test.

126. Upon information and belief, Defendants' failed to properly conduct quality controls and testing on the Hernia Mesh Device manufacturing system and the meshes themselves.

127. Upon information and belief, Defendants' failed to control the quality and the similarity of the raw materials purchased and utilized in the manufacture of the Hernia Mesh Device.

128. Upon information and belief, Defendants' failed to develop adequate post-manufacturing testing procedures.

129. Upon information and belief, Defendants' failed to investigate, identify, and correct manufacturing defects that caused certain lots and Hernia Mesh Device to deviate from design and performance specifications.

130. Upon information and belief, Defendants' failed to conduct adequate stability testing, and failure to report upon same to the FDA.

131. The Hernia Mesh Device, as manufactured and constructed by Defendants, were unreasonably dangerous to end consumers including Plaintiff and posed an unreasonable degree of risk, danger and harm to Plaintiff.

132. The Hernia Mesh Device was expected to reach and did reach Plaintiff's implanting surgeons and Plaintiff without substantial change in the condition in which they were manufactured, suppled, distributed, sold and/or otherwise placed in the stream of commerce.

133. The manufacturing defects in the Hernia Mesh Device implanted in the Plaintiff was not known, knowable or readily visible to Plaintiff's physicians or to Plaintiff, nor were they discoverable upon any reasonable examination by Plaintiff's physicians or Plaintiff.

134. The Hernia Mesh Device was used and implanted in the very manner in which it was intended to be used and implanted by Defendants in accordance with the Instructions for Use and specifications provided by Defendants.

135. The Hernia Mesh Device implanted in Plaintiff was different from the intended design and failed to perform as safely as products manufactured in accordance with the intended design would have performed.

136. The defects in the manufacturing process employed by the Defendants resulted in the sale of defective Hernia Mesh Device to Plaintiff.

137. The defective and unreasonably dangerous condition of the Hernia Mesh Device was a proximate cause of damages and injuries suffered by the Plaintiff.

138. As a direct and proximate result of the Hernia Mesh Device's aforementioned manufacturing defects as described herein, Plaintiff has experienced significant mental and physical pain and suffering, sustained severe and permanent injuries requiring past and future medical treatment, and resulting in disability, impairment, loss of enjoyment of life, loss of care,

comfort, and have incurred financial or economic loss, including, but not limited to, obligations for medical expenses, lost income, and other damages.

139. Defendants are strictly liable to the Plaintiff for designing, manufacturing, marketing, labeling, packaging, and selling a defective product.

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

COUNT III: STRICT LIABILITY - FAILURE TO WARN

140. Plaintiff re-alleges and incorporates by reference every paragraph of this Complaint as if each were set forth fully and completely herein.

141. Defendants designed, manufactured, labeled, supplied, sold, distributed, marketed and/or otherwise place into the stream of commerce their Hernia Mesh Device.

142. Defendants marketed the Hernia Mesh Device as life-long implants.

143. The Hernia Mesh Device implanted in the Plaintiff was not reasonably safe for their intended uses and were defective as described herein, as a matter of law, due to the lack of appropriate and necessary warnings. Among other subjects, Defendants did not provide sufficient or adequate warnings regarding:

a) The lack of data on how the Hernia Mesh Device performs in humans short-term and long-term;

b) The unusually high rate of infection associated with the Hernia Mesh Device;

c) The risk associated with collagen film;

d) The risk associated with PLA;

e) The risk associated with PGLA;

f) The risks associated with polyester;

g) Dense adhesions;

h) That loose and filmy adhesions would become denser over time;

i) That dense adhesions to all small percentage of the meshes surface results in the same rate of severe complications, such as bowel obstructions, erosion, bowel resections, chronic pain, and infection, compared to a mesh entirely covered in dense adhesions;

j) That severe complications as a result of dense adhesions to the mesh are frequently latent, in that symptoms don't manifest for years or even decades;

k) That the profound inflammatory response to polyester;

l) Organ perforation;

m) Bowel obstruction;

n) Cholecystitis;

o) Seromas;

p) Fistulas;

q) The frequency of long-term recurrence;

r) The propensity of the Hernia Mesh Device to contract, retract, deform, and/or shrink inside the body;

s) The propensity of the Hernia Mesh Device to degrade, fragment, fray, unravel, and/or disintegrate;

t) The risk of chronic inflammation resulting from the Hernia Mesh Device;

u) The risk of systemic complications from uncontrolled chronic inflammation;

v) The potential mesh failure modes and injuries caused by chronic inflammation;

w) The risk of chronic, and untreatable infections resulting from the Hernia Mesh Device;

x) The risk of chronic, debilitating, and intractable pain from the Hernia Mesh Device;

y) The likely need for corrective or revision surgery to adjust or remove the Hernia Mesh Device within a decade;

z) That the Hernia Mesh Device would likely fail during the lifetime of the patient requiring additional and more complex surgeries;

aa) The possibility that the Hernia Mesh Device is not fully removable;

bb) The severity of complications that could arise if the Hernia Mesh Device is removed;

cc) The severity of complications that could arise as a result of the implantation of the Hernia Mesh Device;

dd) The hazards associated with the Hernia Mesh Device;

ee) The Hernia Mesh Device defects as described herein;

ff) Treatment with the Hernia Mesh Device is no more effective than feasible, available alternatives;

gg) Treatment with the Hernia Mesh Device exposes patients to greater risk than feasible, available alternatives;

hh) Use of the Hernia Mesh Device puts the patient at a greater risk of requiring additional surgery than feasible, available alternatives;

ii) Removal of the Hernia Mesh Device due to complications may involve multiple surgeries over several years, and may significantly and permanently impair the patient's quality of life;

jj) Complete removal of the Hernia Mesh Product may not result in complete resolution of the complications, including pain; and

kk) Complete removal of the Hernia Mesh Device may not be possible.

144. Defendants failed to properly and adequately warn and instruct Plaintiff and Plaintiff's treating physicians that Defendants' Hernia Mesh Device was designed and/or manufactured in a way that could cause injuries and damages, including lasting and permanent injuries. Defendants further failed to inform or warn Plaintiff and Plaintiff's treating physicians with respect to the selection of appropriate candidates to receive Defendants' Hernia Mesh Device and the most effective techniques to remove the Defendants' Hernia Mesh Device in the event of complications.

145. Defendants failed to properly and adequately warn and instruct Plaintiff and Plaintiff's treating physicians as to the risks of the Defendants' Hernia Mesh Device. To the contrary, Defendants withheld information from Plaintiff and Plaintiff's physicians regarding the true risks related to implantation of their Hernia Mesh Device.

146. Defendants failed to properly and adequately warn and instruct Plaintiff and Plaintiff's treating physicians that inadequate research and testing of Defendants' Hernia Mesh Device was done prior to the Hernia Mesh Device being placed on the market and in the stream of commerce and that Defendants lacked a safe, effective procedure for removal of the Hernia Mesh Device once complications from their meshes arise.

147. Defendants intentionally, recklessly, and maliciously misrepresented the efficacy, safety, risks, and benefits of Defendants' Hernia Mesh Device, understating the risks and exaggerating the benefits in order to advance their own financial interest, with wanton and willful disregard for the rights, safety and health of Plaintiff.

148. Plaintiff and Plaintiff's physicians were unaware of the defects and dangers of Defendants' Hernia Mesh Device, and were unaware of the frequency, severity and duration of the risks associated with the Hernia Mesh Device.

149. Defendants failed to adequately warn or train Plaintiff or their physicians that the surgery required to remove the Hernia Mesh Device in the event of complications would obviate any purported benefit associated with implantation, and would involve additional, significant risks to the patient.

150. If Plaintiff or Plaintiff's physicians had been properly warned of the defects and dangers of Defendants' Hernia Mesh Device, and of the frequency, severity and duration of the risks associated with the Hernia Mesh Device, Plaintiff would not have consented to the implant, and Plaintiff's physician would not have implanted the Defendants' Hernia Mesh Device.

151. As a direct and proximate result of the Defendants' design, manufacture, marketing, sale, labeling and distribution of the Hernia Mesh Device, Plaintiff have experienced significant mental and physical pain and suffering, sustained severe and permanent injuries requiring past and future medical treatment, resulting in disability, impairment, loss of enjoyment of life, loss of care, comfort, and have incurred financial or economic loss, including, but not limited to, obligations for medical expenses, lost income, and other damages.

152. Defendants are strictly liable to the Plaintiff for their wrongful conduct in failing to properly warn Plaintiff and Plaintiff's physicians, and for designing, manufacturing, marketing, labeling, packaging, and/or selling a defective product.

153. Defendants are equitably estopped from asserting a learned intermediary defense due to Defendants' fraudulent concealment, through affirmative misrepresentations and omissions, from Plaintiff and Plaintiff's physicians of the risks and defects associated with the Hernia Mesh Device, including the severity, duration and frequency of risks and complications. Defendants affirmatively withheld and/or misrepresented facts concerning the safety of the Hernia Mesh Device, including but not limited to adverse data and information from studies and testing conducted with respect to the Hernia Mesh Device that showed the risks and dangers associated with the Hernia Mesh Device was unreasonable, which were intentionally withheld from Plaintiff and Plaintiff's physicians. As a result of Defendants' misrepresentations and concealment, Plaintiff and Plaintiff's 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.

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

COUNT IV: NEGLIGENCE

154. Plaintiff re-alleges and incorporates by reference every paragraph of this Complaint as if each were set forth fully and completely herein.

155. At all relevant times, Defendants had a duty to individuals, including the Plaintiff, to exercise reasonable and ordinary care in the manufacture, design, labeling, instructions, warnings, sale, marketing, and distribution of the Defendants' Hernia Mesh Device, as well as in the recruitment and training of physicians to implant the Defendants' Hernia Mesh Device.

156. Defendants had a continued duty to warn individuals, including Plaintiff and Plaintiff's physicians of the known severe complications caused by Defendants' Hernia Mesh Device, and grave bodily harm that could result when attempting to explant the Defendants' Hernia Mesh Device.

157. Defendants breached their duty of care to the Plaintiff, as aforesaid, in the manufacture, design, labeling, instructions, warnings, sale, marketing, distribution, and recruitment and training of physicians to implant the Defendants' Hernia Mesh Device, by:

a) Failing to design the Hernia Mesh Device so as to avoid an unreasonable risk of harm to the patients in whom the Hernia Mesh Device is implanted, including the Plaintiff.

b) Failing to manufacture the Hernia Mesh Device so as to avoid an unreasonable risk of harm to patients in whom the Hernia Mesh Device is implanted, including the Plaintiff.

c) Failing to use reasonable care in the testing and study of the Hernia Mesh Device, so as to avoid an unreasonable risk of harm to patients in whom the Hernia Mesh Device is implanted, including the Plaintiff.

d) Failing to use reasonable care in inspecting the Hernia Mesh Device so as to avoid an unreasonable risk of harm to patients in whom the Hernia Mesh Device is implanted, including the Plaintiff.

e) Withholding adverse information regarding Hernia Mesh Device within their knowledge, including but not limited to information from testing or study of Hernia Mesh Device and/or Device with similar design features and adverse event reporting demonstrating unacceptable risks, and thereby preventing Plaintiff and Plaintiff's physicians from understanding the risks associated with the Hernia Mesh Device.

f) Failing to adequately instruct, train, or warn physicians regarding the use of the Hernia Mesh Device, the risks associated with the Hernia Mesh Device, including the frequency, severity and duration of such risks, and the appropriate treatment for complications associated with Hernia Mesh Device.

g) Negligently or carelessly failing to properly train physicians in the implantation and/or removal of Hernia Mesh Device and in the appropriate treatment of complications associated with Hernia Mesh Device.

h) Otherwise negligently or carelessly designing, manufacturing, marketing, labeling, packaging and/or selling the Hernia Mesh Device.

158. The reasons that Defendants' negligence caused the Hernia Mesh Device to be unreasonably dangerous and defective include, but are not limited to:

a) The use of polyester material in the Hernia Mesh Device and the immune reaction that results from such materials, causing short and long-term adverse reactions and injuries.

b) The propensity of the polyester component of the Hernia Mesh Device to degrade and fragment inside the body, causing a chronic inflammatory and fibrotic reaction, resulting in injury over time, such as adhesions, pain, seroma,

infection, and mesh deformation

c) Biomaterial issues with the design of the Hernia Mesh Product, including the use of a collagen film, which:

   i. Carries a high risk of infection;

   ii. Does not prevent and/or adequately reduce adhesion formation;

   iii. Is delicate and prone to tearing and/or degrading during implantation.

   iv. Allows bare polyester to come into contact with the viscera; and

   v. Increases the risk of adverse immunological responses.

d) Biomechanical issues with the design of the Hernia Mesh Device, including the propensity to shrink or contract inside of the body, which causes surrounding tissue to become fibrotic and also contract, resulting in additional chronic inflammation, mesh deformation, chronic pain, recurrence and other injuries.

e) Biomaterial issues with the design of the Hernia Mesh Device, including the use of PLA and PGLA in general, which elicits an intense inflammatory response as it resorbs and significantly reduces the local pH, resulting in delayed wound healing and infection, while also promoting the formation of immature collagen, increasing the risk of recurrence.

f) Biomechanical issues with the design of the Hernia Mesh Device, including PLA Microgrips, which are Velcro-like hooks utilized to adhere the polyester to the underlying tissue, which results in one of the following if the Defendants' Hernia Mesh Device fails:

   i. Removal of large amounts of native tissue, resulting in a significantly larger defect than the Defendants' Hernia Mesh Device was initially

utilized to repair, and thereby increasing the complexity of future repairs and increasing the probably that future repairs will fail.

ii. Inability to remove portions of Defendants' failed Hernia Mesh Device and stop the complications that the failed Hernia Mesh Device is causing.

159. Defendants also negligently failed to warn or instruct Plaintiff or Plaintiff's physicians of subjects, including, but not limited to the following:

a) The unusually high rate of infection associated with the Hernia Mesh Device.

b) The propensity of the PLA and PGLA to decrease the local pH where it is implanted.

c) The propensity of the Hernia Mesh Device to shrink, contract, or deform within the body.

d) The propensity of the Hernia Mesh Device to degrade, fragment, fray, and unravel.

e) The risk of intense, chronic inflammation resulting from the Hernia Mesh Device and the resulting potential short and long-term complications.

f) The greatly increased risk of chronic infections resulting from the Hernia Mesh Device, which can form biofilms and become essentially immune from antibiotic treatment.

g) The likely need for corrective surgery to adjust, remove, or revise the Hernia Mesh Device during the patient's lifetime.

h) The frequency and severity of complications associated with the Hernia Mesh Device when utilized as intended.

i) The Hernia Mesh Device defects described herein.

j) Treatment with the Hernia Mesh Device is no more effective than feasible, available alternatives.

k) Treatment with the Hernia Mesh Device expose patients to more risk than feasible, available alternatives.

l) Use of the Hernia Mesh Device put patients at a greater risk of requiring additional surgeries than feasible, available alternatives.

m) Use of the Hernia Mesh Device make any future surgery in the same location on the patient much more complex and dangerous than if other hernia mesh Device or procedures were utilized.

n) Removal of the Hernia Mesh Device due to complications may significantly, and permanently impair the patient's quality of life and may not result in complete resolution of Plaintiff's injuries.

160. Defendants knew or should have known that their failure to exercise ordinary care in the manufacture, design, labeling, instructions, warnings, sale, marketing, distribution, and recruitment and training of physicians to implant the Defendants' Hernia Mesh Device would cause foreseeable harm, injuries and damages to individuals implanted with the Defendants' Hernia Mesh Device, including the Plaintiff.

161. Defendants knew, or in the exercise of reasonable care should have known, that the Hernia Mesh Device was defectively and unreasonably designed and were unreasonably dangerous and likely to injure patients in whom Hernia Mesh Device was implanted, like Plaintiff. Defendants knew or should have known that Plaintiff and Plaintiff's physicians were unaware of the dangers and defects inherent in the Hernia Mesh Device.

162. As a direct, proximate, and foreseeable result of the Defendants' negligence, Plaintiff have experienced significant mental and physical pain and suffering, sustained severe and permanent injuries requiring past and future medical treatment, and resulting in disability, impairment, loss of enjoyment of life, loss of care, comfort, and have incurred financial or economic loss, including, but not limited to, obligations for medical expenses, lost income, and other damages.

163. Each act or omission of negligence was a proximate cause of the damages and injuries to Plaintiff.

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

COUNT V: BREACH OF EXPRESS WARRANTY

164. Plaintiff re-alleges and incorporates by reference every paragraph of this Complaint as if each were set forth fully and completely herein.

165. At all relevant and material times, Defendants designed, manufactured, labeled, supplied, sold, distributed, marketed and otherwise placed into the stream of commerce Defendants' Hernia Mesh Device.

166. In advertising, marketing and otherwise promoting Defendants' Hernia Mesh Device to physicians, hospitals and other healthcare providers, Defendants expressly warranted that their Hernia Mesh Device was safe for use and reasonably fit for their intended purposes. In advertising, marketing and otherwise promoting Defendants' Hernia Mesh Device, Defendants' intended that physicians, hospitals and other healthcare providers rely upon their representations

regarding safety and fitness in an effort to induce them to implant the Hernia Mesh Device in their patients.

167. Defendants represented and market their Hernia Mesh Device as life-long medical implants.

168. Defendants made the following express representations regarding their Hernia Mesh Device to Plaintiff, Plaintiff's physicians, hospitals, other healthcare providers, and/or the general public, including, but not limited to:

a) "Fits perfectly to groin anatomy"

b) "safe and effective mesh for open hernia repair"

c) "Easy for surgeons to use"

d) "Provides better outcomes for patients than other fixation methods."

e) "Reduced Patient Pain"

f) "Reduced Dosage of Analgesics"

g) "An Effective and Durable Hernia Repair"

h) "The microgrip technology provides immediate, effective, tension-free fixation."

i) "Equivalent recurrence rate compared to laparoscopic repair with fixation"

j) "Resorbable, atraumatic microgrips preserve cord and nerve structures"

k) "Low post-operative pain and fast recovery in laparoscopic inguinal hernia repair"

l) "The possible complications associated with the use of [Defendant's Hernia Mesh Device] are those typically associated with surgically implantable materials"

m) "The Fast Way to Patient Comfort."

n) "three-dimensional polyester mesh provides long term reinforcement of soft

tissues."

169. With respect to the Plaintiff, Defendants intended that the Hernia Mesh Device be implanted by Plaintiff's treating surgeons in the reasonable and foreseeable manner in which they were implanted and in accordance with the Instructions for Use and product specifications provided by Defendants. The Plaintiff was in privity with Defendants.

170. Defendants expressly warranted to physicians, hospitals, other healthcare providers and the general public, including Plaintiff, that Defendants' Hernia Mesh Device was safe and fit for use by consumers, that they were of merchantable quality, that their risks, side effects and potential complications were minimal and comparable to competing hernia mesh products, that they were adequately researched and tested in a non-biased way, and that they were fit for their intended use. Plaintiff and Plaintiff's physicians and healthcare providers reasonably relied upon Defendants' express representations and warranties, and consequently, Plaintiff was implanted with Defendants' Hernia Mesh Device.

171. Defendants breached these express warranties because the Hernia Mesh Device implanted in Plaintiff was unreasonably dangerous, defective, and not as Defendants had represented.

172. Defendants breached express representations and warranties made to the Plaintiff, as well as Plaintiff's physicians and healthcare providers, with respect to the Hernia Mesh Device, including, but not limited to, the following particulars:

a) Defendants represented to Plaintiff and Plaintiff's physicians and healthcare providers through labeling, advertising, marketing materials, detail persons, seminar presentations, wet labs, publications, notice letters, regulatory submissions, and among other ways that the Defendants' Hernia Mesh Device was

safe, meanwhile Defendants fraudulently withheld and concealed information about the substantial risks of serious injury associated with using Defendants' Hernia Mesh Device;

b) Defendants represented to Plaintiff and Plaintiff's physicians and healthcare providers that the Defendants' Hernia Mesh Device was as safe and/or safer than other alternative procedures and Device on the market, meanwhile Defendants fraudulently concealed information that demonstrated that Defendants' Hernia Mesh Device was not safer than alternative therapies and products available on the market; and

c) Defendants represented to Plaintiff and Plaintiff's physicians and healthcare providers that the Defendants' Hernia Mesh Device was more efficacious than other alternative procedures, therapies and/or devices, meanwhile Defendants fraudulently concealed information regarding the true efficacy of Defendants' Hernia Mesh Device.

d) Defendants represented to Plaintiff, Plaintiff's physicians, and regulatory bodies that their Hernia Mesh Device performed favorably in animal models, meanwhile Defendants fraudulently concealed information regarding study flaws and manipulation.

e) Defendants represented to Plaintiff and Plaintiff's physicians that their Hernia Mesh Device reduced the severity and rate of chronic pain when compared to competitor Device and procedures. However, not only did Defendants not possess sufficient human data to support such a claim, Defendants were aware of significant evidence to the contrary.

f) Defendants represented to Plaintiff and Plaintiff's physicians that their Hernia Mesh Device did not increase the rate of infections. However, Defendants were aware that their Hernia Mesh Device had significantly high rates of early infections, latent infections, chronic infections, infections not responsive to treatment, sepsis, and death.

g) Defendants represented to Plaintiff and Plaintiff's physicians that changing their Hernia Mesh Device to monofilament fixed the complications that were being observed with their multifilament Hernia Mesh Device. However, Defendants were aware that infections were still prevalent with their monofilament Hernia Mesh Device, and that their monofilament Hernia Mesh Device was far too weak and would rupture, tear or blow out due to normal abdominal pressures, such as from coughing, sneezing, jumping, lifting, or defecating.

h) Defendants represented to Plaintiff and Plaintiff's physicians that their Hernia Mesh Device was permanent medical implants that would last the lifetime of the patient. However, not only did Defendants not have adequate support for this claim, they knew that a significant portion of their Hernia Mesh Device would fail within a decade.

173. Defendants' breach of their express warranties resulted in the implantation of unreasonably dangerous and defective products in the Plaintiff, placing said Plaintiff's health and safety in jeopardy.

174. At the time of making such express warranties, Defendants knew or should have known that Defendants' Hernia Mesh Device did not conform to the express warranties. Defendants' acts were motivated by financial gain, while the adverse consequences of Defendants'

conduct was outrageous, fraudulent, oppressive, done with malice or gross negligence, and evidenced a reckless indifference to Plaintiff's rights, health and safety.

175. As a direct and proximate result of Defendants' breaches of the aforementioned express warranties, Plaintiff has experienced significant mental and physical pain and suffering, sustained severe and permanent injuries requiring past and future medical treatment, and resulting in disability, impairment, loss of enjoyment of life, loss of care, comfort, and have incurred financial or economic loss, including, but not limited to, obligations for medical expenses, lost income, and other damages.

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

COUNT VI: BREACH OF IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS OF PURPOSE

176. Plaintiff re-alleges and incorporates by reference every paragraph of this Complaint as if each were set forth fully and completely herein.

177. At all relevant and material times, Defendants designed, manufactured, labeled, supplied, sold, distributed, marketed and otherwise placed into the stream of commerce Defendants' Hernia Mesh Device.

178. Defendants impliedly warranted that the Hernia Mesh Device was merchantable and were fit for the ordinary purposes for which it was intended.

179. Defendants impliedly warranted that their Hernia Mesh Device was of merchantable quality, safe and fit for the intended use of implantation in Plaintiff and was properly and adequately tested prior to being placed in the stream of commerce.

180. When the Hernia Mesh Device was implanted in the Plaintiff, they were being used for the ordinary purposes for which they were intended.

181. Defendants intended that their Hernia Mesh Device be implanted for the purposes and in the manner that Plaintiff's surgeons implanted the Hernia Mesh Device, in accordance with the Instructions for Use and product specifications provided by Defendants.

182. Defendants were aware that consumers, such as the Plaintiff, would be implanted with Defendants' Hernia Mesh Device by Plaintiff was treating physicians in accordance with the Instructions for Use and product specifications provided by Defendants.

183. The Plaintiff was foreseeable users of Defendants' Hernia Mesh Device and were in privity with Defendants.

184. Defendants breached implied warranties with respect to their Hernia Mesh Device, including, but not limited to the following particulars:

a) Defendants implied that the peritoneum, which is a single cell layer thick and has the appearance of saran wrap, would be sufficient to protect the patient's internal organs from their Hernia Mesh Device for their entire life. However, Defendants were aware that their Hernia Mesh Device could erode through a patient's peritoneum.

b) Defendants implied that their Hernia Mesh Device reduced the severity and rate of chronic pain when compared to competitor Device and procedures. However, not only did Defendants not possess sufficient human data to support such a claim, Defendants were aware of significant evidence to the contrary.

c) Defendants implied that their Hernia Mesh Device was safe, meanwhile Defendants fraudulently withheld and concealed information about the substantial risks of serious injury associated with their Hernia Mesh Device.

d) Defendants implied that their Hernia Mesh Device was as safe and/or safer than other alternative procedures and Device on the market, meanwhile Defendants fraudulently concealed information that demonstrated that their Hernia Mesh Device was not safer than alternative therapies and products available on the market.

e) Defendants implied that their Hernia Mesh Device was more efficacious than other alternative procedures, therapies and/or devices, meanwhile Defendants fraudulently concealed information regarding the true efficacy of their Hernia Mesh Device.

f) Defendants implied that their Hernia Mesh Device performed favorably in animal models, meanwhile Defendants fraudulently concealed information regarding study flaws and manipulation.

g) Defendants implied that nearly all failures of their Hernia Mesh Device occurred within months to a year of the mesh being implanted. However, Defendants knew that their Hernia Mesh Device continued to fail at significant rates regardless of how long the mesh had been implanted, and that some of the most significant injuries were happening years to over a decade after implantation.

185. The Plaintiff individually and/or by and through Plaintiff's physicians, relied upon Defendants' implied warranties in consenting to have the Hernia Mesh Device implanted.

186. In reliance upon Defendants' implied warranties, Plaintiff's implanting surgeons used Defendants' Hernia Mesh Device to treat Plaintiff in the foreseeable manner normally intended, recommended, promoted, and marketed by Defendants and in accordance with the Instructions for Use and product specification provided by Defendants.

187. Defendants breached their implied warranties to Plaintiff because Defendants' Hernia Mesh Device was not of merchantable quality, safe and fit for their intended uses, as warranted, nor were they adequately tested prior to being placed in the stream of commerce.

188. Defendants' breach of their implied warranties resulted in the implantation of unreasonably dangerous and defective products in the bodies of the Plaintiff, placing said Plaintiff's health and safety in jeopardy.

189. Defendants' acts were motivated by financial gain while the adverse consequences of the conduct were actually known by Defendants. Defendants' conduct was outrageous, fraudulent, oppressive, done with malice and with gross negligence, and evidenced reckless disregard and indifference to Plaintiff's rights, health and safety.

190. As a direct and proximate result of Defendants' breach of the aforementioned implied warranties, Plaintiff has experienced significant mental and physical pain and suffering, sustained severe and permanent injuries requiring past and future medical treatment, and resulting in disability, impairment, loss of enjoyment of life, loss of care, comfort, and have incurred financial or economic loss, including, but not limited to, obligations for medical expenses, lost income, and other damages.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and request compensatory damages, together

with interest, cost of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT VII: FRAUDULENT CONCEALMENT

191. Plaintiff re-alleges and incorporates by reference every paragraph of this Complaint as if each were set forth fully and completely herein.

192. At all times relevant hereto, it was known or knowable to Defendants that their Hernia Mesh Device failed at a high rate and resulted in a high rate of complications. Moreover, it was known or knowable to Defendants that the surgical technique and training of implanting physicians was not the cause of the adverse events associated with their Hernia Mesh Device. It was known or knowable to Defendants that the safety and efficacy of their Hernia Mesh Device had not been proven with respect to, among other things, the products, their components, performance, and method of insertion. It was known or knowable to Defendants that their Hernia Mesh Device was not safe and/or effective prior to Plaintiff being implanted with Defendants' Hernia Mesh Device. Defendants continue to represent that their Hernia Mesh Device is safe and effective, including but not limited to the following representations:

a) Has no serious side effects different from older generations of similar products and/or procedures;

b) Is the fastest way to patient comfort;

c) Provides a secure and durable repair;

d) Causes less pain;

e) Reduces the need for pain medication;

f) Easy and quick to implant;

g) Fits perfectly to groin anatomy;

h) Is safe for human implantation;

i) Was adequately tested and/or studied prior to entering the stream of commerce;

j) Could be safely removed in the event of complications, such as infection;

k) Low complication rates;

l) When complications occur, they are minor;

m) Safer than alternatives;

n) Better than alternatives;

o) Cheaper than alternatives;

p) Does not contract;

q) Preserves sensitive tissue;

r) Preserves sensitive organs;

s) Preserves nerves;

t) Has been adequately sterilized;

u) Can safely be cut and/or resized.

193. Defendants concealed information about their Hernia Mesh Device from Plaintiff, Plaintiff's surgeons, and the medical community, prior to Plaintiff's being implanted, including but not limited to:

a) Defendants knew from other doctors and, by and through their agents, employees, sales representatives and distributors that their Hernia Mesh Device was failing at a high rate, and Defendants failed to disclose this information to Plaintiff or Plaintiff's physicians prior to implantation of their Hernia Mesh Device.

b) Prior to the installation of the Hernia Mesh Device into Plaintiff, Defendants knew from other doctors and, by and through their agents, employees, sales

representatives and distributors, that other patients experienced problems with the Hernia Mesh Device, and Defendants failed to disclose such information to Plaintiff and Plaintiff's surgeon, including but not limited to the following:

i. Inability to safely remove in the event of device failure or complications;

ii. Inability to completely remove;

iii. Need for multiple, extensive revision surgeries if removal is necessary;

iv. How to remove;

v. Resulting defect if removed;

vi. How to repair resulting defect if removed;

vii. How to safely cut or resize;

viii. An increased risk of complications, when compared to available feasible alternatives;

ix. More severe complications when complications arise, as compared to available feasible alternatives;

x. Complications are more difficult to treat when complications arise, as compared to available feasible alternatives;

xi. Causes more severe, acute, chronic, and/or debilitation pain than available feasible alternatives;

xii. Mesh significantly contracts over time;

xiii. Complication rates increase the longer the mesh is implanted;

xiv. Incites a severe and chronic inflammatory response;

xv. Polyester degrade over time,

xvi. Polyester fibers can detach form the mesh and travel throughout the body,

xvii. Not safe for human implantation.

c) Failing to disclose that they were aware of and/or witnessed revision surgeries in which their Hernia Mesh Device had failed prior to the installation of the Hernia Mesh Device into Plaintiff, including but not limited to the following device failures:

xviii. Mesh migration;

xix. Mesh unraveling;

xx. Development of biofilm;

xxi. Mesh contracture;

xxii. Polyester degradation, and

xxiii. Nerve entrapment.

xxiv. Significant adhesions to underlying organs.

xxv. Mesh rupture/tearing

d) Failing to disclose that the surgeons were complaining about the Hernia Mesh Device and were experiencing extreme difficulty removing the Hernia Mesh Device, all prior to the installation of the Hernia Mesh Device into Plaintiff.

e) Failing to disclose that the animal studies Defendants conducted on their Hernia Mesh Device was intentionally underpowered and manipulated in various ways, such as administering drugs to the animals that would impact the study end points.

194. Despite what was known or knowable to Defendants about the lack of safety and efficacy of their Hernia Mesh Device, Defendants failed to disclose this information to the Plaintiff, Plaintiff's physicians, regulatory bodies, and to the public at large.

195. At all times relevant hereto, Defendants had a duty and obligation to disclose to Plaintiff and Plaintiff's physicians the true facts concerning their Hernia Mesh Device, that is, that said Hernia Mesh Device was dangerous and defective, lacking efficacy for its purported use and lacking safety in normal use, and how likely they were to cause serious consequences to users, including permanent and debilitating injuries. Defendants concealed these material facts prior to the time that Plaintiff was implanted with Defendants' Hernia Mesh Device.

196. Defendants were under a duty to Plaintiff to disclose and warn of the defective nature of their Hernia Mesh Device because:

a) Defendants were in a superior position to know the true quality, safety, and efficacy of their Hernia Mesh Device;

b) Defendants knowingly made false claims about the safety and quality of their Hernia Mesh Device in documents and marketing materials;

c) Defendants fraudulently and affirmatively concealed the defective nature of their Hernia Mesh Device from Plaintiff and Plaintiff's physicians.

197. The facts concealed and/or not disclosed by Defendants to Plaintiff was material facts that a reasonable person would have considered to be important in deciding whether or not to purchase or use the Defendants' Hernia Mesh Device.

198. At all times relevant hereto, Defendants and each of them, willfully, intentionally, and maliciously concealed facts as set forth above from Plaintiff and Plaintiff's physicians with the intent to defraud, as alleged herein.

199. Defendants intentionally concealed or failed to disclose the true defective nature of their Hernia Mesh Device so that Plaintiff would request and purchase the Defendants' Hernia Mesh Device, and Plaintiff's healthcare providers would dispense, prescribe, and recommend the

Defendants' Hernia Mesh Device, and Plaintiff and/or Plaintiff's healthcare providers justifiably acted or relied upon the concealed and/or non-disclosed facts to their detriment.

200. Prior to Plaintiff's surgery, Plaintiff and Plaintiff's surgeons were induced to act in reliance on Defendants' misrepresentations and/or omissions and in fact purchased the Hernia Mesh Device and implanted the Hernia Mesh Device in Plaintiff.

201. At all times relevant hereto, neither Plaintiff nor Plaintiff's physicians were aware of the facts set forth above, and had they been aware of said facts, they would not have acted as they did, that is, would not reasonably relied upon said representations of safety and efficacy and utilized Defendants' Hernia Mesh Device in their treatment. Defendants' failure to disclose this information was a substantial factor in Plaintiff's physicians selecting Defendants' Hernia Mesh Device. The failure to disclose also resulted in the provision of incorrect and incomplete information to Plaintiff, as patients.

202. Upon information and belief, Defendants and/or their sales representative(s) were present during the implantation surgery, and failed to disclose the falsity of the misrepresentation and/or omissions set forth herein, and knowingly let a defective product be installed in Plaintiff.

203. Plaintiff was ignorant of Defendants' misrepresentations and omissions.

204. Plaintiff and Plaintiff's surgeons relied on the truth of Defendants' representations and/or omissions about the Hernia Mesh Device and had a right to rely on such.

205. As a direct and proximate result of this conduct, Plaintiff was injured.

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

COUNT VIII: DISCOVERY RULE, TOLLING, AND FRAUDULENT CONCEALMENT

206. Plaintiff re-alleges and incorporates by reference every paragraph of this Complaint as if each were set forth fully and completely herein.

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

208. Plaintiff pleads that the discovery rule should be applied to toll the running of the statute until Plaintiff knew, or through the exercise or reasonable care and diligence should have known, of facts indicated that Plaintiff had been injured, the cause of the injury, and the tortious nature of the wrongdoing that cause the injury.

209. Despite diligent investigations by Plaintiff into the cause of Plaintiff's injuries, including consultations with Plaintiff's medical providers, the nature of Plaintiff's injuries and damages, and their relationship to the Hernia Mesh Device was not discovered, and through reasonable care and diligence could not have been discovered until a date within the applicable statute of limitations for filing Plaintiff's claims. Therefore, under appropriate applications of the discovery rule, Plaintiff's suits were filed well within the applicable statutory limitations period.

210. The running of the statute of limitations in this cause of action is tolled due to equitable tolling. Defendants are estopped form asserting a statute of limitations defense due to Defendants' fraudulent concealment, through misrepresentations and omissions, from Plaintiff and Plaintiff's physician of the true risks associated with their Hernia Mesh Device. As a result of Defendants' fraudulent concealment, Plaintiff and Plaintiff's physician 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 omissions of the Defendants.

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

COUNT IX: NEGLIGENT MISREPRESENTATIONS

211. Plaintiff re-alleges and incorporates by reference every paragraph of this Complaint as if each were set forth fully and completely herein.

212. Defendants had a duty to accurately and truthfully represent to the medical and healthcare community, Plaintiff, Plaintiff's surgeons, and the public, that their Hernia Mesh Device had not been adequately tested and not been found to be a safe and effective treatment. The representations made by Defendants were, in fact, false.

213. Defendants failed to exercise ordinary care in the representations concerning their Hernia Mesh Device while they were involved in their design, manufacture, sale, labeling, supplying, marketing, testing, quality assurance, quality control, and distribution in interstate commerce, because Defendants negligently misrepresented the Hernia Mesh Device high risk of unreasonable and dangerous adverse side effects.

214. Defendants breached their duty by making misrepresentations of material facts about their Hernia Mesh Device to Plaintiff, Plaintiff's surgeons, and the medical community, prior to Plaintiff's implantation surgery, including but not limited to:

a) Has no serious side effects different from older generations of similar products and/or procedures;

b) Provides a secure and durable repair;

c) Prevents adhesions;

d) Is safe for human implantation;

e) Was adequately tested and/or studied prior to entering the stream of commerce;

f) Could be safely removed in the event of complications, such as infection;

g) Low complication rates;

h) When complications occur, they are minor;

i) Safer than alternatives;

j) Better than alternatives;

k) Cheaper than alternatives;

l) Does not contract;

m) Preserves sensitive tissue;

n) Preserves sensitive organs;

o) Preserves nerves;

p) Has been adequately sterilized;

q) Can safely be cut and/or resized.

r) Is the fastest way to patient comfort;

s) Causes less pain;

t) Reduces the need for pain medication;

u) Fits perfectly to groin anatomy;

215. Defendants concealed information about their Hernia Mesh Device from Plaintiff, Plaintiff's surgeons, and the medical community, prior to Plaintiff's implantation, including but not limited to:

a) Defendants knew from other doctors and, by and through their agents, employees, sales representatives and distributors that their Hernia Mesh Device was failing at a high rate, and failed to disclose this information to Plaintiff or Plaintiff's physicians prior to implantation of the Hernia Mesh Device.

b) Prior to the installation of the Hernia Mesh Device into Plaintiff, Defendants knew from other doctors and, by and through their agents, employees, sales representatives and distributors, that other patients experienced problems with their Hernia Mesh Device, and Defendants failed to disclose such information to Plaintiff and Plaintiff's surgeon, including but not limited to the following:

i. Inability to safely remove in the event of device failure and/or complications;

ii. Inability to completely remove;

iii. Need for multiple, extensive revision surgeries if removal is necessary;

iv. How to remove;

v. Resulting defect if removed;

vi. How to repair resulting defect if removed;

vii. How to safely cut or resize;

viii. An increased risk of complications, when compared to available feasible alternatives;

ix. More severe complications when complications arise, as compared to available feasible alternatives;

x. Complications are more difficult to treat when complications arise, as compared to available feasible alternatives;

xi. Causes more severe, acute, chronic, and/or debilitation pain than available feasible alternatives;

xii. Mesh significantly contracts over time;

xiii. Complication rates increase the longer the mesh is implanted;

xiv. Incites a severe and chronic inflammatory response;

xv. Polyester degrades over time;

xvi. Polyester fibers can detach form the mesh and travel throughout the body;

xvii. Not safe for human implantation.

xviii.

c) Failing to disclose that they were aware of and/or witnessed revision surgeries in which their Hernia Mesh Device had failed prior to the installation of the Hernia Mesh Device into Plaintiff, including but not limited to the following device failures:

i. Mesh migration;

ii. Mesh unraveling;

iii. Development of biofilm;

iv. Mesh contracture;

v. Polyester degradation, and

vi. Nerve entrapment.

vii. Significant adhesions to underlying organs.

viii. Mesh rupture/tearing

d) Failing to disclose that surgeons were complaining about the Hernia Mesh Device and were experiencing extremely difficulty in removing the Hernia Mesh Device, all prior to the implantation of the Hernia Mesh Device into Plaintiff.

216. As a foreseeable, direct, and proximate result of the negligent misrepresentation of Defendants, as set forth herein, Defendants knew, and had reason to know, that the Hernia Mesh

Device had been insufficiently tested, or had not been tested at all, and that they lacked adequate and accurate warnings, and that they created a high risk—and/or higher than acceptable risk, and/or higher than reported and represented risk—of adverse side effects, including, but not limited to, dense adhesions, pain, graft rejection, graft migration, organ damage, complex seroma, fistula, sinus tract formation, delayed wound closure, infection, sepsis, and death.

217. The above representations and/or omissions were material and made with the intent that Plaintiff and Plaintiff's surgeons rely on and were made to persuade and induce them to choose the Hernia Mesh Device to be surgically implanted in Plaintiff.

218. Defendants failed to exercise ordinary care in making the above representations and instead made the above representations and/or omissions knowing the representations were false or were ignorant of the truth of the assertion.

219. Prior to Plaintiff's implantation surgeries, Plaintiff and Plaintiff's surgeons were induced to act in reliance on Defendants' misrepresentations and/or omissions and in fact purchased the Hernia Mesh Device and implanted the Hernia Mesh Device in Plaintiff.

220. Upon information and belief, Defendants and/or their sales representative(s) were present during the implantation surgery, and failed to disclose the falsity of the misrepresentation and/or omissions set forth herein, and knowingly let a defective product be installed in Plaintiff.

221. Plaintiff was ignorant of Defendants' misrepresentations and/or omissions.

222. Plaintiff and Plaintiff's surgeon relied on the truth of Defendants' representations and omissions about the Hernia Mesh Device and had a right to rely on such.

223. As a direct and proximate result of the Defendants' conduct, Plaintiff has been injured and sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and economic damages.

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

COUNT VI: PUNITIVE DAMAGES

224. Plaintiff re-alleges and incorporates by reference every paragraph of this Complaint as if each were set forth fully and completely herein.

225. Defendants failed to adequately test and study the Hernia Mesh Device 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 the Hernia Mesh Device after obtaining knowledge and information that the products were defective and unreasonably unsafe. The limited testing and study that was undertaken by Defendants prior to release and after release of the Hernia Mesh Device, including but not limited to animal studies and human clinical studies, revealed to Defendants that the risks associated with the Hernia Mesh Device was 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 Hernia Mesh Device. Defendants were aware of the probable consequences of implantation of the dangerous and defective Hernia Mesh Device, 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 Hernia Mesh Device, including Plaintiff, justifying the imposition of punitive damages.

226. At all times relevant hereto, Defendants knew or should have known that the Defendants' Hernia Mesh Device was 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.

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

228. Defendants' misrepresentations included knowingly withholding material information from the medical community and the public, including Plaintiff and their treating physicians, concerning the safety and efficacy of the Defendants' Hernia Mesh Device.

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

230. 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 Hernia Mesh Device, including but not limited to data regarding the frequency, severity and duration of those risks and complications and the difficulty in effectively treating such complications.

231. Notwithstanding their knowledge, Defendants continued to market the Defendants' Hernia Mesh Device to consumers without disclosing the true risk of side effects and complications, or the frequency, severity and duration of those risks, or the difficulty in effectively treating such complications.

232. Defendants knew of the Hernia Mesh Device' defective and unreasonably dangerous nature, but continued to manufacture, produce, assemble, market, distribute, and sell the Device 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 hmm caused by the Hernia Mesh Device.

233. 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 request judgment in Plaintiff's 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

Plaintiff demands judgment against Defendants, and each of them, individually, jointly and severally and prays for the following relief in accordance with the applicable law and equity, and in an amount to be proven at the time of trial:

i. General and Compensatory damages to Plaintiff for past, present, and future damages, including, but not limited to, pain and suffering for severe and permanent personal injuries sustained by Plaintiff, permanent impairment, mental pain and suffering, loss of enjoyment of life, past and future health and medical care costs

and economic damages including past and future lost earnings and/or earning capacity together with interest and costs as provided by law;

ii. Punitive or exemplary damages for Defendants' wanton, willful, fraudulent, and reckless acts, established by their demonstration of complete disregard and reckless indifference for the safety and welfare of Plaintiff and the general public, in an amount sufficient to punish Defendants and deter future similar conduct;

iii. Special Damages;

iv. Statutory damages as set forth above;

v. Restitution and disgorgement of profits;

vi. Reasonable attorneys' fees as provided by law;

vii. The costs of these proceedings, including past and future cost of the suit incurred herein;

viii. All ascertainable economic damages;

ix. Pre-judgment interest on all damages as is allowed by law;

x. Post-judgment interest; and

xi. Such other and further relief as this Court deems just and proper.

DEMAND FOR JURY TRIAL

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

Dated: December 14, 2022

Respectfully submitted,

/s/ Rhett A. McSweeney
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