UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE: COVIDIEN HERNIA MESH PRODUCTS LIABILITY LITIGATION NO. II, **This Document Relates To:** **All Cases**	**MDL No. 1:22-md-03029-PBS**

MASTER LONG FORM COMPLAINT

Plaintiffs, by and through the undersigned lead counsel, file this Master Long Form Complaint as an administrative method to set forth potential claims individual Plaintiffs may assert against Defendants in this litigation. By operation of MDL Case Management Order No. 7, all allegations pled in this Master Long Form Complaint are deemed pled in any Short Form Complaint filed in the future.[1]

This Master Long Form Complaint does not necessarily include all claims asserted in all of the transferred actions to this Court, nor is it intended to consolidate, for any purpose, the separate claims of Plaintiffs in this MDL. Any separate facts and additional claims of individual Plaintiffs may be set forth in the Short Form Complaints filed by the respective Plaintiffs or their counsel. This Master Long Form Complaint does not constitute a waiver or dismissal of any actions or claims asserted in any individual action, nor do any Plaintiffs relinquish the right to move to amend their individual claims to seek any additional claims as discovery proceeds and facts and other circumstances may warrant.

[1] The Short Form Complaint, which incorporates the Master Long Form Complaint by reference, is attached as Exhibit A. It is to be used by every Plaintiff who files a case in this Court pursuant to the Direct Filing Order (ECF No. 35) and CMO No. 7 (Governing Initial Pleadings) (ECF No. 86).

Plaintiffs allege the following:

I. PARTIES

PLAINTIFFS

1. Plaintiffs are men and women implanted with one or more of Defendants' Hernia Mesh Devices ("Hernia Mesh Devices," or "Devices") to repair their hernias. The Devices are listed in Paragraph No. 19 of this Master Long Form Complaint.

2. Plaintiffs may also include the spouses of the individuals implanted with the Hernia Mesh Devices, as well as others with standing to assert claims arising from and/or damages resulting from the Devices. Those Plaintiffs will be identified in the Short Form Complaint and are referred to as "Consortium Plaintiffs."

DEFENDANTS[2]

3. Defendant Covidien LP ("Covidien"), f/k/a Covidien Ltd. and Tyco Healthcare Group LP, is a Delaware based corporation with its principal place of business at 15 Hampshire Street, Mansfield, Massachusetts 02048. Covidien LP is a medical device company involved throughout all states and territories in the United States in the research, development, testing, manufacture, production, marketing, promotion and/or sale of medical devices, including the Hernia Mesh Devices in this litigation. Defendant Covidien LP has derived substantial revenue related to Hernia Mesh Devices from its business throughout each of the states and territories of the United States.

[2] Pursuant to CMO No. 6 (Dismissal of Certain Defendant Entities) (ECF No. 85), Defendants Covidien, Inc., Covidien Ltd., Covidien plc, Covidien Holding, Inc., Medtronic USA, Inc., Medtronic PL, Medtronic plc, Covidien, LLC, Tyco International Ltd., Tyco International Group, SA, Surgical Solutions Group, United States Surgical Group, United States Surgical Corp., and Sofradim Corp. are not included in this Master Complaint. Plaintiffs reserve all rights as to these Defendants and incorporate CMO No. 6 by reference.

4. Upon information and belief, Covidien LP designed, initially manufactured, and first placed the Hernia Mesh Devices on the market from its headquarters in Massachusetts.

5. Upon information and belief, Covidien LP corporate executives drafted FDA communications pertaining to the Hernia Mesh Devices from its headquarters in Massachusetts.

6. Upon information and belief, Covidien LP also conducts all sales force oversight and training management from its Massachusetts headquarters..

7. Defendant Sofradim Production SAS ("Sofradim") 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.

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

9. 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.

10. Defendant Sofradim has derived substantial revenue related to Hernia Mesh Devices from its business throughout the states and territories of the United States.

11. The above-named entities are hereinafter referenced collectively as "Defendants." Defendants had a legal duty to ensure the safety and effectiveness of their Mesh Devices prior to marketing and selling it for permanent implantation in Plaintiffs. Prior to marketing and selling the Mesh Devices, Defendants were required to weigh the reasonably knowable risks against the benefits of the device's design and to consider all information that may bear on the safety and efficacy of the design, including the gravity, severity, likelihood, and avoidance of the dangers associated with that design. In addition to making these assessments, the Defendants were required to weigh the benefits against the knowable risks to ensure that the risks do not outweigh the benefits and to mitigate any known or knowable risks through providing adequate warnings and instructions and adequately communicating those warnings and instructions to device users. Defendants had an obligation not to release a product that posed greater risks or more frequent, more severe or longer lasting risks, than other Devices sold for the same use. Because implantation of Defendants' Mesh 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 Plaintiffs, the risks of the Mesh Devices outweigh any purported benefits, both generally and specifically with respect to the Plaintiff in this case.

12. 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.

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

14. Defendants have expected or should have expected their acts to have consequences within each of the states and territories of the United States, and have derived substantial revenue related to the Hernia Mesh Devices from interstate commerce in each of the states and territories of the United States.

15. Defendants are also vicariously liable for the acts and omissions of their employees and/or agents who were at all material times acting on Defendants' behalf and within the scope of their employment or agency.

II. JURISDICTION AND VENUE

16. Federal subject matter jurisdiction in the constituent actions is based upon 28 U.S.C. § 1332(a), in that complete diversity of citizenship between every Plaintiff and Defendants exists in each constituent action, and the amount in controversy exceeds $75,000 in each.

17. Consistent with the Due Process Clause of the Fifth and Fourteenth Amendments, Defendants are subject to personal jurisdiction in the federal judicial district identified in the Short Form Complaint.

18. A substantial part of the events and omissions giving rise to Plaintiffs' causes of action occurred in the federal judicial district identified in the Short Form Complaint. Venue is proper in that federal judicial district pursuant to 28 U.S.C. §1391(a).

III. FACTS COMMON TO ALL COUNTS

COVIDIEN HERNIA MESH DEVICES

19. Defendants' Hernia Mesh Devices in this litigation are defined as hernia mesh devices that were designed, manufactured, marketed, labeled, distributed, sold, or otherwise placed on the market by Defendants, including the related products listed below:[3]

a) Dextile Anatomical Mesh
b) Parietene DS Mesh
c) Parietene Polypropylene Mesh
d) Parietene Progrip Mesh
ProGrip Self-Fixating Mesh using polypropylene with PLA midrogrips
e) Parietex Composite Mesh
f) Parietex Composite Mono PM Mesh
g) Parietex Composite PCO-OS or PCO-OB Mesh
h) Parietex Composite Ventral Patch
i) Parietex Hydrophilic 2D Mesh
j) Parietex Hydrophilic 3D Mesh
k) Parietex Hydrophilic Anatomical Mesh
l) Parietex Monofilament Polyester Mesh
m) Parietex Optimized Composite Mesh
n) Parietex Plug & Patch
o) Parietex ProGrip
p) ProGrip Laparoscopic
q) SurgiPro
r) SurgiPro Plug & Patch
s) Symbotex Composite Mesh

20. Defendants sought and obtained FDA clearance to market their Hernia Mesh Devices 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" to other predicate devices 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

[3] A detailed description of each Hernia Mesh Device is available at: https://www.medtronic.com/covidien/en-us/products/hernia-repair/mesh-products.html (last visited Feb. 13, 2023).

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 Devices.

DEFENDANTS' ACTS & OMISSIONS REGARDING THEIR DEFECTIVE DEVICES

21. At all material times, Defendants were responsible for design, manufacture, production, testing, study, inspection, labeling, marketing, advertising, sale, promotion, and distribution of their Hernia Mesh Devices. This duty includes the obligation to adequately warn and instruct physicians and patients.

22. Defendants' Hernia Mesh Devices were defectively designed. Defendants' Hernia Mesh Devices were also defective as marketed due to inadequate warnings, instructions, labeling and/or inadequate testing, despite Defendants' knowledge of the defects and poor safety profiles.

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

24. Defendants also knew or should have known that their Hernia Mesh Devices unreasonably exposed Plaintiffs 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.

25. Defendants made claims regarding the benefits of implanting the Devices 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 Devices. Examples of these claims include but are not limited to:

a. All Parietex™ devices are created from a macroporous polyester material which produce superior cellular proliferation when compared to polypropylene mesh in vitro. [4]
b. Hydrophilic absorbable collagen film supports tissue integration while minimizing visceral attachment.[5]
c. Symbotex™ composite mesh provides good level of neoperitonization and better minimizing tissue attachment compared to Physiomesh™ flexible composite mesh and Ventralight™ ST mesh.[6]
d. Parietex ProGrip™ self-fixating mesh delivers security, patient comfort and ease of use. Its advanced microgrip technology provides immediate fixation of the entire mesh surface for a secure repair and even distribution of tension for patient comfort. Designed for ease of use, the resorbable polylactic acid (PLA) microgrips enable surgeons to position and place the mesh in under 60 seconds without the use of additional fixation. Surgeons and patients can depend on a secure repair with the potential for greater patient comfort.[7]

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

27. Defendants have marketed and continue to market their Hernia Mesh Devices to Plaintiffs 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 Devices as safer and more effective than available feasible alternative treatments for hernias, and other competing devices. 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 Devices.

---

[4] Medtronic Hernia Mesh device webpage at https://www.medtronic.com/covidien/en-us/products/hernia-repair/mesh-products.html (last visited November 7, 2022).
[5] Medtronic Hernia Repair/Parietex™ Composite Ventral Patch device webpage at https://www.medtronic.com/covidien/en-us/products/hernia-repair/parietex-composite-ventral-patch.html (last visited September 30, 2022).
[6] Medtronic Hernia Repair/Symbotex™ Composite Mesh device webpage at https://www.medtronic.com/covidien/en-us/products/hernia-repair/symbotex-composite-mesh.html (last visited September 30, 2022).
[7] Medtronic Hernia Repair Mesh Device webpage under Parietex ProGrip™ Self-Fixating Mesh at https://www.medtronic.com/covidien/en-us/products/hernia-repair/mesh-products.html (last visited September 30, 2022).

28. Indeed, Defendants received reports of failure of the Hernia Mesh Devices and knew of failures including but not limited to reports of 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.

29. Defendants omitted mention of the Devices' risks, dangers, defects, and disadvantages when they advertised, promoted, marketed, sold and distributed the Hernia Mesh Devices as safe even though Defendants knew, or should have known, that the Hernia Mesh Devices were not safe for their intended purposes, and that they would and did cause serious medical problems, including severe and permanent injuries and damages—and in some Plaintiffs, catastrophic injuries and death.

30. At all relevant times, Defendants have a duty to investigate the reports of failures of their Hernia Mesh Devices, analyze any removed Hernia Mesh Devices, and report the findings to the FDA.

31. The Safety Medical Devices Act of 1990 requires manufacturers to report to the FDA death, serious illnesses, and injuries associated with medical Devices.

32. Revision surgeries are considered a mandatory reportable concern to the Center for Devices and Radiological Health of the FDA who is responsible for issuing Safety Alerts, Public Health Advisories and Notices relative to medical devices.

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

34. Defendants knew or should have known that at all material times their communications about the benefits, risks and adverse effects of the Hernia Mesh Devices, including communications in labels, advertisements and promotional materials, were materially false and misleading.

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

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

37. 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 Devices.

38. The Americas Hernia Society Quality Collaborative (AHSQC) reports that Defendants' Hernia Mesh Devices result in significantly higher rates of numerous severe complications when compared to competitor hernia meshes. However, Defendants failed to disclose this information to healthcare providers, patients and the public.

39. The Hernia Mesh Devices are defective due to Defendants' failure to adequately warn or instruct Plaintiffs and their health care providers concerning at least the following subjects:

a) The Hernia Mesh Devices' propensities for degradation and fragmentation.
b) The rate and manner of mesh erosion or extrusion in the Devices.
c) The risk of chronic inflammation resulting from the Devices.
d) The risk of chronic infections resulting from the Devices.
e) The Devices 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 Devices.

g) The need for corrective or revision surgery to revise or remove the Devices.
h) The severity of complications that could arise as a result of implantation of the Devices.
i) The hazards associated with the Devices.
j) The Devices' defects described in this Complaint.
k) Treatment of hernias with the Devices 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 Devices makes future surgical repairs more difficult than with feasible available alternatives.
m) Use of the Devices puts patients at greater risk of requiring additional surgery than use of feasible available alternatives.
n) Complete removal of the Devices may not be possible and may not result in complete resolution of the complications, including pain.
o) The Hernia Mesh Devices are 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 Devices significantly contract, harden, and deform post-implantation.
q) Increased risk of cancer initiation and escape due to the profound and chronic inflammation the Hernia Mesh Device itself elicits, and from the bacteria the Hernia Mesh Device harbors.

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

41. Defendants further failed to conduct adequate study and testing of their Hernia Mesh Devices to determine and ensure that the device was safe and effective before releasing it for sale for permanent human implantation; and they continued to manufacture, distribute, and sell those defective Hernia Mesh Devices after obtaining knowledge and information that the Hernia Mesh Devices were defective with unreasonable risks, unsafe for being permanent human implant.

42. Defendants failed to adequately test the Hernia Mesh Devices they were manufacturing, marketing, distributing, repackaging, and selling to doctors and patients, like Plaintiff and their physicians. This inadequate testing went on for years, such that the unsafe Hernia Mesh Devices were distributed to millions of American consumers, as well as consumers throughout the world.

43. In marketing and selling the Hernia Mesh Devices, Defendants provided false and misleading labels to physicians and patients, including to Plaintiffs and their physicians, which failed to disclose one or more risks associated with the defective Hernia Mesh Devices.

44. As a result of Defendants' failure to disclose the unreasonable risks of their Hernia Mesh Devices, their failure to conduct proper testing, their failure to have adequate quality control measures in place, as well as other actions mentioned in this Complaint, Defendants made profits from selling their defective Hernia Mesh Devices.

45. Defendants marketed and sold their Hernia Mesh Devices 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.

46. At all material times, Defendants had a financial incentive to increase both the number of surgeons implanting their Hernia Mesh Devices, and the rate of their implantation. Hernia Mesh Devices that could be implanted inside the peritoneal cavity (intraperitoneally or IPOM) would further this purpose because Defendants could tout the ease and speed of implantation.

BARE POLYMER HERNIA MESH DEVICES: DEFECTS & RISKS

47. Defendants' Bare Polymer Hernia Mesh Devices share one common denominator: they all contain a permanent, non-inert polymer, specifically polyester or polypropylene. Despite Defendants' claims that polyester and polypropylene are inert, scientific evidence shows that both polyester and polypropylene are 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 Bare Polymer Hernia Mesh Devices.

48. Several of Defendant's Bare Polymer Hernia Mesh Devices are multifilament (as opposed to monofilament) and are comprised of numerous tightly-bound small fibers (filaments) instead of a single strand.[8]

49. Defendant's multifilament Bare Polymer Hernia Mesh Devices are substantially thicker, heavier, and denser than alternative lightweight monofilament designs and have far more surface area in contact with tissue which increases the foreign body load and response and creates and prolongs excessive inflammatory and foreign body reaction to the mesh, leading to scarification and adhesion.[9]

---

[8] Defendants' Bare Polymer Hernia Mesh Devices that are multifilament products include Parietex™ Mesh and Surgipro™ Multifilament Polypropylene Flat Sheet Mesh.

[9] Halaweish, et. al. *Novel in vitro medel for assessing susceptibility of synthetic hernia repair meshes to Staphylococcus aureus infection using green fluorescent protein-labeled bacteria and modern imagine techniques.* **Surg Infect (Larchmt)**. 2010; 11(5):449-54 ("It is estimated that the surface area of multifilament material is 157% higher than that of monofilament materials…."); Klosterhalfen, et al. *Polymers in hernia repair-common polyester vs. polypropylene surgical meshes.* **J Mater. Sc.** 2000;35(19);4769-76 (significant increase in rate of local inflammation with multifilament polyester group, Mersilene and Parietex, compared with sham group and polypropylene group; unlike any other mesh in the study, interface of Parietex showed acute inflammatory reaction characterized by evidence of polymorphonuclear granulocytes ("PMNs") and areas of fibroid necrosis, which PMNs formed micro-abcesses after 21 days, and at the end of the 90-day study PMNs were still leading cell-group).

50. Published scientific literature establishes that infection of multifilament materials requires complete mesh removal due to the inability to ride the body of the infection with medication or through the body's immune response. [10]

51. The Bare Polymer Hernia Mesh Devices are defective due to their high rates of failure, injury, and complications, their failure to perform as intended, their requirement of frequent and often debilitating re-operations, and their cause of severe and irreversible injuries, conditions, and damage to numerous patients, including Plaintiffs.

a) The specific nature of the Bare Polymer Hernia Mesh Devices' defects includes, but is not limited to, the following: The use of polyester/polypropylene in the Bare Polymer Hernia Mesh Devices and the immune reactions resulting from such material, cause adverse reactions and injuries.
b) Adverse reactions to the polyester/polypropylene in the Bare Polymer Hernia Mesh Devices consist of adhesions, injuries to nearby organs, nerves, or blood vessels, and other complications, including infection, chronic pain, and hernia recurrence.
c) The Bare Polymer Hernia Mesh Devices have 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/polypropylene acts as a chronic trigger for inflammation.
d) The weave of the Bare Polymer Hernia Mesh Devices 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/polypropylene.
e) The polyester and polypropylene contain numerous additive compounds, which leach from the Bare Polymer Hernia Mesh Devices and are toxic to tissue, enhancing the inflammatory reaction and the intensity of fibrosis.
f) Scanning electron microscopy has shown polyester and polypropylene to not be inert, with degradation leading to flaking, fissuring, and release of toxic compounds. This enhances the inflammatory and fibrotic reactions.
g) For decades, polyester and polypropylene mesh was known to shrink 30-50+%.

[10] Berrovoet, et. al., *Infected large pore meshes may be salvaged by topical negative pressure therapy*. **Hernia**. 2013; 17(1):67-73("In our series, it was striking that the only meshes that had to be completely or partially removed because of ongoing infection…were multifilament polyester meshes.").

h) Polyester and polypropylene are subject to oxidation by acids and other byproducts produced during the inflammatory reaction, causing degradation and loss of compliance.
i) Defendants' Bare Polymer Hernia Mesh Devices also have 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.
j) After implantation in the human body, polyester and polypropylene are known to depolymerize, cross-link, undergo oxidative degradation by free radicals, and stress crack.
k) The Bare Polymer Hernia Mesh Devices have a tendency to unravel or fray, causing polyester or polypropylene fibers to protrude from the mesh, which harden after implantation, causing an increased foreign body reaction, pain, and risk of organ perforation.
l) The large surface area of polyester and polypropylene promotes wicking of fluids and bacteria, and is a "bacterial super highway" providing a safe haven for bacteria.
m) Common complications associated with polyester and polypropylene include restriction of abdominal wall mobility and local wound disturbances. Failures of polyester and polypropylene 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.
n) Some of Defendants' Bare Polymer Hernia Mesh Devices also utilize a "monofilament" or lighter weight design. However, "monofilament" Hernia Mesh Devices have too low of a burst strength, resulting in the Hernia Mesh Device rupturing or tearing, and subsequent eventration of the hernia through the Hernia Mesh Device.

52. Defendants' Bare Polymer Hernia Mesh Devices have inter-filament distances and pores that are small and close together, increasing the risk of bridging by scar tissue. In turn, this results in shrinkage, stiffness and deformation of the Bare Polymer Hernia Mesh Devices.

53. Defendants also knew or should have known that the Bare Polymer Hernia Mesh Devices implanted in or near the groin would be subject to movement and bending.

54. Polyester and polypropylene, particularly when placed in or near the groin, have a higher likelihood of folding and bunching, and scar tissue fills the spaces between the folds. This results in a phenomenon termed meshoma" because the mesh forms a tumor-like mass.

Omissions and Failure to Warn Regarding Bare Polymer Devices

55. Defendants concealed the information showing that the polymers used in their Hernia Mesh Devices are non-inert; on the contrary, Defendants represented them as inert and therefore safe for permanent human implant.

56. Defendants omitted the warning of risks for using non-inert polymer hernia mesh devices for permanent human implant and further misled medical professional and patients into believing that their Hernia Mesh Devices are safe for permanent human implant.

Injuries Caused by the Bare Polymer Devices

57. Because of the defects in the Bare Polymer Hernia Mesh Devices, as well as Defendants' failure to adequately warn and instruct implanting physicians on the defects and risks associated with Bare Polymer Hernia Mesh Devices, plaintiffs suffered, and many continue to suffer, from significant personal injury. These injuries include but are not limited to:

a. Adhesions;
b. Infections;
c. Seroma;
d. Fistula Formation;
e. Bowel Complications and Obstructions;
f. Erosion;
g. Organ Perforation;
h. Organ Removal;
i. Injuries to nearby organs, blood vessels, tissues and nerves;
j. Chronic Pain;
k. Hernia Recurrence;
l. Chronic Inflammatory and Fibrotic Reaction;
m. Loss of Compliance;
n. Increased scar tissue;
o. Formation of a tumor like mass or meshoma;
p. Granulomatous Response;
q. Allergic Reaction;
r. Rejection of the Hernia Mesh;
s. Improper Wound Healing;
t. Foreign Body Response;
u. Bowel Strangulation; and
v. Death.

58. The Hernia Mesh Devices were at all times utilized and implanted in a manner foreseeable to Defendants: Defendants generated Instructions for Use for the Devices, 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 Devices, subsequent anatomical changes, and aftercare of patients, including Plaintiffs.

59. The Hernia Mesh Devices implanted in Plaintiffs were in the same or substantially similar condition as when they left Defendants' possession, and in the condition directed by and expected by Defendants.

60. As a result of having the Hernia Mesh Devices implanted, Plaintiffs have 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.

ADDITIONAL DEFECTS: CERTAIN HERNIA MESH DEVICES

61. At all material times, Defendants had a financial incentive to increase both the number of surgeons implanting their Devices, and the rate of their implantation. Hernia Mesh Devices that could be implanted inside the peritoneal cavity (intraperitoneally) would further this purpose because Defendants could tout the ease and speed of implantation.

62. Extreme risks of adhesion formation, bowel complications, erosion, fistula formation, and other complications occur when a polyester or polypropylene device is placed intraperitoneally, *i.e.*, next to the bowel and other organs. So Defendants instituted design modifications intended to separate the dangerous polyester or polypropylene base material from patients' internal organs when their Hernia Mesh Devices are placed intraperitoneally.

RESORBABLE COLLAGEN BARRIERS: DEFECTS & RISKS

63. Extreme risks of adhesion formation, bowel complications, erosion, fistula formation, infection and other complications occur when a polyester or polypropylene device is placed intraperitoneally, i.e., next to the bowel and other organs. Defendants recognized the defects and risks associated with their Hernia Mesh Devices and implemented design modifications intended to separate the dangerous base material (i.e., polyester or polypropylene) from patients' internal organs when their Hernia Mesh Devices are placed intraperitoneally.

64. As described more fully below, some of the Hernia Mesh Devices, such as Parietex Composite Parastomal Mesh, Parietex PCO, Parietex PCOx, Parietex Composite Ventral Patch, Symbotex, and Parietene DS Composite Mesh utilize a resorbable collagen adhesion barrier.[11] The resorbable collage adhesion barrier applied to the already defective and dangerous polyester or polypropylene Hernia Mesh Devices merely created added defects and risks to those previously mentioned above.

65. Defendants' Resorbable Collagen Barrier Devices were defectively designed and are not reasonably safe for their intended use in hernia repair. Further, the risks of the design outweighed any potential benefits associated with the design.

66. More specifically, the collagen layer, which was marketed, promoted and intended as an adhesion barrier, was only temporary—it was expected and intended to degrade over time inside the body. Thus, the collagen layer potentially prevented tissue ingrowth for only the first few days. Once the collagen is absorbed, "naked" polyester or polypropylene mesh is exposed to the viscera. Once any portion of the base material is exposed, the inflammatory nature of the

[11] Parietex ProGrip and Parietene ProGrip also utilize a collagen film, but their Instructions for Use note that the collagen film is not intended to minimize tissue attachment.

polyester or polypropylene inevitably stimulates adhesion formation to the viscera, initiating a cascade of adverse consequences that can take years to fully manifest.

67. Additionally, the polyester or polypropylene mesh within the defective Resorbable Collagen Barrier Devices alone were dangerous and defective, especially when utilized in the manner intended by Defendants. Further, the particular polyester and polypropylene material in the Resorbable Collagen Barrier Devices were substandard, adulterated and/or non-medical grade, and were unreasonably subject to oxidative degradation within the body, additionally exacerbating the adverse reactions to the device once the collagen barrier resorbed.

68. When implanted adjacent to the bowel and other internal organs, as Defendants intended for the Resorbable Collagen Barrier Devices, the organs are unreasonably susceptible to adhesion formation, bowel obstruction or perforation, erosion, fistula formation, infection, bowel strangulation or hernia incarceration, as well as other injuries.

69. The collagen layer is hydrophilic and therefore attracts fluids to the mesh, increasing the risk of seroma and infection.

70. The collagen layer incites an inflammatory response while it resorbs.

71. The collagen layer inhibits and delays reperitonealization.

72. Defendants knew or reasonably should have known that any purported beneficial purpose of the resorbable collagen barriers (*i.e.*, to prevent adhesions to the bowel and other viscera) did not exist. The collagen barrier provided no benefit, while substantially increasing the risks to Plaintiffs and others.

73. As a result of the defective design and/or manufacture of the Resorbable Collagen Barrier 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; adhesions to internal organs; bowel obstructions; organ removal; scarification; improper wound healing; infection; sepsis; seroma; abscess; fistula; tissue damage; nerve damage; chronic pain; recurrence of hernia; death and other complications.

74. Additionally, some Resorbable Collagen Barrier Devices contain resorbable poly(glycolide-co-L-lactide) expanders (PGLA Expanders), which are intended to facilitate placement and fixation of the mesh.

75. The PLGA Expanders do not ensure that the mesh lays flat after implantation.

76. The PGLA Expanders reduce the local pH while they are resorbing, inhibiting wound healing, adequate incorporation, reperitonealization, while also increasing the risk of infection and chronic pain.

77. The PGLA Expanders further incite a profound inflammatory response while they are being resorbed, increasing the risk of adhesion formation and mesh deformation.

78. The PGLA Expanders are hydrophilic and therefore attract fluids to the mesh, increasing the risk of seroma and infection.

79. Several of Defendant's Polymer Hernia Mesh Products Coated with Resorbable Collagen Barriers are multifilament (as opposed to monofilament) and are comprised of numerous tightly-bound small fibers (filaments) instead of a single strand.[12]

80. Defendant's Polymer Hernia Mesh Products Coated with Resorbable Collagen Barriers that are multifilament are substantially thicker, heavier, and denser than alternative lightweight monofilament designs and have far more surface area in contact with tissue which

12 Defendant's Polymer Hernia Mesh Products Coated with Resorbable Collagen Barriers that are multifilament products include Parietex™ Hydrophilic Mesh, Parietex™ Composite (comes in both monofilament and multifilament designs), and Parietex™ Optimized Composite Mesh.

increases the foreign body load and response and creates and prolongs excessive inflammatory and foreign body reaction to the mesh, leading to scarification and adhesion.[13]

81. Additionally, due to the hydrophilic nature of several of Defendant's Polymer Hernia Mesh Products Coated with Resorbable Collagen Barriers that are multifilament designs, the multifilament strands attract and retain bodily fluids, resulting in excessive swelling of the mesh, future 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.

82. Because of the hydrophilic and multifilament nature of some of Defendant's Polymer Hernia Mesh Products Coated with Resorbable Collagen Barriers, those products attract bodily fluids and harbor bacteria, leading to chronic and often severe infections, including fistulae and abscesses.[14]

---

[13] Halaweish, et. al. *Novel in vitro medel for assessing susceptibility of synthetic hernia repair meshes to Staphylococcus aureus infection using green fluorescent protein-labeled bacteria and modern imagine techniques.* **Surg Infect (Larchmt)**. 2010; 11(5):449-54 ("It is estimated that the surface area of multifilament material is 157% higher than that of monofilament materials…."); Klosterhalfen, et al. *Polymers in hernia repair-common polyester vs. polypropylene surgical meshes.* **J Mater. Sc.** 2000;35(19);4769-76 (significant increase in rate of local inflammation with multifilament polyester group, Mersilene and Parietex, compared with sham group and polypropylene group; unlike any other mesh in the study, interface of Parietex showed acute inflammatory reaction characterized by evidence of polymorphonuclear granulocytes ("PMNs") and areas of fibroid necrosis, which PMNs formed micro-abcesses after 21 days, and at the end of the 90-day study PMNs were still leading cell-group).

[14] *See*, *e.g.,* Merritt, et al. *Tissue colonization from implantable biomaterials with low numbers of bacteria.* **J Biomed Mater Res.** 1999; 44(3):261-5 ("The infection risk with the implantation of multifilament sutures was significantly greater than with monofilament sutures…." "The risk of infection with monofilament materials was considerably lower than for multifilament materials."); Hanna, et al. *Mesh ingrowth with concomitant bacterial infection resulting in inability to explant: a failure of mesh salvage*. **Hernia**. 2015;19(2):339-44 ("[C]complex 3D multifilament prostheses…favored increased bacterial colonization."

83. Published scientific literature establishes that infection of multifilament materials requires complete mesh removal due to the inability to ride the body of the infection with medication or through the body's immune response. [15]

Omissions and Failure to Warn re Resorbable Collagen Barrier Mesh

84. Defendants provided no warning about the risks/increased risks specifically associated with the unique design of the Resorbable Collagen Barrier Devices, including the fact that the collagen could resorb within a few days.

85. The Instructions for Use accompanying Defendants' Resorbable Collagen Barrier Devices note that the collagen film is essentially degraded in less than 1 month. However, the Instructions for Use are silent on the most relevant point—how soon after implantation any amount of bare polyester or polypropylene could be exposed to the viscera, as any amount of exposed polyester or polypropylene could incite viscera adhesions and disastrous long-term consequences.

86. Defendants marketed the Resorbable Collagen Barrier Devices as providing visceral protection for 1 month. However, bare polyester or propylene can be exposed to the viscera in a matter of days.

87. Defendants did not inform surgeons that the collagen film would incite an inflammatory response while being resorbed.

88. Defendants did not inform surgeons that the collagen film would inhibit wound healing and delay reperitonealization.

[15] Berrovoet, et. al., *Infected large pore meshes may be salvaged by topical negative pressure therapy*. **Hernia**. 2013; 17(1):67-73("In our series, it was striking that the only meshes that had to be completely or partially removed because of ongoing infection…were multifilament polyester meshes.").

89. No other company in the U.S. sells a polyester or polypropylene hernia mesh with the dangerous and defective resorbable collagen barrier that Defendants apply to their Resorbable Collagen Barrier Devices.

90. Defendants' Instructions for Use for the Resorbable Collagen Barrier Devices also failed to adequately warn Plaintiffs' health care providers of numerous risks that Defendants knew or should have known were associated with their Resorbable Collagen Barrier Devices. They include but are not limited to: immunologic response; pain; dehiscence; encapsulation; rejection; migration; scarification; contraction; increased adhesions to internal organs and viscera; bowel obstruction; erosion through adjacent tissue and viscera; infection; and hernia incarceration or strangulation.

91. Defendants expressly intended for their Resorbable Collagen Barrier Devices to be implanted in contact with the bowel and internal organs; and marketed and promoted them for that purpose. Although Defendants represented to health care providers that the collagen film would prevent or reduce adhesions, they failed to warn health care providers that adhesions would still form long after the collagen film resorbs, and therefore at best would provide only temporary adhesion reduction. Further, Defendants did not warn health care providers that when the collagen film inevitably degraded, the exposed polyester or polypropylene would become adhered to the bowel or visceral tissue.

92. With respect to Defendants' warnings about the complications associated with the Resorbable Collagen Barrier Devices, they provided no information about their frequency, severity and duration—even though the complications were more frequent, more severe and longer lasting than those associated with existing safer feasible alternative hernia repair devices and treatments.

93. If Plaintiffs or their health care providers had been properly warned of the defects and dangers of Defendants' Resorbable Collagen Barrier Devices, and of the frequency, severity and duration of the risks associated with the Resorbable Collagen Barrier Devices, Plaintiffs would not have consented to allow them to be implanted, and their health care providers would not have implanted the Devices in Plaintiffs.

94. Defendants provided no warning about the risks/increased risks specifically associated with the unique design of the PGLA Expanders, including that the PGLA Expanders would further increase the inflammation response, and could increase the risk and severity of chronic pain, infection, and mesh deformation.

95. Defendants represented to surgeons that the PGLA Expanders would ensure that the mesh laid flat after implantation.

96. Defendants did not warn surgeons that the PGLA Expanders would inhibit and delay reperitonealization.

97. Defendants did not warn surgeons that the PGLA Expanders would increase the risk of adhesion formation.

98. If Plaintiffs or their health care providers had been properly warned of the defects and dangers of Defendants' PGLA Expanders, and of the frequency, severity and duration of the risks associated with their Hernia Mesh Devices containing PGLA Expanders, Plaintiffs would not have consented to allow them to be implanted, and their health care providers would not have implanted the Devices in Plaintiffs.

Injuries Caused by the Resorbable Collagen Barrier Mesh devices

99. Exposure to the Resorbable Collagen Barrier cause Plaintiffs to suffer these injuries:

a. Adhesions;
b. Infections;
c. Seroma;
d. Fistula Formation;
e. Bowel Complications and Obstructions;
f. Erosion;
g. Organ Perforation;
h. Organ Removal;
i. Injuries to nearby organs, blood vessels, tissues and nerves;
j. Chronic Pain;
k. Hernia Recurrence;
l. Chronic Inflammatory and Fibrotic Reaction;
m. Loss of Compliance;
n. Increased scar tissue;
o. Formation of a tumor like mass or meshoma;
p. Granulomatous Response;
q. Allergic Reaction;
r. Rejection of the Hernia Mesh;
s. Improper Wound Healing;
t. Foreign Body Response;
u. Bowel Strangulation; and
v. Death

100. Additionally, the Resorbable Collagen Barrier cause Plaintiffs to suffer these additional injuries:

a. Delayed Reperitonealization;
b. Delayed Incorporation; and
c. Immature Collagen Formation

PLA MICROGRIPS: DEFECTS & RISKS

101. As an alternative to suturing or tacking a hernia mesh during an implantation surgery, Defendants added thousands of resorbable polylactic microgrips (PLA Microgrips) to the polyester or polypropylene meshes, creating devices such as the Parietex ProGrip, Parietene ProGrip, and ProGrip (PLA Microgrip Devices).[16]

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

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

103. 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.

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

105. 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.

106. 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.

Omissions and Failure to Warn Re the Micro-Grip Devices

107. 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.

108. 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.

109. 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.

110. 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.

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

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

113. The Instructions for Use of Defendant's PLA Microgrip Devices warn that the possible complications associated with the use of PLA Microgrip Devices are those "typically

associated with surgically implantable materials." However, Defendants' PLA Microgrip Devices are the only hernia mesh devices on the market utilizing PLA Microgrips, which greatly increase the risk of inflammation, chronic pain, infection, seroma, mesh deformation, and not being able to fully remove the device when compared with other surgically implantable materials.

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

Injuries Caused by the Micro-Grip Devices

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

a. Adhesions;
b. Infections;
c. Seroma;
d. Fistula Formation;
e. Bowel Complications and Obstructions;
f. Erosion;
g. Organ Perforation;
h. Organ Removal;
i. Injuries to nearby organs, blood vessels, tissues and nerves;
j. Chronic Pain;
k. Hernia Recurrence;
l. Chronic Inflammatory and Fibrotic Reaction;
m. Loss of Compliance;
n. Increased scar tissue;
o. Formation of a tumor like mass or meshoma;
p. Granulomatous Response;
q. Allergic Reaction;
r. Rejection of the Hernia Mesh;

s. Improper Wound Healing;
t. Foreign Body Response;
u. Bowel Strangulation;
v. Immature Collagen Formation; and
w. Death

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

DISCOVERY RULE; STATUTORY OR EQUITABLE TOLLING; ESTOPPEL

117. Plaintiffs assert all applicable state statutory and common law rights and theories related to the tolling or extension of any applicable statute of limitations, including statutory and equitable tolling, delayed discovery, discovery rule, and/or fraudulent concealment.

118. The discovery rule applies to toll limitations until Plaintiffs knew, or through the exercise of reasonable care and diligence should have known, of facts indicating their injuries; the cause of the injuries; or the tortious nature of the wrongdoing that caused the injuries.

119. The nature of Plaintiffs' injuries, damages, or their resulting relationship to Defendants' conduct was not discovered, and through reasonable care and due diligence could not have been discovered, until a date within the applicable statute of limitations for filing Plaintiffs' claims.

120. Limitations are tolled due to equitable or statutory tolling. Defendants are therefore estopped from asserting a statute of limitations defense due to their fraudulent concealment, through affirmative misrepresentations and omissions, from Plaintiffs and their health care providers of the risks and defects associated with Defendants' Hernia Mesh Devices, including the severity, duration and frequency of risks and complications. Defendants affirmatively withheld

and/or intentionally misrepresented facts concerning the safety of their Devices, including adverse data and information from studies and testing conducted with respect to the Devices, showing that the risks and dangers associated with the Hernia Mesh Devices were unreasonable.

121. As a result of Defendants' misrepresentations and concealment, Plaintiffs and their health care providers were unaware, and could not have known or have learned through reasonable diligence, that Plaintiffs had been exposed to the risks alleged in this Master Complaint; and that those risks were the direct and proximate result of Defendants' wrongful acts and or omissions. Defendants are estopped from asserting any limitations defense based on their intentional acts of withholding material information about the safety of the Hernia Mesh Devices from Plaintiffs and their health care providers.

IV. COUNTS

COUNT I
STRICT PRODUCT LIABILITY: DEFECTIVE DESIGN

122. Plaintiffs reallege and incorporate by reference all paragraphs in this Master Complaint.

123. Defendants' Hernia Mesh Devices are defectively designed and unreasonably dangerous.

124. At the time their Hernia Mesh Devices were implanted in Plaintiffs, the Devices were defectively designed. As described in this Master Complaint, there was an unreasonable risk that a Device would not perform safely and effectively for the purposes for which it was intended. Defendants failed to design against such dangers, and failed to provide adequate warnings and instructions concerning the risks.

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

126. Defendants expected and intended the Hernia Mesh Devices to reach users like Plaintiffs in the condition in which the Devices were sold.

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

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

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

130. When the Hernia Mesh Devices were implanted in Plaintiffs, there existed safer alternative designs for hernia mesh products, which were economically and technologically feasible at the time the Devices left Defendants' control. In all reasonable probability, those alternative designs would have reduced the likelihood, severity, frequency, and duration of the injuries Plaintiffs suffered, without substantially impairing the utility of the hernia mesh products.

131. The Hernia Mesh Devices implanted in Plaintiffs failed to reasonably perform as intended and resulted in complications. In many cases, these complications necessitated further surgery to repair the injuries caused by the defective Devices, and to repair the very issue the Devices were intended to repair. Thus, the Devices provided no benefit to Plaintiffs.

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

133. Defendants' Hernia Mesh Devices injured Plaintiffs.

134. Defendants are strictly liable to Plaintiffs for designing defective products. Defendants' actions give rise to a claim for damages under the product liability statutes and common law jurisprudence in all states and territories of the U.S.

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

136. Plaintiffs are entitled to recover compensatory, non-compensatory, punitive, and all other damages available under law for injuries sustained as a result of Defendants' defectively designed Hernia Mesh Devices.

COUNT II
STRICT PRODUCT LIABILITY: FAILURE TO WARN

137. Plaintiffs reallege and incorporate by reference all paragraphs in this Master Complaint.

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

139. Their Devices are inherently dangerous.

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

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

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

143. At the time the Devices were implanted in Plaintiffs, Defendants' warnings and instructions for them were inadequate and defective. As described in this Master Complaint, there was an unreasonable risk that any Device would not perform safely and effectively for the purposes for which it was intended. Defendants failed to design and/or manufacture against such dangers and failed to provide adequate warnings and instructions concerning these risks.

144. Defendants failed to properly and adequately warn and instruct Plaintiffs and their health care providers concerning the risks of Hernia Mesh Devices, given Plaintiffs' conditions and need for that information.

145. Defendants also failed to properly and adequately warn and instruct Plaintiffs and their health care providers concerning the inadequate research and testing of Hernia Mesh Devices, and the complete lack of a safe, effective procedure for removal of the Devices.

146. Defendants expected and intended the Hernia Mesh Devices to reach Plaintiffs, their health care providers, and other consumers in the condition in which their products were sold.

147. Plaintiffs and their health care providers were unaware of the defects and dangers of Hernia Mesh Devices; and were further unaware of the frequency, severity, and duration of the defects and risks associated with the Devices.

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

149. Defendants' Instructions for Use for the Hernia Mesh Devices failed to adequately warn Plaintiffs or their health care providers of numerous risks Defendants knew or should have known were associated with the Devices.

150. Defendants failed to adequately train or warn Plaintiffs or their health care providers about the necessity for surgical intervention in the event of complications, or how to properly treat such complications associated with the Hernia Mesh Devices when they occurred.

151. Defendants failed to adequately warn Plaintiffs, their health care providers, and the general public, that the necessary surgical removal of a Hernia Mesh Device in the event of complications would leave the hernia unrepaired, and would necessitate a further attempt to repair the same hernia that the failed Device was intended to treat.

152. With respect to Defendants' warnings about complications associated with the Devices, they provided inadequate or no information regarding the complications, frequency, severity, and duration, even though the complications were more frequent and more severe, and lasted longer than those associated with safer feasible alternative hernia repair treatments.

153. If Plaintiffs or their health care providers had been properly warned of the defects and dangers of Hernia Mesh Devices, and of the frequency, severity and duration of the risks associated with the Devices, Plaintiffs would not have consented to allow the Devices to be implanted, nor would their health care providers have implanted them.

154. Defendants are strictly liable in tort to Plaintiffs for their wrongful conduct, including their failure to warn or provide adequate instructions regarding Hernia Mesh Devices.

Defendants' actions give rise to a claim for damages under the product liability statutes and common law jurisprudence of all states.

155. As a direct and proximate result of Defendants' inadequate and defective warnings and instructions, Plaintiffs have been injured and undergone medical treatment, and will likely undergo future medical treatment. They have also sustained severe and permanent physical and mental pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort and consortium, economic loss, and damages, including medical expenses, lost income, and other damages (and in some cases death).

156. Plaintiffs' injuries were a reasonably foreseeable result of Defendants' failure to provide adequate warnings and instructions.

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

158. As a result of Defendants' failure to warn or to provide adequate warnings, Plaintiffs and their health care providers were unaware, and could not have known or learned through reasonable diligence, that Plaintiffs had been exposed to the risks alleged in this Master Complaint; and that those risks were the direct and proximate result of Defendants' wrongful acts and/or omissions.

COUNT III
STRICT PRODUCT LIABILITY: MANUFACTURING DEFECT

159. Plaintiffs reallege and incorporate by reference all paragraphs in this Master Complaint.

160. Defendants' Hernia Mesh Devices were not reasonably safe for their intended use and were defective with respect to their manufacture, in that they deviated materially from Defendants' manufacturing and/or design specifications, and thus posed unreasonable risks of serious bodily harm to Plaintiffs.

161. Defendants' Hernia Mesh Devices were unreasonably dangerous as a result of a malfunction, failure to properly manufacture to specifications as intended, improper assembly, or improperly broken or damaged packaging.

162. At the time the Hernia Mesh Devices were implanted, the Devices were defective with respect to their manufacture, in that Defendants deviated materially from their manufacturing and/or design specifications and thus posed an unreasonable risk of harm to Plaintiffs in whom the Hernia Mesh Devices were implanted.

163. The manufacturing defects associated with the Hernia Mesh Devices were not known, knowable or readily visible to Plaintiffs' health care providers or to Plaintiffs, nor were they discoverable upon reasonable examination. The Hernia Mesh Devices were used and implanted in the very manner in which they were intended to be used and implanted, in accordance with Defendants' Instructions for Use and marketing materials.

164. The Hernia Mesh Devices implanted in Plaintiffs were different from their intended design, and failed to perform as safely as Devices manufactured in accordance with the intended design would have performed.

165. As a direct and proximate result of the aforementioned defects, Plaintiffs have been injured and undergone medical treatment and will likely undergo future medical treatment and procedures. They have also sustained severe and permanent physical and mental pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort and consortium, economic

loss, and damages, including medical expenses, lost income, other damages (and in some cases death).

166. Defendants' defective manufacture of Hernia Mesh Devices was a proximate cause of the damages and injuries Plaintiffs suffered.

167. Defendants are strictly liable to Plaintiffs for designing, manufacturing, marketing, labeling, packaging and selling defective Hernia Mesh Devices.

168. Defendants' actions give rise to a claim for damages under the product liability statutes and common law jurisprudence of all states.

169. Plaintiffs are entitled to recover compensatory, non-compensatory, punitive, and all other damages available under law for injuries sustained as a result of Defendants' defectively manufactured Hernia Mesh Devices.

COUNT IV
NEGLIGENCE

170. Plaintiffs reallege and incorporate by reference all paragraphs in this Master Complaint.

171. Defendants owed a duty to Plaintiffs to exercise reasonable care when designing, manufacturing, producing, marketing, labeling, packaging and selling Defendants' Hernia Mesh Devices, and when creating instructions and warnings for them.

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

173. In addition to the acts and omissions described in this Master Complaint, Defendants, by and through their authorized divisions, subsidiaries, agents, servants and/or employees, acted with carelessness, recklessness, negligence, gross negligence and/or willful,

wanton, outrageous and reckless disregard for human life and safety in manufacturing, designing, labeling, creating instructions and warnings, marketing, distributing, supplying, selling and/or placing into the stream of commerce their Hernia Mesh Devices, including but not limited to the following:

a) failing to use due care in design and/or manufacture of the Hernia Mesh Devices so as to avoid the aforementioned risks to Plaintiffs and others;

b) failing to conduct adequate testing, including pre-clinical and clinical testing and post-marketing surveillance to determine the safety of their Hernia Mesh Devices;

c) failing to recognize the significance of their own and other testing, and information regarding their Hernia Mesh Devices, which testing and information evidenced such products are dangerous and potentially harmful when implanted in humans;

d) failing to respond promptly and appropriately to their own and other testing, and information regarding the Hernia Mesh Devices; and failing to promptly and adequately warn of the injuries as described in this Master Complaint;

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

f) failing to properly, appropriately and adequately monitor the post-market performance of their Hernia Mesh Devices;

g) aggressively promoting, marketing, advertising and/or selling their Hernia Mesh Devices despite their knowledge and experience of the Devices' dangers and risks;

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

i) failing to accompany their Hernia Mesh Devices with proper and adequate warnings regarding all possible adverse effects and risks associated with the implantation of the Devices;

j) failing to disclose to Plaintiffs and their health care providers their full knowledge and experience regarding the potential risks and harm associated with the implantation of the Hernia Mesh Devices;

k) failing to disclose to Plaintiffs and their health care providers in an appropriate and timely manner, facts relative to the potential risks and harm associated with the implantation of the Hernia Mesh Devices;

l) failing to warn Plaintiffs and their health care providers of the severity and duration of such adverse effects;

m) failing to warn Plaintiffs and their health care providers directly or indirectly, whether orally or in writing, before actively encouraging the sale of their Hernia Mesh Devices, about the increased risk associated with the Devices;

n) placing and/or permitting the placement of the Hernia Mesh Devices into the stream of commerce without adequate warnings that their implantation is harmful to humans and/or without proper warnings of the Devices' risks;

o) failing to respond or react promptly and appropriately to reports that the Hernia Mesh Devices caused harm to patients;

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

q) under-reporting, underestimating or downplaying the serious dangers and risks of their Hernia Mesh Devices;

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

s) failing to adequately warn Plaintiffs and their health care providers of the known or reasonably foreseeable danger that Plaintiffs would suffer serious injuries or death after being implanted with their Hernia Mesh Devices;

t) promoting the Hernia Mesh Devices in advertisements, websites and other modes of communication aimed at creating or increasing the rate and frequency of implantation of the Devices, without regard to the dangers and risks associated with their implantation;

u) failing to conduct or respond to post-marketing surveillance of complications and injuries associated with the implantation of the Hernia Mesh Devices;

v) failing to use due care under the circumstances; and

w) other acts or omissions constituting negligence and carelessness, as may appear during the course of discovery or at the trial of this matter.

174. Defendants knew or should have known that their failure to exercise ordinary care in the manufacture, design, packaging, labeling, the creation of warnings and instructions, sale, marketing and distribution of the Devices, and their training of health care providers to implant the Devices or to treat Device complications, would cause foreseeable harm, injuries, and damages to individuals implanted with Hernia Mesh Devices, including Plaintiffs.

175. Defendants knew, or in the exercise of reasonable care should have known, that the Hernia Mesh Devices were defectively and unreasonably manufactured and/or designed, and were unreasonably dangerous and likely to injure patients in whom Hernia Mesh Devices were implanted. Defendants knew or should have known that Plaintiffs and their health care providers were unaware of the dangers and defects inherent in the Devices.

176. Defendants' Hernia Mesh Devices caused Plaintiffs to suffer injuries.

177. Plaintiffs suffered injuries as a result of Defendants' failure to exercise reasonable care in designing, manufacturing, producing, marketing, labeling, packaging and selling, and creating instructions or warnings for Hernia Mesh Devices.

178. Defendants' actions constitute negligence under the common law of all states.

179. Defendants' negligence proximately caused the damages and injuries to Plaintiffs.

180. As a direct and proximate result of Defendants' negligence in designing, testing, inspecting, manufacturing, packaging, labeling, marketing, distributing and training, and preparing inadequate and improper written instructions and warnings for Hernia Mesh Devices, Plaintiffs have been injured and undergone medical treatment, and will likely undergo future medical treatment and procedures, sustained severe and permanent physical and mental pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort and consortium, economic

loss, and damages, including, but not limited to, medical expenses, lost income, other damages (and in some cases death).

181. Plaintiffs are entitled to recover compensatory, non-compensatory, punitive, and all other damages available under law for injuries resulting from Defendants' negligence.

COUNT V
NEGLIGENCE *PER SE*

182. Plaintiffs reallege and incorporate by reference all paragraphs in this Master Complaint.

183. Defendants' actions also constitute negligence *per se* under the applicable health and safety statutes and regulations of all state, as well as federal laws.

184. The applicable statutes and regulations are aimed at preserving the health and safety of Plaintiffs and the general public.

185. Plaintiffs are among the class of individuals that the statutes and regulations were meant to protect.

186. Plaintiffs' injuries are among the type that the statutes and regulations were intended to prevent.

187. As a result of the acts and omissions described in this Master Complaint, Plaintiffs were caused to suffer serious injuries as described in this Master Complaint, which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life and financial expenses for hospitalization and medical care.

188. Defendants' negligence *per se* proximately caused the damages and injuries to Plaintiffs.

189. Plaintiffs are entitled to recover compensatory, non-compensatory, punitive, and all other damages available under law for injuries resulting from Defendants' negligence *per se*.

COUNT VI
GROSS NEGLIGENCE

190. Plaintiffs reallege and incorporate by reference all paragraphs in this Master Complaint.

191. Defendants' conduct, as described in this Master Complaint, was extreme and outrageous. Defendants risked the lives of Plaintiffs, and other consumers and users of their products, with knowledge of the safety and efficacy problems with their products; and they withheld their knowledge from Plaintiffs, their health care providers, and others. Further, Defendants made conscious decisions not to redesign, re-label, warn or inform unsuspecting consumers.

192. Defendants' wrongs were aggravated by the kind of malice, fraud, and grossly negligent disregard for the rights of others, the public, and Plaintiffs, for which the law would allow—and for which Plaintiffs will seek at the appropriate time under governing law—the imposition of exemplary damages. Defendants' conduct was specifically intended to cause substantial injury to Plaintiffs, or when viewed objectively from Defendants' standpoint at the time of the conduct, involved an extreme degree of risk, considering the probability and magnitude of the potential harm to others. Further, Defendants were actually subjectively aware of the risk involved, but nevertheless proceeded with conscious indifference to the rights, safety, or welfare of others, including Plaintiffs. Defendants' outrageous conduct warrants an award of punitive damages.

193. As a direct and proximate result of Defendants' gross negligence, Plaintiffs have been injured and undergone medical treatment, and will likely undergo future medical treatment. They have also sustained severe and permanent physical and mental pain, suffering, disability,

impairment, loss of enjoyment of life, loss of care, comfort and consortium, economic loss, and damages, including medical expenses, lost income, other damages (and in some cases death).

194. Defendants' actions constitute gross negligence under the common law of all states.

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

COUNT VII
STATE CONSUMER PROTECTION LAWS

196. Plaintiffs reallege and incorporate by reference all paragraphs in this Master Complaint.

197. Plaintiffs purchased and used Defendants' Hernia Mesh Devices primarily for personal use. Therefore, each Plaintiff suffered ascertainable losses as a result of Defendants' actions in violation of the consumer protection laws applicable in the state where the Device was purchased and used.

198. Had Defendants properly advised Plaintiffs or their health care providers of the defects and risks associated with the Hernia Mesh Devices, including the frequency, severity and duration of those risks, Plaintiffs would not have purchased or paid for the Devices, would not have consented to allow the Devices to be implanted, and would not have suffered injuries and incurred related medical costs.

199. Defendants engaged in wrongful conduct, while at the same time obtaining, under false pretenses, moneys from Plaintiffs for Hernia Mesh Devices, which Plaintiffs would not have paid had Defendants not engaged in unfair and deceptive conduct.

200. Deceptive acts or practices proscribed by law include the following:

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

b. advertising goods or services with the intent not to sell them as advertised; and

c. engaging in fraudulent or deceptive conduct that creates a likelihood of confusion or misunderstanding.

201. The cumulative effect of Defendants' conduct directed at Plaintiffs, their health care providers, and the general public, was to create demand for and sell Hernia Mesh Devices. Each aspect of Defendants' conduct combined to artificially create sales of their Devices.

202. Plaintiffs were injured by the cumulative nature of Defendants' conduct.

203. Defendants have a statutory duty to refrain from unfair or deceptive acts or trade practices in the design, labeling, development, manufacture, promotion, and sale of their Hernia Mesh Devices throughout the states.

204. Defendants' deceptive, unconscionable or fraudulent representations, or material omissions to Plaintiffs, their health care providers, and the general public, constituted unfair and deceptive acts and trade practices in violation of the consumer protection statutes of all states.

205. Defendants' actions constitute unfair, unconscionable, deceptive or fraudulent acts or trade practices, in violation of consumer protection statutes and regulations in states where the purchases and/or implantation of the Hernia Mesh Devices occurred.

206. Under applicable state laws protecting consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising, Defendants are the suppliers, manufacturers, advertisers, and sellers, making them subject to liability under such state law for unfair, deceptive, fraudulent and unconscionable consumer sales practices.

207. Defendants violated the laws in states where the purchase and/or implantation of Hernia Mesh Devices occurred. Those state laws were enacted to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising. Defendants' violations occurred by their knowingly false representations that the Hernia Mesh Devices were fit for the purpose for which the Devices were intended, when in fact they were defective and dangerous; and by other acts alleged in this Master Complaint.

208. Defendants' acts and omissions are uncured or incurable deceptive acts under all state laws enacted to protect consumers, including Plaintiffs, against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising. Defendants had actual knowledge of the defective and dangerous conditions of their Hernia Mesh Devices but failed to take any action to cure such defective and dangerous conditions.

209. Plaintiffs, their health care providers, and the general public, relied upon Defendants' misrepresentations and omissions in determining to use the Hernia Mesh Devices or in allowing the Devices to be implanted.

210. As a direct and proximate result of Defendants' violations of the states' consumer protection laws, Plaintiffs have been injured and undergone medical treatment, and will likely undergo future medical treatment. They have also sustained severe and permanent physical and mental pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort and consortium, economic loss, and damages, including medical expenses, lost income, other damages (and in some cases death).

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

COUNT VIII
BREACH OF IMPLIED WARRANTY

212. Plaintiffs reallege and incorporate by reference all paragraphs in this Master Complaint.

213. Defendants sold the Hernia Mesh Devices implanted in Plaintiffs.

214. Defendants knew or reasonably should have known at the time of sale, that each Hernia Mesh Device was intended to be used for the purpose of hernia repair through surgical implantation in the human body.

215. Defendants warranted to Plaintiffs, their health care providers, and other consumers, that the Devices were of merchantable quality, and safe for the use for which they were intended.

216. Plaintiffs and their health care providers reasonably relied on Defendants' judgment, indications, and statements that Hernia Mesh Devices were fit for such use. Because of that reliance, Defendants' Hernia Mesh Devices were implanted in Plaintiffs.

217. Defendants distributed into the stream of commerce and sold Hernia Mesh Devices that were unsafe for their intended use, and not of merchantable quality as warranted by Defendants, in that the Devices had dangerous propensities when used as intended and implanted.

218. As a result of Defendants' conduct, Plaintiffs suffered injuries and damages, making Defendants liable for breaching their implied warranties.

219. As a direct and proximate result of Defendants' breach of the implied warranties associated with their Hernia Mesh Devices, Plaintiffs have been injured and undergone medical treatment, and will likely undergo future medical treatment. They have also sustained severe and permanent physical and mental pain and suffering, disability, impairment, loss of enjoyment of

life, loss of care, comfort and consortium, economic loss, and damages, including medical expenses, lost income, other damages (and in some cases death).

COUNT IX
BREACH OF EXPRESS WARRANTY

220. Plaintiffs reallege and incorporate by reference all paragraphs in this Master Complaint.

221. Defendants warranted and represented to Plaintiffs, their health care providers, and other consumers, that their Hernia Mesh Devices were safe and reasonably fit for their intended purposes.

222. Plaintiffs and their health care providers chose Hernia Mesh Devices based upon Defendants' warranties and representations regarding the safety and fitness of their Devices, as described in this Master Complaint.

223. Plaintiffs and their health care providers reasonably relied upon Defendants' express warranties and guarantees that the Devices were safe, merchantable, and reasonably fit for their intended purposes.

224. Defendants breached these express warranties because their Hernia Mesh Devices were unreasonably dangerous and defective, and not as Defendants had represented them to be.

225. Defendants' breach of their express warranties resulted in the implantations of unreasonably dangerous and defective Hernia Mesh Devices in Plaintiffs, placing their health and safety in jeopardy.

226. As a direct and proximate result of Defendants' breach of the express warranties associated with Hernia Mesh Devices, Plaintiffs have been injured and undergone medical treatment, and will likely undergo future medical treatment. They have also sustained severe and permanent physical and mental pain, suffering, disability, impairment, loss of enjoyment of life,

loss of care, comfort and consortium, economic loss, and damages, including medical expenses, lost income, other damages (and in some cases death).

COUNT X
NEGLIGENT INFLICTION OF EMOTIONAL DISTRESS

227. Plaintiffs reallege and incorporate by reference all paragraphs in this Master Complaint.

228. As described in this Master Complaint, Defendants engaged in negligent conduct by failing to use due care in adequately designing and constructing effective and safe Hernia Mesh Devices, by failing to warn of their dangerous propensities, and by negligently studying, designing, developing, testing, inspecting, manufacturing, advertising, marketing, promoting, labeling, distributing, and/or selling the Hernia Mesh Devices.

229. As a direct and proximate result of Defendants' negligence, Plaintiffs have suffered severe emotional distress, as well as economic loss, and damages, including medical expenses, lost income, and other damages.

230. The emotional distress damages Plaintiffs incurred were a reasonably foreseeable result of Defendants' actions.

231. Defendants' actions constitute negligent infliction of emotional distress under the common law of all states.

COUNT XI
INTENTIONAL INFLICTION OF EMOTIONAL DISTRESS

232. Plaintiffs reallege and incorporate by reference all paragraphs in this Master Complaint.

233. As described in this Master Complaint, Defendants engaged in intentional, willful, reckless, extreme, and outrageous conduct by failing to adequately design and construct effective

and safe Hernia Mesh Devices, by failing to warn of their dangerous propensities, and by improperly studying, designing, developing, testing, inspecting, manufacturing, advertising, marketing, promoting, labeling, distributing, and/or selling the Devices.

234. The emotional distress damages Plaintiffs incurred were a reasonably foreseeable result of Defendants' actions.

235. Defendants' actions constitute intentional infliction of emotional distress under the common law of all states.

COUNT XII
NEGLIGENT MISREPRESENTATION

236. Plaintiffs reallege and incorporate by reference all paragraphs in this Master Complaint.

237. From the time Defendants' Hernia Mesh Devices were first tested, studied, researched, evaluated, endorsed, manufactured, marketed and distributed, through the present, Defendants made misrepresentations to Plaintiffs, their health care providers, and the general public. Defendants' misrepresentations included but were not limited to representing that the Hernia Mesh Devices were safe and effective for the repair of hernias. At all relevant times, Defendants conducted sales and marketing campaigns to promote the sale and implantation of the Hernia Mesh Devices and willfully deceived Plaintiffs, their health care providers, and the general public as to the health risks and consequences of the implantation of the Hernia Mesh Devices.

238. Defendants had a duty to ensure that the representations they made about their Devices were true and complete when made. Defendants made the foregoing representations without any reasonable ground for believing them to be true and complete.

239. At all relevant times, Defendants conducted sales and marketing campaigns to promote the sale and implantation of their Hernia Mesh Devices and deceived Plaintiffs and their

health care providers, as well as other consumers, as to the health risks and consequences of the use of their Hernia Mesh Devices.

240. Defendants made these false and misleading representations concerning the safety and efficacy of Hernia Mesh Devices for the repair of hernias without any reasonable ground for believing them to be true.

241. These false and misleading representations were made directly by Defendants, their sales representatives and other authorized agents, to Plaintiffs, their health care providers and the general public, in publications, the popular press, and other written materials directed to them; and on Internet websites and applications also directed to them, with the intention of inducing and influencing the demand for, and the ultimate implantation of, their Hernia Mesh Devices in Plaintiffs and other patients.

242. The above representations were in fact false, in that Defendants' Hernia Mesh Devices were not safe, fit or effective for permanent implantation as labeled; implanting the Devices was hazardous to consumers' health; and the Devices had a propensity to cause serious injuries to patients, as described in this Master Complaint.

243. Defendants' representations were made with the intention of inducing reliance and the ultimate implantation of the Devices in Plaintiffs and other patients.

244. In reliance on Defendants' false and misleading representations, Plaintiffs' health care providers were induced to purchase and recommend implantation of the Devices in Plaintiffs; and Plaintiffs were induced to consent to such implantation. If Plaintiffs or their health care providers had known the truth and the facts Defendants concealed, the health care providers would not have recommended, and Plaintiffs would not have consented to, the implantation of Defendants' Hernia Mesh Devices. The reliance of Plaintiffs and/or their health care providers on

Defendants' misrepresentations was justified because such misrepresentations were made and conducted by individuals and entities in a position to know all facts.

245. Defendants' acts and omissions caused Plaintiffs to suffer serious injuries that are permanent and lasting in nature (and in some cases death); physical pain and mental anguish; diminished enjoyment of life; and financial expenses for hospitalization and medical care.

246. Defendants' conduct, as described in this Master Complaint, was extreme and outrageous. Defendants risked the lives of the recipients of these Devices, including Plaintiffs, with knowledge of the safety and efficacy problems with their Hernia Mesh Devices and suppressed this knowledge from the general public, Plaintiffs, and/or Plaintiffs' health care providers. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

COUNT XIII
FRAUD AND FRAUDULENT MISREPRESENTATION

247. Plaintiffs reallege and incorporate by reference all paragraphs in this Master Complaint.

248. Defendants designed, manufactured, marketed, and sold their Hernia Mesh Devices, and provided inadequate warnings and information about the Devices.

249. When Plaintiffs or their healthcare providers received the inadequate information and warnings, the Devices were defective and unreasonably dangerous for their intended and reasonably foreseeable use.

250. Further, Defendants fraudulently represented to Plaintiffs, their health care providers, and the general public that their Hernia Mesh Devices were safe and effective permanent implants. Additionally, even though Defendants were fully aware of the dangerous and defective

nature of the Devices, which could and did cause injuries such as those Plaintiffs suffered, Defendants intentionally concealed the defects in the Devices from Plaintiffs.

251. Defendants fraudulently represented to Plaintiffs, their health care providers, and the general public, that their Hernia Mesh Devices had been adequately tested, were safe for the repair of hernias, and were accompanied by adequate warnings.

252. Defendants widely advertised, marketed and promoted their Hernia Mesh Devices as safe and effective for permanent implantation in the human body, and for the repair of hernias.

253. Defendants made these representations with the intent of deceiving Plaintiffs, their health care providers, and other potential consumers; and with the intent of inducing the implantation of their Hernia Mesh Devices, under circumstances that Defendants knew were dangerous and unsafe, and created a high risk of harm.

254. Defendants also made material representations that were false. Further, Defendants knew they were false when made, or willfully, wantonly, and recklessly disregarded whether the representations were true or false. Defendants intended that Plaintiffs, their health care providers, and other potential consumers would rely and act upon the false representations.

255. Plaintiffs and/or their health care providers relied upon Defendants' fraudulent misrepresentations in allowing the defective Hernia Mesh Devices to be implanted. Plaintiffs thus sustained severe and permanent personal injuries, and/or were at an increased risk of sustaining severe and permanent personal injuries in the future.

256. Defendants knew or should have known that their Hernia Mesh Devices had not been sufficiently tested, were defective in nature and/or lacked adequate warnings and information.

257. Defendants' actions constituted common law fraud and/or fraudulent misrepresentation in all states.

258. As a direct and proximate result of Defendants' fraud or fraudulent misrepresentation, Plaintiffs have been injured and undergone medical treatment and will likely undergo future medical treatment and procedures. They have also sustained severe and permanent physical and mental pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort and consortium, economic loss, and damages, including medical expenses, lost income, other damages (and in some cases death).

COUNT XIV
FRAUDULENT CONCEALMENT

259. Plaintiffs reallege and incorporate by reference all paragraphs in this Master Complaint.

260. Before Defendants' Hernia Mesh Devices were implanted in Plaintiffs, Defendants fraudulently concealed material information regarding the safety and efficacy of their Hernia Mesh Devices, including information regarding adverse events, pre-marketing and post-marketing injuries, and literature indicating unreasonable risks associated with the implantation of the Hernia Mesh Devices.

261. Defendants knew from other doctors and, by and through their agents, employees, sales representatives and distributors that their Hernia Mesh Devices were failing at a high rate, and Defendants failed to disclose this information to Plaintiffs or Plaintiffs' physicians prior to implantation of their Hernia Mesh Devices.

262. Prior to the implementation of the Hernia Mesh Devices into Plaintiffs, 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 Devices, and Defendants failed to disclose such information to Plaintiffs and Plaintiffs' surgeons.

263. Although Defendants were aware of the dangerous and defective condition of the Hernia Mesh Devices, they intentionally concealed such information from Plaintiffs, their health care providers, and the general public. The significant dangers Defendants concealed included a warning that the material was not suited for permanent human implantation. Further, the dangers were not readily obvious to the ordinary user of the Devices, even after post-implant complications had arisen.

264. Defendants made these omissions with the intent of defrauding and deceiving Plaintiffs and their health care providers specifically, and other consumers generally; and with the further intent of specifically inducing health care providers to recommend implantation of the Hernia Mesh Devices. All such acts and omissions evinced Defendants' callous, reckless, willful, depraved indifference to the health, safety and welfare of Plaintiffs.

265. When Defendants made the foregoing partial disclosures and fraudulent omissions, and at the time Plaintiffs were implanted with the Hernia Mesh Devices, Plaintiffs and/or their health care providers were unaware of their falsity and reasonably believed the misrepresentations and omissions to be true.

266. Defendants fraudulently concealed the safety issues associated with the implantation of their Hernia Mesh Devices, to induce health care providers to recommend implanting the Devices in patients like Plaintiffs, and to induce Plaintiffs to consent to the implantation of the Devices.

267. Plaintiffs' health care providers reasonably relied on Defendants' omissions when they recommended implantation of the Hernia Mesh Devices in Plaintiffs, thereby causing Plaintiffs to sustain severe and permanent personal injuries. Defendants knew, or should have

known, that their Hernia Mesh Devices had not been sufficiently tested and were defective in nature, and/or that their Hernia Mesh Devices lacked adequate warnings.

268. Defendants also knew or should have known that their Hernia Mesh Devices had a potential to, and would, cause severe injury to those implanted with their Devices, and that the Devices were inherently dangerous in a manner exceeding any purported warnings.

269. Defendants had a duty to provide Plaintiffs, their health care providers, and the general public, with full, complete, accurate and truthful information concerning their Hernia Mesh Devices.

270. By virtue of Defendants' omissions and partial disclosures about the Hernia Mesh Devices, in which Defendants touted their Devices as a safe and effective for implantation in patients, Defendants had a duty to disclose all facts about the risks associated with the Devices, including the risks described in this Master Complaint.

271. Plaintiffs' health care providers reasonably relied on these material and fraudulent omissions when recommending implantation of the Devices in Plaintiffs, and Plaintiffs reasonably relied on the material and fraudulent omissions when consenting to have the Devices implanted.

272. Defendants did not provide Plaintiffs' health care providers with the information necessary to adequately warn Plaintiffs.

273. The Hernia Mesh Devices were improperly marketed to Plaintiffs and their health care providers because Defendants did not provide proper instructions on how to implant the Devices and did not adequately warn about the risks associated with implantation.

274. Plaintiffs could not know in the exercise of reasonable diligence that Defendants' statements concerning their Hernia Mesh Devices were knowingly and intentionally false and

misleading, or that Defendants had not disclosed material facts and information to Plaintiffs or their health care providers that would have been material to the choice of treatment.

275. As a direct and proximate result of Defendants' malicious and intentional concealment of material information from Plaintiffs and/or their health care providers, Defendants caused or contributed to Plaintiffs' injuries (and in some cases death).

276. Had Plaintiffs' health care providers been aware of the hazards associated with the implantation of Defendants' Hernia Mesh Devices, they would have used safer alternative devices for the repair of Plaintiffs' hernias.

277. Defendants' conduct was reckless, willful, wanton, and outrageous, and manifested a reckless indifference for the safety and well-being of Plaintiffs and other consumers.

278. As a direct and proximate result of Defendants' intentional and willful fraudulent concealment of material facts and information from Plaintiffs and/or their health care providers, Defendants caused, and increased the risk of harm of the injuries and damages Plaintiffs suffered after having been implanted with Defendants' Hernia Mesh Devices.

279. Had Plaintiffs been aware of the hazards associated with the implantation of the Hernia Mesh Devices, they would not have consented to their implantation.

280. Defendants actively and fraudulently concealed information in their exclusive possession regarding the hazards associated with the implantation of their Hernia Mesh Devices, for the purpose of preventing Plaintiffs and their health care providers from discovering these hazards.

281. Defendants' conduct was outrageous and shocked the conscience, and knowingly and intentionally placed considerations of financial gain, revenues and profits, market share and marketing advantage over patient safety and well-being.

282. As a result of the foregoing material and fraudulent omissions, Plaintiffs were caused to suffer serious injuries as described in this Master Complaint, which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life and financial expenses for hospitalization and medical care.

283. Defendants' conduct, as described in this Master Complaint, was extreme and outrageous. Defendants risked the lives of Plaintiffs and other consumers and users of their products. Although Defendants had knowledge of the safety and efficacy problems with their Devices, they concealed this knowledge from Plaintiffs, their health care providers, and the general public. Further, Defendants made conscious decisions not to redesign, re-label, or warn unsuspecting consumers. Defendants' outrageous conduct warrants an award of punitive damages.

COUNT XV
WRONGFUL DEATH

284. Plaintiffs reallege and incorporate by reference all paragraphs in this Master Complaint.

285. This wrongful death claim is brought on behalf of the estate and for the benefit of the lawful beneficiaries of Plaintiffs-decedents.

286. As a proximate result of Defendants' conduct and the defective nature of their Hernia Mesh Devices as described in this Master Complaint, Plaintiffs-decedents suffered bodily injury resulting in pain and suffering, disability, disfigurement, mental anguish, loss of capacity of the enjoyment of life, shortened life expectancy, expenses for hospitalization, medical and nursing treatment, loss of earnings, loss of ability to earn, funeral expenses and death.

287. By reason of the death of Plaintiffs-decedents, their heirs, next-of-kin and/or survivors (collectively beneficiaries) have suffered a pecuniary and/or non-pecuniary loss,

including but not limited to support, income, services and guidance of Plaintiffs-decedents. All were permanently damaged as a result.

288. The beneficiaries have incurred hospital, nursing and medical expenses, and estate administration expenses as a result of the Plaintiff-decedents' death caused by Defendants' wrongful conduct. The beneficiaries bring these claims for damages and for all pecuniary losses they sustained, pursuant to applicable state law.

COUNT XVI
LOSS OF CONSORTIUM

289. Plaintiffs reallege and incorporate by reference all paragraphs in this Master Complaint.

290. At all material times, and as specified in their Short Form Complaints, certain Plaintiffs had spouses, or others with standing to assert claims, who also suffered injuries and losses as a result of Defendants' Hernia Mesh Devices. Those individuals will be referred to as "Consortium Plaintiffs" in the Short Form Complaints.

291. As a direct and proximate result of Defendants' conduct, the Consortium Plaintiffs specified in the Short Form Complaints have suffered and will continue to suffer the loss of their Plaintiffs' support, companionship, services, society, love, and affection.

292. The Consortium Plaintiffs have suffered emotional pain and mental anguish.

293. Plaintiffs allege that their relationships have been impaired, and their associations altered as to all Consortium Plaintiffs.

294. The Consortium Plaintiffs have sustained and will continue to sustain physical injuries, severe emotional distress, economic losses, and other harm for which they are entitled to damages.

COUNT XVII
PUNITIVE DAMAGES

295. Plaintiffs reallege and incorporate by reference all paragraphs in this Master Complaint.

296. Defendants sold Hernia Mesh Devices to health care providers throughout the United States, without conducting adequate testing to ensure that the Devices were reasonably safe for implantation.

297. Defendants knew their Devices posed unreasonable risks, including degradation, excessive and chronic inflammation, inadequate or complete failure to incorporate in tissue, adhesion formation, migration, infection, erosion, abscess, fistula formation, nerve damage, excessive scarification, contracture, shrinkage, breakage, and other harm-causing defects.

298. Defendants sold their Hernia Mesh Devices to health care providers throughout the United States, despite knowing of these unreasonable risks.

299. At all material times, Defendants attempted to misrepresent, and did misrepresent, facts concerning the safety of their Hernia Mesh Devices, including adverse data and information from studies and testing conducted with respect to the Devices, which showed that the risks and dangers associated with the Devices were unreasonable.

300. Defendants' misrepresentations, omissions, and partial disclosures, included knowingly withholding material information from the medical community and the public, including Plaintiffs, concerning the safety and efficacy of Defendants' Hernia Mesh Devices.

301. At all material times, Defendants knew and intentionally and/or recklessly disregarded the fact that their Hernia Mesh Devices caused severe and potentially permanent complications with greater frequency than safer and feasible alternative devices or treatments.

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

303. Defendants knew of their Devices' defective and unreasonably dangerous nature. But they continued to manufacture, produce, assemble, market, distribute, and sell the Devices, and failed to include adequate warnings about them. Defendants' acts and omissions were taken with reckless disregard of the foreseeable harm caused by the Hernia Mesh Devices, so as to maximize sales and profits at the expense of the health and safety of the public, including Plaintiffs.

304. Defendants' conduct described in this Master Complaint shows willful misconduct, malice, fraud, wantonness, oppression, or that entire want of care raising the presumption of conscious indifference to consequences. Therefore, an award of punitive damages is justified.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment against Defendants Covidien and Sofradim, jointly and severally, on each of the above claims or causes of action, as follows:

a) Compensatory damages in excess of $75,000, including, but not limited to damages for pain, suffering, discomfort, physical impairment, emotional distress, loss of enjoyment of life, loss of consortium, wrongful death, and other noneconomic damages in an amount to be determined at trial;

b) economic damages in the form of medical expenses, out-of-pocket expenses, lost earnings and other economic damages, in an amount to be determined at trial;

c) 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 Plaintiffs and the general public, in an amount sufficient to punish Defendants and deter future similar conduct;

d) prejudgment interest;

e) post-judgment interest;

f) an award of reasonable attorneys' fees;

g) costs of these proceedings; and

h) any further relief this Court deems just and proper.

JURY DEMAND

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

Dated: February 13, 2023

Respectfully submitted,

/s/ Kelsey L. Stokes

Kelsey L. Stokes
Plaintiffs' Interim Co-Lead Counsel
Texas Bar No. 24083912
FLEMING, NOLEN & JEZ, L.L.P.
2800 Post Oak Blvd., Suite 4000
Houston, TX 77056-6109
Tel: (713) 621-7944
Fax: (713) 621-9638
kelsey_stokes@fleming-law.com

Timothy M. O'Brien
Plaintiffs' Interim Co-Lead Counsel
Florida Bar No. 055565
LEVIN, PAPANTONIO, RAFFERTY, PROCTOR, BUCHANAN, O'BRIEN, BARR & MOUGEY, P.A.
316 South Baylen St., Ste. 600
Pensacola, FL 32502
Tel: (850) 435-7084
Fax: (850) 436-6084
tobrien@levinlaw.com

Walter Kelley, Esq.
Plaintiffs' Liaison Counsel
BBO# 670525
4 Court Street
Plymouth, MA 02360
Tel: (617) 420-1111
Fax: (617) 830-0712
wkelley@realjustice.com

Attorneys for Plaintiffs

CERTIFICATE OF SERVICE

I hereby certify that on this 13th day of February 2023, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system, which will send a notice of this electronic filing to all counsel of record.

/s/ *Kelsey Stokes*
Plaintiffs' Interim Co-Lead Counsel

EXHIBIT A

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE: COVIDIEN HERNIA MESH PRODUCTS LIABILITY LITIGATION NO. II,	
This Document Relates To: _____	**MDL No. 1:22-md-03029-PBS**

SHORT FORM COMPLAINT

Plaintiff(s) file(s) this Short Form Complaint pursuant to Case Management Order No. 7, and is to be bound by the rights, protections, and privileges and obligations of that Order. Plaintiff(s) hereby incorporate(s) the Master Complaint in MDL No. 3029 by reference. Plaintiff(s) further show(s) the Court as follows:

1. The name of Plaintiff/the person implanted with Defendants' Hernia Mesh Device(s):

_____

2. The name of any Consortium Plaintiff (if applicable):

_____

3. Other Plaintiff(s) and Capacity (i.e., administrator, executor, guardian, conservator):

_____

4. Current State of Residence:

_____

5. District Court and Division in which action would have been filed absent direct filing:

_____

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

☐ A. Covidien LP

☐ B. Sofradim Production SAS

☐ C. Other (please list: _____)

7. Identify which of Defendants' Hernia Mesh Device(s) was/were implanted (Check all device(s) implanted):

☐ Dextile Anatomical Mesh

☐ Parietene DS Mesh

☐ Parietene Polypropylene Mesh

☐ Parietene Progrip Mesh

☐ Parietex Composite Mesh

☐ Parietex Composite Mono PM Mesh

☐ Parietex Composite PCO-OS or PCO-OB Mesh

☐ Parietex Composite Ventral Patch

☐ Parietex Hydrophilic 2D Mesh

☐ Parietex Hydrophilic 3D Mesh

☐ Parietex Hydrophilic Anatomical Mesh

☐ Parietex Monofilament Polyester Mesh

☐ Parietex Optimized Composite Mesh

☐ Parietex Plug & Patch

☐ Parietex ProGrip

☐ ProGrip Laparoscopic

☐ SurgiPro

☐ SurgiPro Plug & Patch

☐ Symbotex Composite Mesh

☐ Other (please list in space provided below):

_____

8. Defendants' Hernia Mesh Device(s) about which Plaintiff is making a claim (Check all applicable device(s)):

- ☐ Dextile Anatomical Mesh
- ☐ Parietene DS Mesh
- ☐ Parietene Polypropylene Mesh
- ☐ Parietene Progrip Mesh
- ☐ Parietex Composite Mesh
- ☐ Parietex Composite Mono PM Mesh
- ☐ Parietex Composite PCO-OS or PCO-OB Mesh
- ☐ Parietex Composite Ventral Patch
- ☐ Parietex Hydrophilic 2D Mesh
- ☐ Parietex Hydrophilic 3D Mesh
- ☐ Parietex Hydrophilic Anatomical Mesh
- ☐ Parietex Monofilament Polyester Mesh
- ☐ Parietex Optimized Composite Mesh
- ☐ Parietex Plug & Patch
- ☐ Parietex ProGrip
- ☐ ProGrip Laparoscopic
- ☐ SurgiPro
- ☐ SurgiPro Plug & Patch
- ☐ Symbotex Composite Mesh
- ☐ Other (please list in space provided below):

_____

9. Date of Implantation and State of Implantation (if multiple devices, list date of implantation for each device and list the device implanted on such date):

_____

10. As of the date of filing this Short Form Complaint, has the person implanted with Defendants' Hernia Mesh Device(s) had subsequent surgical intervention due to the Hernia Mesh Device(s)?: Yes____ No____

11. Basis of Jurisdiction:

☐ Diversity of Citizenship

☐ Other: _____

12. Counts in the Master Complaint adopted by Plaintiff(s):

☐ Count I – Strict Product Liability- Defective Design

☐ Count II – Strict Product Liability- Failure to Warn

☐ Count III – Strict Product Liability- Manufacturing Defect

☐ Count IV– Negligence

☐ Count V– Negligence Per Se

☐ Count VI– Gross Negligence

☐ Count VII – State Consumer Protection Laws (Please identify applicable State Consumer Protection law(s)):

_____

_____

☐ Count VIII – Breach of Implied Warranty

☐ Count IX – Breach of Express Warranty

☐ Count X – Negligent Infliction of Emotional Distress

☐ Count XI – Intentional Infliction of Emotional Distress

☐ Count XII – Negligent Misrepresentation

☐ Count XIII – Fraud and Fraudulent Misrepresentation

☐ Count XIV – Fraudulent Concealment

☐ Count XV – Wrongful Death

☐ Count XVI – Loss of Consortium

☐ Count XVII – Punitive Damages

☐ Other Count(s) (please identify and state factual and legal bases for other claims not included in the Master Complaint below):

☐ Jury Trial is Demanded as to All Counts

☐ Jury Trial is NOT Demanded as to All Counts; if Jury Trial is Demanded as to Any Count(s), identify which ones (list below):

Respectfully submitted this ____ day of _____, 202__.