KeInUNITED STATES DISTRICT COURT
DISTRICT OF RHODE ISLAND

ROBERT BRAY,	)	**Civil Action No.:**
	)	
	)	
Plaintiff,	)	
	)	**JURY TRIAL DEMANDED**
v.	)	
	)	
	)	
DAVOL, INC., C.R. BARD, INC., JOHNSON & JOHNSON AND ETHICON, INC.,	)	
	)	
	)	
	)	
Defendants.	)	
	)	

COMPLAINT

Plaintiff, Robert Bray, ("Plaintiff"), by and through his undersigned counsel, brings this Complaint for damages against Defendants, C.R. Bard, Inc., Davol, Inc. Johnson & Johnson and Ethicon, Inc. (hereinafter collectively referred to as "Defendants"), and in support thereof, states the following:

1. This is a medical device civil tort action brought on behalf of the Plaintiff arising out of the failure of the Defendants' hernia mesh products, the Bard Ventralight ST Mesh ("ST Bard Mesh") and the Ethicon Proceed Ventral Patch ("Proceed" or "Ethicon Multi-Layered Hernia Mesh"), collectively known as "Mesh Products". As a result, Plaintiff suffered permanent injuries and significant pain and suffering, emotional distress, lost wages and earning capacity, and diminished quality of life. The Plaintiff respectfully seeks damages in excess of $75,000.00 for all damages to which he may be legally entitled.

PARTIES

2. Plaintiff is a citizen and resident of the Beebe, Arkansas and the United States.

3. Defendant Davol, Inc. ("Davol") is a corporation that is incorporated under the laws of the State of Rhode Island. Davol has its principal place of business in the State of Rhode Island. It manufactures the ST Bard Mesh and is located at 100 Crossings Boulevard, Warwick, Rhode Island. Davol is a medical device company involved in the research, development, testing, manufacture, production, marketing, promotion and/or sale of medical devices including the ST Bard Mesh.

4. Defendant C. R. Bard, Inc. ("Bard") is a corporation that is incorporated under the laws of the State of New Jersey. Bard's principal place of business is located at 730 Central Avenue, Murray Hill, New Jersey, 07974. Bard is a multinational marketer, promoter, seller, producer, manufacturer, and developer of medical devices. Bard controls the largest market share of the hernia mesh market. It is the corporate parent/stockholder of Davol and participates in the manufacture and distribution of the ST Bard Mesh. Bard also manufactures and supplies Davol with material that forms part of the ST Bard Mesh.

5. At all material times, Bard was responsible for Davol's actions and exercised control over its functions, specific to the oversight and compliance with applicable safety standards relating to the ST Bard Mesh sold in the United States. In such capacity, Bard committed, or allowed to be committed, tortious and wrongful acts, including the violation of numerous safety standards relating to device manufacturing, quality assurance/control, and conformance with design and manufacturing specifications. Bard's misfeasance and malfeasance caused Plaintiff to suffer injury and damages.

6. Defendant Johnson & Johnson ("J&J") is a corporation incorporated under the laws

of New Jersey with its principal place of business located at One Johnson & Johnson Plaza, New Brunswick, New Jersey. All acts and omissions of J&J 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. J&J is a manufacturer of medical devices, diagnostics and consumer products related to healthcare, health, beauty products, and medical devices. J&J's misfeasance and malfeasance caused Plaintiff to suffer injury and damages.

7. Defendant J&J organizes its subsidiary businesses into individual Business Units, which coordinate the development, manufacture, testing, marketing, promoting, training, distribution, and sale of J&J products, including its hernia repair mesh devices such as the Proceed at issue here. The corporate structure of J&J contains three sectors: (1) medical devices and diagnostics; (2) pharmaceutical; and (3) consumer.

8. Within the medical devices and diagnostic sector are "Business Units" as well, including the "Ethicon Franchise". J&J charged the Ethicon Franchise with the design, development, promotion, marketing, testing, training, distribution and sale of the Proceed, the hernia repair device that was implanted in Plaintiff.

9. Gary Pruden, the Company Group Chairman and Worldwide Franchise Chairman for the Ethicon Franchise, is a J&J employee. The companies comprising the Ethicon Franchise are thus controlled by Defendant J&J, and include Defendant Ethicon, Inc.

10. Defendant Ethicon, Inc. ("Ethicon") is a corporation incorporated under the laws of New Jersey with its principal place of business in Sommerville, New Jersey. It is a wholly owned subsidiary of Defendant J&J. All acts and omissions of Ethicon 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. Ethicon is a is a medical device

company involved in the research, development, testing, manufacture, production, marketing, promotion and/or sale of medical devices, including the Proceed, which is an Ethicon Multi-Layered Hernia Mesh. Ethicon's secondary corporate headquarters is located in Cincinnati, Ohio. Ethicon's misfeasance and malfeasance caused Plaintiff to suffer injury and damages.

11. "C.R. Bard" and "Davol" are collectively hereinafter referred to as the "Bard Defendants."

12. "J&J" and "Ethicon" are collectively hereinafter referred to as the "Ethicon Defendants."

13. C.R. Bard, Davol, J&J, and Ethicon are hereinafter collectively referred to as "Defendants," unless under a heading that designates Ethicon or Bard allegations and facts.

14. 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 defective Mesh Products at issue in the instant suit, effectuated directly and indirectly through their respective agents, servants, employees and/or owners, all acting within the course and scope of their representative agencies, services, employments and/or ownership.

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

JURISDICTION & VENUE

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

17. This Court has personal jurisdiction over each of the Bard Defendants as Davol has its principal place of business in Rhode Island and Bard was responsible for Davol's actions. This Court has personal jurisdiction over all Defendants as they transact business within the State of Rhode Island, contracted to sell and supply their Mesh Products in the State of Rhode Island, and committed tortious acts and omissions in Rhode Island. Defendants' tortious acts and omissions caused injury to Plaintiff. Defendants employ sales representatives in the State of Rhode Island to sell their Mesh Products throughout the State, including the Mesh Products implanted in Plaintiff. Defendants have purposefully engaged in the business of developing, manufacturing, publishing information, marketing, distributing, promoting and/or selling, either directly or indirectly, through third parties, as successor in interest, or other related entities, medical devices including Mesh Products in Rhode Island, for which they derived significant and regular income. The Defendants intended and reasonably expected that that their defective Mesh Products would be sold and implanted in Rhode Island and could cause injury in Rhode Island.

18. Bard Defendants are registered to transact business in Rhode Island.

19. Venue is proper in this Court pursuant to 28 U.S.C. § 1332(a)-(c) by virtue of the fact that (a) a substantial part of the events or omissions giving rise to the claims occurred in this District; (b) Defendants' products are sold to and consumed by individuals in the State of Rhode Island; and (c) Davol has its principle place of business in Rhode Island and Bard was responsible for Davol's actions; thereby, subjecting Defendants to personal jurisdiction in this action and making them all "residents" of this judicial District.

20. Defendants have and continue to conduct substantial business in the State of Rhode Island and in this District, distribute the Mesh Products in this District, receive substantial compensation and profits from sales of Mesh Products in this District, and made material

omissions and misrepresentations and breaches of warranties in this District, so as to subject all Defendants to in personam jurisdiction in this District.

PROCEED HISTORY

21. Defendants were the designers, manufacturers, marketers, distributors and suppliers of the Ethicon Proceed Ventral Patch at all material times.

22. Defendants warranted the Ethicon Multi-Layered Hernia Mesh and placed the device into the United States stream of commerce.

23. Defendants knew that the oxidized regenerated cellulose layer of the Ethicon Multi-Layered Hernia Mesh was ineffective at preventing adhesion formation to the underlying polypropylene of the Proceed before Defendants set out to design the Proceed Ventral Patch in 2006, and even before Defendants set out to design the Proceed Surgical Mesh predicate device in 2003.

24. Before 2003, Defendants were aware that the Oxidized Regenerated Cellulose utilized in the Ethicon Multi-Layered Hernia Mesh had pores which were too large to prevent adhesion formation.

25. Before 2003, Defendants were aware that increased adhesion formation would result in increased mesh shrinkage.

26. Before 2003, Defendants were aware that utilizing Oxidized Regenerated Cellulose in their mesh products would result in dense adhesions in the presence of blood or fibrinous exudate.

27. Before 2003, Defendants were aware that polypropylene elicits a chronic, life-long inflammatory response that is accompanied by exudation of fibrinogen.

28. Before 2003, Defendants were aware that any exposure to gamma radiation would

weaken and embrittle the polypropylene of the Ethicon Multi-Layered Hernia Mesh.

29. Before 2006, Defendants were aware that adding Vicryl and other additional layers to the Proceed Surgical Mesh to create the Proceed Ventral Patch, would increase the intensity and duration of inflammation and foreign body response (FBR), thus increasing fibrinous exudate.

30. Before placing the Ethicon Multi-Layered Hernia Mesh on the market, Defendants were required to mitigate risks of the product, including any element of design or sterilization which could render the device ineffective, weaken the structural integrity of the device, or increase or prolong inflammation once the device is implanted that would result in an increase in adhesion formation, mesh shrinkage, pain, bowel complications, hernia recurrence, and/or the need for early surgical revision in patients-consumers.

31. Defendants designed, manufactured, and marketed the Ethicon Multi-Layered Hernia Mesh, despite long-standing knowledge that the materials utilized in the Proceed would cause dense adhesions, chronic pain, mesh shrinkage, bowel obstructions, and early hernia recurrence.

32. Defendants sterilized the Ethicon Multi-Layered Hernia Mesh with gamma radiation, despite long-standing knowledge that polypropylene will degrade and embrittle if exposed to any amount of gamma radiation.

33. The Ethicon Proceed Ventral Patch is made of the following, starting with the component placed closest to the bowel of the patient-consumer:

- Oxidized Regenerated Cellulose (ORC) barrier layer
- Polydioxanone (PDS) film layer
- Large pore polypropylene (Prolene soft mesh)
- PDS film layer
- PDS reinforcing element
- PDS ring
- PDS film layer
- Vicryl

- PDS film layer

34. Polypropylene hernia meshes are traditionally sterilized with ethylene oxide.

35. The ORC layer of the Ethicon Multi-Layered Hernia Mesh will react and degrade in the presence of ethylene oxide.

36. Defendants sterilize the Ethicon Multi-Layered Hernia Mesh with gamma radiation.

37. Gamma radiation degrades, weakens, and embrittles the polypropylene base of the Ethicon Multi-Layered Hernia Mesh.

38. Decades before the release of the Ethicon Multi-Layered Hernia Mesh, Defendants were aware that polypropylene degrades, weakens, and embrittles when exposed to gamma irradiation.[1]

39. The embrittled polypropylene of the Ethicon Multi-Layered Hernia Mesh increases its propensity to tear away from the securing devices, such as sutures or tacks.

40. The polypropylene base is the only permanent, non-resorbable portion of the Ethicon Multi-Layered Hernia Mesh.

41. Defendants designed, manufactured, promoted, sold and/or marketed the Ethicon Multi-Layered Hernia Mesh to be utilized in anyone with a soft tissue defect, including, but not limited to: "infants, children, pregnant women, or women planning pregnancies…"[2]

42. For decades, the medical community had concerns about severe complications if polypropylene was placed too close to the bowel or other underlying organs, due to the formation of dense adhesions to the polypropylene.

43. Defendants were aware that the ORC layer in the Ethicon Multi-Layered Hernia

[1] U.S. Patent No. 3,943,933 (Issued Mar. 16, 1976).
[2] Proceed Ventral Patch Instructions for Use, RMC 8550915, Status 9/08.

Mesh was ineffective at preventing adhesion formation to polypropylene over a decade before Defendants brought the Ethicon Multi-Layered Hernia Mesh to market.[3]

44. Despite significant evidence to the contrary, Defendants marketed the Ethicon Multi-Layered Hernia Mesh and its ORC layer as a tissue-separating barrier that would prevent adhesion formation from the underlying polypropylene to any nearby organs.

45. The following studies have investigated complications associated with the Ethicon Multi-Layered Hernia Mesh:

> a. In 2006, a study out of The Netherlands evaluating the use of new prosthetic meshes for ventral hernia repair was published in Surgical Endoscopy. **Proceed showed significantly less incorporation… Proceed composite has a smooth surface designed to prevent adhesion formation. However, it is less smooth than other composite meshes with antiadhesive barriers. Furthermore, the barrier applied is oxidized cellulose, which may not prevent mesh adhesions as effectively as anticipated or as reported previously.**
>
> Burger, J.W. et al, *Evaluation of New Prosthetic Meshes for Ventral Hernia Repair*. Surg Endosc. 20:1320 – 1325 (2006). DOI: 10.1007/s00464-005-0706-4.
>
> b. In 2009, a study out of The Netherlands on adhesions prevention during hernia mesh repair was published in the Annals of Biomedical Engineering. **The uncoated Prolene meshes were found to invoke a moderate inflammatory response in their immediate vicinity, characterized by the presence of active macrophages. A stronger inflammatory response was observed with the Proceed meshes, presumably due to ongoing phagocytosis of the oxidizing regenerated cellulose and polydioxanone coating… Most remarkable were adhesions with Proceed. Although adhesion scores were the lowest at day 7, they increased by day 30 and exceeded adhesion scores of NVP/BMA-coated Prolene mesh and Prolene.**
>
> Emans, P. et al, *Polypropylene Meshes to Prevent Abdominal Herniation. Can Stable Coatings Prevent Adhesions in the Long Term?* Annals of Biomedical Engineering. 37(2):410 – 418 (2009). DOI: 10.1007/s10439-008-9608-7.

[3] Robert J. Fitzgibbons, Jr., M.D. et al., *A Laparoscopic Intraperitoneal Onlay Mesh Technique for the Repair of an Indirect Inguinal Hernia*, 219-2 ANNALS OF SURGERY 114 (1994).

c. In 2009, a study out of Saint Louis, Missouri measuring adhesions and mesh contraction was published by Surgical Innovation. The data was previously presented at the American Hernia Society, Third International Hernia Congress on June 9, 2006. **The highest degrees of mesh contraction occurred with DualMesh and Proceed… Proceed exhibited the greatest surface area of adhesion coverage and the highest-grade adhesions.**

Pierce, R. et al, *120-Day Comparative Analysis of Adhesion Grade and Quantity, Mesh Contraction, and Tissue Response to a Novel Omega-3 Fatty Acid Bioabsorbable Barrier Macroporous Mesh After Intraperitoneal Placement*. Surg Innov. (2009). DOI: 10.1177/1553350608330479.

d. In 2010, a study out of Saint Louis, Missouri on adhesion related complications associated with intraperitoneal mesh was published in Surgical Endoscopy. **Nevertheless, there appears to be some differentiation in the adhesion characteristics of the absorbable-barrier-coated meshes… We noticed a similar increase in the adhesion tenacity score of PROCEED in a preclinical study of intraperitoneal placement f absorbable-barrier-coated meshes in a rabbit model.**

Jenkins, E. et al, *Prospective Evaluation of Adhesion Characteristics to Intraperitoneal Mesh and Adhesiolysis-Related Complications During Laparoscopic Re-Exploration After Prior Ventral Hernia Repair*. Surg Endosc. 24:3002 – 3007. DOI: 10.1007/s00464-010-1076-0.

e. In 2010, a study out of Belgium on the lack of convincing data in medical literature regarding to use of intraperitoneal hernia mesh was published in The World Journal of Hernia and Abdominal Wall Surgery. The content of the paper was presented during the 32nd International Congress of the European Hernia Society, in Istanbul, on October 6-8, 2010. **After release of the omental adhesions, we found the [Proceed] mesh to have shrunk and folded up, to a dimension of approximately 3.0 cm in diameter. This means a shrinkage from a circle of diameter 6.4 cm (surface: 3.14 x 3.2^2 = 32.2 cm^2) to a "circle" of diameter 3.0 cm (surface: 3.14 x 1.5^2 = 7.1 cm^2), equivalent to a mesh surface shrinkage of 77.9%... There is a complete lack of convincing data on these mesh devices in the medical literature.**

Muysoms, F.E. et al, *Complications of Mesh Devices for Intraperitoneal Umbilical Hernia Repair: A Word of Caution*. Journal of Hernia. 15:463-468 (2011). DOI: 10.1007/s10029-010-0692-x.

f. In 2012, a study out of Saint Louis, Missouri on the effectiveness of barrier hernia mesh was published in Surgical Endoscopy. **This study also demonstrated increased adhesion formation for all of the barrier mesh**

prostheses between 7 and 30 days, which the authors attributed to increased inflammation related to the degradation and resorption of the barrier layer components, which were ongoing between 7 and 30 days. This effect was most pronounced in PROCEED Surgical Mesh materials, which again highlights the influence that the chemistry of the particular barrier components may have over the inflammatory response and subsequent adhesion formation.

Deeken, C. et al, *A Review of the Composition, Characteristics, and Effectiveness of Barrier Mesh Prostheses Utilized for Laparoscopic Ventral Hernia Repair*. Surg Endosc. 26:566-575 (2012). DOI: 10.1007/s00464-011-1899-3.

g. In 2014, a study out of Belgium on the Proceed Ventral Patch (PVP) was published in The World Journal of Hernia and Abdominal Wall Surgery. **Polypropylene meshes, like the PVP, have demonstrated an in vivo centripetal shrinkage percentage of up to 77% in some patients. This finding of mesh contraction was confirmed in those patients. This finding of mesh contraction was confirmed in those patients that were re-operated for recurrence in 21% of the patients where the radiologist was able to visualize the mesh. The overlap obtained with a mesh of 6.4 cm in diameter is in sufficient with hernias larger than 2 cm. Therefore, we recommend not to use PVP in hernias of 2cm or more.**

Bontinck, J. et al, *Single Centre Observational Study to Evaluate the Safety and Efficacy of the Proceed Ventral Patch to Repair Small Ventral Hernias*. Journal of Hernia. 18:671 – 680 (2014). DOI: 10.1007/s10029-013-1140-5.

h. In 2015, a study out of Belgium on the Proceed (PP/ORC) was published in The World Journal of Hernia and Abdominal Wall Surgery. **In our opinion, there are several factors contributing to the extensive FBR and shrinkage/mesh contraction of the PP/ORC device. First, the composition of the PP/ORC device out of nine different layers will lead to a more extensive FBR. Second, absorption of 8 of these 9 layers will create a severe inflammatory reaction as, e.g.. shown with vicryl mesh absorption, also being one of the components of the PP/ORC device. A third possible explanation is delamination of the device.**

Reynvoet, E. et al, *Intraperitoneal Mesh Devices for Small Midline Hernias: Mesh Behavior in a Porcine Model*. Journal of Hernia. 19:955 – 963 (2015). DOI: 10.1007/s10029-015-1368-3.

i. In 2016, a study out of Bosnia and Herzegovina was published by The Royal Belgian Society for Surgery. **The extent of [adhesion] site involvement after 28 days was statistically significantly greater in the Proceed group.**

Delibegovic, S. et al, *Formation of Adhesions After Intraperitoneal Applications of TiMesh: Experimental Study on a Rodent Model*. The Royal Belgian Society for Surgery. (2016). DOI 10.1080/00015458.2016.1179513

j. In 2016, a study out of Germany on the adhesion prevention efficacy of Proceed (PCM) was published in International Journal of Medical Sciences. **PCM does not provide significant adhesion prevention.**

Winny, M. et al, *Adhesions Prevention Efficacy of Composite Meshes Parietex, Proceed, and 4DryField PH Covered Polypropylene Meshes in an IPOM Rat Model*. Int. J. Med. Sci. 13:936 – 941 (2016). DOI: 10.7150/ijms.16215.

k. In 2017, a Proceed (PVP) randomized controlled trial out of The Netherlands was published in the World Journal of Surgery. **At this point, PVP device usage shows an easier and faster operating procedure. Nevertheless, this advantage is outweighed by the significantly higher incidence of early re-operations due to early complications.**

Ponten, J.E. et al, *Mesh Versus Patch Repair for Epigastric and Umbilical Hernia (MORPHEUS Trial); One-Year Results of a Randomized Controlled Trial*. World J. Surg. (2017). DOI: 10.1007/s00268-017-4297-8.

l. In 2017, a study out of Brazil was published on adhesions and collagen formation following mesh implantation. **The study follow-up time, 90 days, was established because there were no articles in the literature with prolonged follow-up… What we can formulate is that absorption of the regenerated oxidized cellulose exposes the polypropylene layer to the abdominal visceral content and that this consequently led to the adhesions found… The adhesion formation is a complex process and is basically started by the tissue injury process which breaks down the balance between coagulation and fibrinolysis. Fibrin deposition results in a matrix where the fibroblasts produce extracellular matrix. The end process generates various degrees of adhesion… In the present study, type III collagen was expressed more in the coated group and based on the result of the research this could increase hernia formation.**

Rossi, L. et al, *Peritoneal Adhesions Type I, III and Total Collagen on Polypropylene and Coated Polypropylene Meshes: Experimental Study in Rats*. ABCD Arq Bras Cir Dig 30(2):77 – 82 (2017). DOI: 10.1590/0102-6720201700020001.

FAILURE TO WARN PHYSICIANS OF THE DANGERS ASSOCIATED WITH ETHICON MULTI-LAYERED HERNIA MESH

46. Defendants marketed the Ethicon Multi-Layered Hernia Mesh to general surgeons, hospitals, and group purchasing organizations (GPOs), rather than end-user patients.

47. Defendants had the ability to inform surgeons, hospitals, or GPOs of developing problems or defects in its devices through e-mail, letter, recalls, warnings in product inserts, and/or through its product representatives, who work directly with surgeons.

48. The nine layers of the Ethicon Multi-Layered Hernia Mesh increase the intensity and duration of the inflammatory response. That response in turn increases dense adhesion formation from underlying organs to the Ethicon Proceed, resulting in bowel complications, mesh contracture, hernia recurrence, increased foreign body reaction, chronic severe pain, and more.

49. Defendants downplayed the intensity of the inflammatory reaction caused by Vicryl by stating in the Ethicon Proceed Instructions for Use (IFU) that the Vicryl elicits "only a mild tissue reaction during absorption."

50. Defendants state in the Proceed IFU that "The PROLENE Soft Mesh components are constructed of knitted filaments of extruded polypropylene, identical in composition to that used in PROLENE Polypropylene Suture, Nonabsorbable Surgical Suture, U.S.P." This statement is false, or at the very least misleading, as the Proceed undergoes gamma irradiation that changes the composition of the polypropylene.

51. Defendants also state in the Proceed IFU that the polypropylene material "when used as a suture, has been reported to be non-reactive and to retain its strength indefinitely in clinical use. The PROLENE Soft Mesh affords excellent strength, durability and surgical adaptability, with a porous structure to enable mesh incorporation into surrounding tissues." This statement is false, or at the very least misleading, as Defendants are aware that the Ethicon Proceed

is reactive and does not retain its strength. Furthermore, Defendants are aware of reports that the small polypropylene sutures do elicit a small reaction, and increasing amounts of polypropylene greatly increase such reaction. The very reason the Defendants added the ORC layer to the Prolene Soft Mesh was to protect organs from reacting with the polypropylene of the Prolene Soft Mesh.

52. The Proceed IFU has a section for contraindications, which lists "None known."

53. The Proceed IFU has a section for adverse reactions, which lists "Potential adverse reactions are those typically associated with surgically implantable materials…" The polypropylene base of the Ethicon Proceed carries many potential adverse reactions, such as a life-long inflammatory response that other surgically implantable materials do not present. Additionally, the multiple layers of the Ethicon Multi-Layered Hernia Mesh further increase the inflammatory response and rate of infection, adhesion formation, chronic pain, seroma formation, fistula formation, hematomas, mesh contracture, hernia recurrence, mesh migration, bowel complications, foreign body response, extrusion, and other additional injuries.

54. The Proceed IFU notes that "Selected mesh size should allow for adequate overlap of the fascial defect on all sides." The IFU never defines what constitutes "adequate overlap." Defendants are aware that the Proceed shrinks over time, with reports of the Proceed shrinking as much as 77%.

55. Defendants failed to warn that the Ethicon Multi-Layered Hernia Mesh will elicit a fibrinous exudate.

56. Defendants failed to warn that the Ethicon Multi-Layered Hernia Mesh creates a solid barrier preventing the body from adequately clearing or transporting fluid, which results in seroma formation, potentiating infections and fistula formation.

57. Defendants never performed any clinical trials and/or studies before marketing the

Ethicon Multi-Layered Hernia Mesh.

58. Defendants did not fully and/or adequately test the configuration of its new, multi-layered hernia mesh patch design with ORC, polypropylene, Vicryl, and six layers of PDS, that was implanted into Plaintiff.

59. Although the United States does not have a complete and accurate database to track problems with hernia mesh implants, controlled studies have investigated the problems with the Ethicon Multi-Layered Hernia Mesh.

60. A single center study was conducted in Belgium, where three surgeons implanted only the Ethicon Proceed in 101 patients between April 2009 and December 2011. The Ethicon Proceed was able to be visualized by ultrasound in 47 patients. Of those 47 patients, 10 were noted to have mesh contraction. The Ethicon Proceed "was removed during the operation in four patients and important centripetal contraction of the mesh, diminishing the surface area, was observed in all cases." The authors concluded the Proceed has "demonstrated an in vivo centripetal shrinkage percentage of up to 77% in some patients. This finding of mesh contraction was confirmed in those patients that were reoperated for recurrence and in 21% of the patients where the radiologist was able to visualize the mesh. The overlap obtained with a mesh of 6.4cm in diameter was insufficient with hernias larger than 2 cm. Therefore, we recommend not to use PVP (Proceed Ventral Patch) in hernias of 2 cm or more." The authors go on to note that their study is likely underpowered as "Most recurrences after ventral hernia repair occur within 2 years after the operation. Since our study had a mean follow-up of 16 months, it is likely that a longer follow-up would yield a higher recurrence rate."[4]

61. In 2015, another study in Belgium confirmed "massive shrinkage" with the Ethicon

[4] J. Bontinck, Single Centre Observational Study to Evaluate the Safety and Efficacy of the Proceed Ventral Patch to Repair Small Ventral Hernias, 18 Hernia 671, Clinical.Trials.gov: NCT01307696 (2013).

Proceed. The authors concluded that "This can however not be considered the ideal indication for a mesh device repair with a suggested mesh overlap of at least 5 cm for incisional hernias."[5]

62. Defendants continue to market the Ethicon Multi-Layered Hernia Mesh without warning of the massive mesh shrinkage or the necessary overlap to prevent early hernia recurrence due to mesh shrinkage.

63. Reassurances of device safety were made through direct promotional contact by Defendants' sales representatives and distributors, through word-of-mouth from Defendants' physician/technical consultants, and/or through industry-targeted promotional materials.

64. Despite these reassurances, the defective design and manufacture of the Ethicon Multi-Layered Hernia Mesh continued to elicit severe and chronic inflammatory responses, resulting in adhesion formation, bowel injuries, mesh contracture, pain, hernia recurrence, infections, seromas, fistulas, erosion, extrusion, and additional complications.

65. Defendants were aware that the ORC layer was ineffective in preventing adhesions to the polypropylene; gamma irradiation would weaken the polypropylene; and the nine-layer mesh would contract massively over time. Nonetheless, Defendants employed the design in the Ethicon Proceed Ventral Patch in reckless disregard for the safety of patients, including Plaintiff.

66. Moreover, despite direct knowledge of significant adverse events reported by patients and physicians, as well as awareness of failures that have been reported in literature and published clinical trials, Defendants have continued to market the Ethicon Multi-Layered Hernia Mesh as being safe and effective for hernia repair.

67. From the time Defendants first began selling the Ethicon Multi-Layered Hernia Mesh in the United States through today, product labeling and the product information failed to

[5] E. Reynvoet, Intraperitoneal Mesh Devices for Small Midline Hernias: Mesh Behavior in a Porcine Model, 19 Hernia 955 (2015).

contain adequate information, instructions, and warnings concerning the following: implantation of the Proceed, specifically its propensity to massively shrink, the increased in duration and intensity of inflammation, and the elevated rate of adhesions, bowel complications, chronic pain, hernia recurrence, seroma formation, hematoma formation, fistula formation, erosion, extrusion, infection, and other injuries occurring at a higher rate than other surgically implanted devices.

USE OF THE ETHICON PRODUCT

68. A defectively designed, manufactured and marketed Ethicon Multi-Layered Hernia Mesh left the hands of Defendants in its defective condition, and was delivered into the stream of commerce. Glen Blue, MD implanted the Proceed Ventral Patch in Plaintiff's abdomen to repair a ventral hernia on or about February 24, 2012 at White County Medical Center, Arkansas. Plaintiff Robert Bray was implanted with a 4.3 cm x 4.3 cm Proceed Ventral Patch, Model No. PVPS.

69. As a direct and proximate result of Defendants' defective design, manufacture, marketing, distribution, and/or sale of the Ethicon Multi-Layered Hernia Mesh, and their placing of their defective product into the stream of commerce, Plaintiff has been injured and damaged as follows:

a. On or about April 18, 2017, Plaintiff underwent removal of the Ethicon Proceed at White County Medical Center, Arkansas, by William Gibbs, MD. Upon visualizing the Ethicon Multi-Layered Hernia Mesh, Dr. Gibbs noted: "the mesh was carefully closed, fired and removed (explanted).".

b. Plaintiff experienced and/or continues to experience severe pain, limited movement, and inflammation, which have impaired his activities of daily living.

c. Plaintiff continues to suffer complications as a result of his implantation with the Ethicon Multi-Layered Hernia Mesh.

d. Plaintiff is at a higher risk of severe complications during an abdominal surgery, to the extent that future abdominal operations might not be feasible.

70. The mechanism of failure in Plaintiff's device was a mechanism of failure that

Defendants had marketed and warranted would not occur because of the Ethicon Multi-Layered Hernia Mesh design and composition. It was also the same failure mechanism that the medical and scientific community had been studying and documenting since the 1990s, *i.e.,* ORC was ineffective at preventing adhesions to polypropylene, and polypropylene contracts when dense adhesions form to it.

71. Moreover, the symptoms and findings associated with Ethicon Multi-Layered Hernia Mesh product failures that have been reported in the literature are identical to those Plaintiff suffered.

72. As a direct and proximate result of Defendants' defective design, manufacturing, marketing, distribution, sale and warnings of the Ethicon Multi-Layered Hernia Mesh, Plaintiff has suffered and continues to suffer injuries and damages, including, but not limited to: past, present and future physical and mental pain and suffering; physical disability; past, present, and future medical, hospital, rehabilitative, and pharmaceutical expenses; and other related damages.

THE FDA'S 510(k) CLEARANCE PROCESS RE: ETHICON/J&J

73. The 510(k) clearance process refers to Section 510(k) of the Medical Device Amendments of 1976 MDA of the Federal Food, Drug and Cosmetic Act. Under this process, device manufacturers are only required to notify the FDA at least 90 days before they market a device claimed to be "substantially equivalent" to a device the FDA had approved for sale before 1976, when the MDA was enacted.

74. No clinical testing is required under this process.

75. Subsequent amendments to the MDA allowed for 510(k) clearance of products deemed "substantially equivalent" to post-MDA, 510(k)-cleared devices.

76. Through this domino effect, devices deemed "substantially equivalent" to devices previously deemed "substantially equivalent" to devices approved for sale by the FDA before 1976 could be sold to patients in a matter of 90 days without any clinical testing.

77. Clearance for sale under the 510(k) process does not equate to FDA approval of the cleared device.

78. In 2012, at the request of the FDA, the National Institute of Health (NIH) conducted a thorough review of the 510(k) process, coming to the following major conclusion:

> **The 510(k) clearance process is not intended to evaluate the safety and effectiveness of medical devices with some exceptions. The 510(k) process cannot be transformed into a pre-market evaluation of safety and effectiveness so long as the standard for clearance is substantial equivalence to any previously cleared device.**

79. The NIH explained, "The assessment of substantial equivalence does not require an independent demonstration that the new device provides a 'reasonable assurance of safety and effectiveness.'" Further, the NIH even pointed out that the classification of predicate devices approved for sale prior to the 1976 MDA "did not include any evaluation of the safety and effectiveness of individual medical devices . . .Thus it is common for devices to be cleared through the 510(k) program by being found substantially equivalent to devices that were never individually evaluated for safety and effectiveness, either through the original device classification program or through the 510(k) process."

80. Defendants cleared the Ethicon Proceed Ventral Patch, and its related components, under the 510(k) Premarket Notification. Under Section 510(k) of the Federal Food, Drug and Cosmetic Act, a medical device does not have to go through the rigors of a clinical study to gain approval by the FDA. Instead, the device was supposed to demonstrate substantial equivalence to a predicate medical device.

81. On June 18, 2002, the Food and Drug Administration issued a document titled "Guidance for Resorbable Adhesion Barrier Devices for Use in Abdominal and/or Pelvic Surgery; Guidance for Industry." The 26 page document starts by explaining:

> **FDA has determined that the resorbable adhesion barrier is a significant risk device as defined in 21 CFR 812.3(m)(4). The resorbable adhesion barrier is a class III device which is subject to premarket approval in accordance with section 515 of the Federal Food, Drug, and Cosmetics (FD&C) Act.**

82. The first Proceed Surgical Mesh did not undergo premarket approval, but instead received 510(k) clearance on or about September 17, 2003. The only predicate device listed on the 510(k) application is the Prolene Soft Polypropylene Mesh, a non-barrier hernia mesh. Defendants did not claim that the Proceed Surgical Mesh was a resorbable adhesion barrier in their 510(k) application. However, after 510(k) clearance, Defendants marketed the Proceed Surgical Mesh as a resorbable adhesion barrier.

83. Defendants applied for 510(k) clearance for the Proceed Surgical Mesh again in May of 2006. The only predicate device listed on the 510(k) application is the prior Proceed Surgical Mesh. In this 510(k) application, Defendants did not claim the intended use of the Proceed was a resorbable adhesion barrier; however, in the device description Defendants note that the "ORC side provides a bioresorbable layer that physically separates the polypropylene mesh from underlying tissue and organ surfaces during the wound-healing period to minimize tissue attachment to the mesh." Defendants continued to market the Proceed Surgical Mesh as a resorbable adhesion barrier.

84. Defendants applied for 510(k) clearance for the Proceed Ventral Patch in December of 2006. Defendants do not mention in the 510(k) application for the Proceed Ventral Patch that the mesh is intended to act as a resorbable adhesion barrier. After 510(k) clearance, Defendants

marketed and continue to market the Proceed Ventral Patch as a resorbable adhesion barrier. Even the Ethicon Proceed IFU notes "The ORC side of the patch provides a bioresorbable layer that physically separates the polypropylene mesh from underlying tissue and organ surfaces while minimizing tissue attachment to the polypropylene mesh during the critical wound healing period."

FACTS COMMON TO BARD/DAVOL

85. On or about September 19, 2017, Plaintiff underwent ventral hernia repair by Dr. Jim City, MD at White County Medical Center, Arkansas. A 4x6 cm Ventralight ST Bard Mesh, Cat no. 5954460, Log No. HUBN2409 was implanted in Plaintiff during this repair.

86. Defendants, manufactured, sold, and/or distributed the ST Bard Mesh to Plaintiff, through his doctors, to be used for treatment of hernia repair.

87. On or about April 3, 2018, Plaintiff underwent revision surgery by Dr. Jim Citty, MD at White County Medical Center, Arkansas.

88. Plaintiff experienced and/or continues to experience severe pain, limited movement, and inflammation, which have impaired his activities of daily living.

89. Plaintiff continues to suffer complications as a result of his implantation with the Ventralight ST Bard Mesh.

90. Plaintiff is at a higher risk of severe complications during an abdominal surgery, to the extent that future abdominal operations might not be feasible.

91. Bard was, at all times relevant hereto, responsible for the actions of Davol and exercised control over Davol's functions specific to the oversight and compliance with applicable safety standards relating to and including ST Bard Mesh sold in the United States. In such capacity, they committed or allowed to be committed tortious and wrongful acts, including the violation of numerous safety standards relating to device manufacturing, quality assurance/control,

and conformance with design and manufacturing specifications. Their misfeasance and malfeasance caused Plaintiff to suffer injury and damages.

92. Defendants were responsible for the research, design, development, testing, manufacture, production, marketing, promotion, distribution and sale of ST Bard Mesh, including providing the warnings and instructions concerning the product.

93. Among the intended purposes for which Defendants designed, manufactured and sold ST Bard Mesh was use by surgeons for hernia repair surgeries, the purpose for which the ST Bard Mesh was implanted in Plaintiff.

94. Defendants represented to Plaintiff and Plaintiff's physicians that ST Bard Mesh was a safe and effective product for hernia repair.

THE FDA'S 510(k) CLEARANCE PROCESS RE: BARD/DAVOL

95. The 510(k) clearance process refers to Section 510(k) of the Medical Device Amendments of 1976 MDA of the Federal Food, Drug and Cosmetic Act. Under this process, device manufacturers are only required to notify the FDA at least 90 days before they market a device claimed to be "substantially equivalent" to a device the FDA had approved for sale before 1976, when the MDA was enacted.

96. No clinical testing is required under this process.

97. Subsequent amendments to the MDA allowed for 510(k) clearance of products deemed "substantially equivalent" to post-MDA, 510(k)-cleared devices.

98. Through this domino effect, devices deemed "substantially equivalent" to devices previously deemed "substantially equivalent" to devices approved for sale by the FDA before 1976 could be sold to patients in a matter of 90 days without any clinical testing.

99. Clearance for sale under the 510(k) process does not equate to FDA approval of the cleared device.

100. In 2012, at the request of the FDA, the National Institute of Health (NIH) conducted a thorough review of the 510(k) process, coming to the following major conclusion:

> **The 510(k) clearance process is not intended to evaluate the safety and effectiveness of medical devices with some exceptions. The 510(k) process cannot be transformed into a pre-market evaluation of safety and effectiveness so long as the standard for clearance is substantial equivalence to any previously cleared device.**

101. The NIH explained, "The assessment of substantial equivalence does not require an independent demonstration that the new device provides a 'reasonable assurance of safety and effectiveness.'" Further, the NIH even pointed out that the classification of predicate devices approved for sale prior to the 1976 MDA "did not include any evaluation of the safety and effectiveness of individual medical devices . . .Thus it is common for devices to be cleared through the 510(k) program by being found substantially equivalent to devices that were never individually evaluated for safety and effectiveness, either through the original device classification program or through the 510(k) process."

102. Defendants cleared the ST Bard Mesh, and its related components, under the 510(k) Premarket Notification. Under Section 510(k) of the Federal Food, Drug and Cosmetic Act, a medical device does not have to go through the rigors of a clinical study to gain approval by the FDA. Instead, the device was supposed to demonstrate substantial equivalence to a predicate medical device.

103. On June 18, 2002, the Food and Drug Administration issued a document titled "Guidance for Resorbable Adhesion Barrier Devices for Use in Abdominal and/or Pelvic Surgery; Guidance for Industry." The 26 page document starts by explaining:

> **FDA has determined that the resorbable adhesion barrier is a significant risk device as defined in 21 CFR 812.3(m)(4). The resorbable adhesion barrier is a class III device which is subject to premarket approval in accordance with section 515 of the Federal Food, Drug, and Cosmetics (FD&C) Act.**

104. Defendants expected and intended the ST Bard Mesh product to reach users such as Plaintiff in the condition in which the product was sold.

105. The implantation of ST Bard Mesh in Plaintiff's body was medically reasonable, and was a type of use that Defendants intended and foresaw when it designed, manufactured and sold the product.

106. At the time the ST Bard Mesh that was implanted in Plaintiff's body, the product was defectively manufactured.

107. Defendants' poor quality control and general non-compliance resulted in the non-conformance of the ST Bard Mesh implanted in Plaintiff. The ST Bard Mesh implanted in Plaintiff did not conform to the Defendants' intended manufacturing and design specifications.

108. Upon information and belief, Defendants utilized substandard and adulterated polypropylene and raw materials used to make the ST coating on their finished ST Bard Meshes, which deviated from Defendants' material and supply specifications.

109. Defendants' ST Bard Mesh was defectively designed and/or manufactured, was not reasonably safe for its intended use in hernia repair, and the risks of the design outweighed any potential benefits associated with the design. As a result of the defective design and/or manufacture of the ST Bard Mesh, there was an unreasonable risk of severe adverse reactions to the mesh or mesh components including: chronic pain; recurrence of hernia; foreign body response; rejection; infection; scarification; improper wound healing; excessive and chronic inflammation; allergic reaction; adhesions to internal organs; erosion; abscess; fistula formation;

granulomatous response; seroma formation; nerve damage; tumor formation, cancer, tissue damage and/or death; and other complications.

110. When affixed to the body's tissue, the impermeable coating of the ST Mesh prevents fluid escape, which leads to seroma formation, and which in turn can cause infection or abscess formation and other complications.

111. The ST coating provides an ideal bacteria breeding ground in which the bacteria cannot be eliminated by the body's immune response, which allows infection to proliferate.

112. Defendants utilize Ethylene Oxide ("ETO") in an attempt to sterilize the ST Mesh. ETO is an effective disinfectant; however, dry spores are highly resistant to ETO. Moisture must be present to eliminate spores using ETO. Presoaking the product to be sterilized is most desirable, but high levels of humidity during the ETO process can also be effective in eliminating spores. ST Mesh implanted with spores will eventually result in an infection. The spores can remain dormant for extended periods of time, resulting in infections months or years after implantation with the ST Mesh. The following non-exhaustive literature discusses the necessity of moisture during ETO sterilization:

A. In January of 1989, a review on sterilization methods of medical devices was published in the Journal of Biomaterials Applications. ETO was among the sterilization methods reviewed. **ETO was noted to be highly resistant to dry spores, moisture must be present; presoaking most desirable. Experiments demonstrated the importance of the state of humidification of organisms at the time of their exposure to ETO. Desiccation of the spores prior to ETO exposure produces a small but significant percentage of organisms which are highly resistant to the sterilization process. Similar resistance to destruction by ETO occurs in desiccated staphylococcus aureus. Rehumidification of such organisms can require prolonged exposure to an atmosphere having a 50 to 90 percent relative humidity. Moisture has been found to be a critical factor in achieving sterility with gaseous ETO. No gas sterilizer can effectively kill desiccated spores.**

   Dempsey, D.J. and Thirucote, R.R., *Sterilization of medical devices: A Review*. Journal of Biomaterials Applications, 3(3), pp. 454-523 (1988).

DOI: 10.1177/088532828800300303

113. The ST Bard Mesh is acidic, causing bacteriostasis (inhibition of the growth of bacteria without killing the bacteria), which results in the inability to properly validate sterilization.

114. The coating on the Defendants' ST Bard Mesh is cytotoxic, immunogenic, and not biocompatible, which causes or contributes to complications such as delayed wound healing, inflammation, foreign body response, rejection, infection, and other complications.

115. The ST coating is designed and intended to resorb in less than 30 days.

116. When the ST coating is disrupted, degrades, and/or resorbs, the "naked" polypropylene mesh and PGA is exposed to the adjoining tissue and viscera, and can become adhered to organs, and cause incarceration of organs, and fistula formation.

117. The ST Bard Mesh has a solid, flat, relatively smooth and continuous surface, which promotes tumor and cancer formation via the "Oppenheimer Effect." A phenomenon identified in the 1950s.

118. The solid, flat, relatively smooth and continuous surface of the ST Bard Mesh inhibits the body's ability to clear toxins.

119. These manufacturing and design defects associated with the ST Bard Mesh were directly and proximately related to the injuries suffered by Plaintiff.

120. Neither Plaintiff nor Plaintiff's implanting physician were adequately warned or informed by Defendants of the defective and dangerous nature of ST Bard Mesh. Moreover, neither Plaintiff nor Plaintiff's implanting physician were adequately warned or informed by Defendants of the risks associated with the ST Bard Mesh.

121. The ST Bard Mesh implanted in Plaintiff failed to reasonably perform as intended. The ST Bard Mesh caused serious injury and had to be surgically removed via invasive surgery, and necessitated additional invasive surgery to repair the hernia that the ST Bard Mesh was initially implanted to treat.

122. At the time the ST Bard Mesh that was implanted in Plaintiff's body, the product was defectively designed. As described above, there was an unreasonable risk that the ST Bard Mesh would not perform safely and effectively for the purposes for which it was intended, and Defendants failed to design against such dangers, and failed to provide adequate warnings and instructions concerning these risks.

123. Defendants expected and intended the ST Bard Mesh product to reach users such as Plaintiff in the condition in which the product was sold.

124. The implantation of ST Bard Mesh in Plaintiff's body was medically reasonable, and was a type of use that Defendants intended and foresaw when it designed, manufactured and sold the product.

125. The risks of the ST Bard Mesh significantly outweigh any benefits that Defendants contend could be associated with the product. The ST coating, which is not used in any other hernia mesh product sold in the United States, incites an intense inflammatory response, leading to encapsulation, deformation, scarification and contraction, migration, erosion and rejection. The impermeable ST coating leads to seroma formation, and provides a breeding ground for infection, and protects bacteria from being eliminated by the body's natural immune response. This ST coating also caused immunogenic response, and was known to be cytotoxic.

126. The coating of the ST Bard Mesh, which was marketed, promoted and intended as a barrier against adhesion to the bowel, was only temporary; it was expected and intended to

degrade over time inside the body. Thus, this coating prevented tissue ingrowth in the short term, and degraded in the long-term, eventually leaving the "naked" polypropylene mesh and PGA exposed to the internal viscera and tissues. Once exposed to the viscera, the polypropylene and PGA will inevitably adhere to the viscera, initiating a cascade of adverse consequences. Any purported beneficial purpose of the coating (to prevent adhesion to the bowel and internal viscera) was non-existent; the product provided no benefit while substantially increasing the risks to the patient.

127. The polypropylene mesh within the defective coating of the ST Mesh was in itself dangerous and defective, particularly when used in the manner intended by Defendants in the ST Bard Mesh. The particular polypropylene material used in the ST Bard Mesh was substandard, adulterated and non-medical grade, and was unreasonably subject to oxidative degradation within the body, further exacerbating the adverse reactions to the product once the ST coating degraded. When implanted adjacent to the bowel and other internal organs, as Defendants intended for ST Bard Mesh, polypropylene mesh is unreasonably susceptible to adhesion, bowel perforation or erosion, fistula formation and bowel strangulation or hernia incarceration, and other injuries.

128. The appropriate treatment for complications associated with ST Bard Mesh involves additional invasive surgery to remove the mesh from the body, thus eliminating any purported benefit that the mesh was intended to provide to the patient.

129. The ST Bard Mesh was designed and intended for intraperitoneal implantation, which required the product to be placed in contact with internal organs, which unnecessarily increased the risks of adhesion, erosion, fistula formation, and other injuries.

130. At the time the ST Bard Mesh was implanted in Plaintiff, there were safer feasible alternative designs for hernia mesh products, including but not limited to, a flat, non-coated, single-layer mesh placed away from the bowel.

131. The ST Bard Mesh product cost significantly more than competitive products because of its unique ST coating, even though the ST coating provided no benefit to consumers, and increased the risks to patients implanted with these devices.

132. The ST Bard Mesh has a solid, flat, relatively smooth and continuous surface. Medical devices which utilize this design greatly increase the risk of tumor and cancer formation:

A. In 1958, a study supported by a research grant from the National Cancer Institute titled The Latent Period in Carcinogenesis by Plastics in Rats and its Relation to the Presarcomatous Stage was published in the Journal of Cancer. **The presence of polymer in a sheet form appears to be of primary importance, as shown by the manifold increase in the percentage of tumors induced by this form, as opposed to textiles, sponges, powders, etc. This may act in some way as a block to the free interchange of tissue constituents, subjecting some cells to an altered environment and changing their pattern of growth. Whether the primary cause is lack of nutrients or oxygen, or the accumulation of products of metabolism, or even a freeing of the cell from some hormonal control, is not a present clear, but undoubtedly the cell is placed under conditions that are favorable to autonomous, unregulated growth. Plastics embedded subcutaneously in rodents in film or sheet form induce malignant tumors in significant numbers (up to 50%), but embedded in other forms, such as textiles, sponges, or powders, they induce tumors only rarely.**

Oppenheimer, B.S. et al, *The Latent Period in Carcinogenesis by Plastics in Rats and its Relations to the Presearcomatous Stage*. Journal of Cancer 1(11). 204 – 213 (1958).

133. The ST Bard Mesh implanted in Plaintiff failed to reasonably perform as intended, and had to be surgically removed necessitating further invasive surgery to repair the very issue that the product was intended to repair, and thus provided no benefit to him.

134. At the time the ST Bard Mesh that was implanted in Plaintiff's body, the warnings and instructions provided by Defendant for the ST Bard Mesh were inadequate and defective. As described above, there was an unreasonable risk that the product would not perform safely and effectively for the purposes for which it was intended, and Defendants failed to design and/or manufacture against such dangers, and failed to provide adequate warnings and instructions concerning these risks.

135. Defendants expected and intended the ST Bard Mesh product to reach users such as Plaintiff in the condition in which the product was sold.

136. Plaintiff and Plaintiff's physicians were unaware of the defects and dangers of ST Bard Mesh, and were unaware of the frequency, severity and duration of the risks associated with the ST Bard Mesh.

137. The Defendants' Instructions for Use provided with the ST Bard Mesh expressly understates and misstates the risks known to be associated specifically with the ST Bard Mesh by representing that the complications such as inflammation associated with the ST Bard Mesh as "possible complications." The ST Bard Mesh will always incite severe inflammation once implanted. The inflammation caused by the ST Bard Mesh is chronic in nature and systemic, not acute localized inflammation. No other surgical mesh sold in the United States has the dangerous and defective ST coating, which itself causes or increases the risks of numerous complications, including increased risk of seroma formation, immunologic response, increased risk for infection, and increased inflammatory reaction and foreign body response. Defendants provided no warning to physicians about the risks or increased risks specifically associated with the unique design of the ST Mesh.

138. The Defendants' Instructions for Use for the ST Mesh failed to adequately warn Plaintiff's physicians of numerous risks which Defendants knew or should have known were associated with the ST Mesh, including the risks of the product's immunologic response, pain, dehiscence, encapsulation, rejection, migration, scarification, contraction, adhesion to internal organs and viscera, erosion through adjacent tissue and viscera, bowel obstruction, or hernia incarceration or strangulation.

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

140. Defendants failed to adequately warn Plaintiff or Plaintiff's physicians that the surgical removal of the ST Bard Mesh in the event of complications would leave the hernia unrepaired, the resulting hernia would be much larger than the original, and would necessitate further, more complicated medical treatment to attempt to repair the same hernia that the failed ST Mesh was intended to treat.

141. Defendants represented to physicians, including Plaintiff's physician, that the ST coating would prevent or reduce adhesions, and expressly intended for the ST Mesh to be implanted in contact with the bowel and internal organs and marketed and promoted the product for said purpose. Defendants failed to warn physicians that the ST coating was only temporary and therefore at best would provide only a temporary adhesion barrier, and when the coating inevitably degraded, the exposed polypropylene and PGA would become adhered to the bowel or tissue.

142. Defendants failed to warn Plaintiff and Plaintiff's physicians that the ST Bard Mesh was considered a significant risk device by the FDA.

143. Defendants marketed and continue to market the ST Bard Mesh in brochures and online without disclosing or making evident that PGA is utilized in the ST Bard Mesh.

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

145. If Plaintiff and/or Plaintiff's physicians had been properly warned of the defects and dangers of ST Bard Mesh, and of the frequency, severity and duration of the risks associated with the ST Bard Mesh, Plaintiff would not have consented to allow the ST Bard Mesh to be implanted, and Plaintiff's physicians would not have implanted the ST Bard Mesh in Plaintiff.

146. Defendants had a duty to use reasonable care in designing, testing, inspecting, manufacturing, packaging, labeling, marketing, distributing, and preparing written instructions and warnings for ST Bard Mesh, but failed to do so.

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

148. Defendants knew or should have known that the MSDS for the polypropylene used to manufacturer its ST Mesh prohibited permanently implanting the polypropylene into the human body.

149. Defendants utilized non-medical grade polypropylene.

150. Defendants knew or should have known that polypropylene is not inert and would degrade, flake, chip, and disperse throughout the body once implanted.

151. Defendants knew or should have known that polypropylene incites a severe inflammatory response once implanted and continues to incite a severe inflammatory response indefinitely or until removed.

152. Defendants knew or should have known that every piece of polypropylene that flakes off and migrates throughout the body also incites its own chronic inflammatory response wherever it embeds.

153. Defendants knew or should have known that PGA induces an intense local inflammatory response following implantation.

154. Defendants knew or should have known that carboxymethylcellulose induces an intense local inflammatory response following implantation.

155. Defendants knew or should have known of the cytotoxic and immunogenic properties of the coating on the ST Mesh prior to introducing it into the stream of commerce.

156. At all relevant and material times, Defendants manufactured, marketed, sold, distributed and otherwise placed in to the stream of commerce ST Bard Mesh.

157. In advertising, marketing and otherwise promoting ST Bard Mesh to physicians, hospitals and other healthcare providers, Defendants expressly warranted that their ST Bard Mesh was safe for use and reasonably fit for their intended purposes. In advertising, marketing and otherwise promoting ST Bard Mesh, Defendants' intended that physicians, hospitals and other healthcare providers rely upon their representations regarding safety and fitness in an effort to induce them to implant Bard ST Mesh in their patients.

158. With respect to the Plaintiff, Defendants intended that ST Bard Mesh be implanted by Plaintiff's treating surgeon in a reasonable and foreseeable manner in which it was implanted and in accordance with the instructions for use and product specifications provided by Defendants. The Plaintiff was in privity with Defendants.

159. Defendants expressly warranted to physicians, hospitals, other healthcare providers and the general public including Plaintiffs that ST Bard Mesh was safe and fit for use by consumers, that it was of merchantable quality, that its risks, side effects and potential complications were minimal and comparable to other hernia mesh products, that it was adequately researched and tested, and that it was fit for its intended use. Plaintiff and Plaintiff's physicians and healthcare providers reasonably relied upon Defendants' express representations and warranties, and consequently, Plaintiff was implanted with Defendants' ST Bard Mesh.

160. The ST Bard Mesh was manufactured from polypropylene, polyglycolic acid fibers coated with a bioresorbable, chemically modified sodium hyalurnate, carboxymethylcellulose, and polyethylene glycol based hydrogel. The ST coating was represented by the Defendants to prevent or minimize adhesion and inflammation and to facilitate incorporation of the mesh into the body, but it did not. Instead, the ST coating caused an intense systemic inflammatory and chronic foreign body response, resulting in an adverse tissue reaction including damage to surrounding tissue in the form of sclerotic, granulomatous and/or fibrotic tissue and improper or delayed healing.

161. Defendant breached these express warranties because the ST Bard Mesh implanted in Plaintiff was unreasonably dangerous, defective, and not as Defendants had represented.

162. Defendants breached express representations and warranties made to the Plaintiff, as well as Plaintiffs physicians and healthcare providers, with respect to the ST Bard Mesh, including, but not limited to, the following particulars:

A. Defendants represented to Plaintiff and Plaintiff's physicians and healthcare provides through labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions among other ways that the Defendants' ST Bard Mesh was safe, meanwhile Defendants fraudulently withheld and concealed information about the substantial risks of serious injury associated with using ST Bard Mesh.

B. Defendants represented to Plaintiff and their physicians and healthcare providers that the Defendants' ST Bard Mesh was as safe and/or safer than other alternative procedures and devices on the market, meanwhile Defendants fraudulently concealed information that demonstrated that ST Bard Mesh was not safer than alternative therapies and products available on the market; and

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

163. Defendants' breach of their express warranties resulted in the implantation of an unreasonably dangerous and defective product into the Plaintiff, placing Plaintiff's health and safety in jeopardy

164. At the time of making such express warranties, Defendants knew or should have known that Defendants' ST Bard Mesh does not conform to the express warranties and

Defendants' acts were motivated by financial gain while the adverse consequences of Defendants' conduct was outrageous, fraudulent, oppressive, done with malice or gross negligence and evidenced reckless indifference to Plaintiff's rights, health and safety so as to warrant the imposition of punitive damages.

165. The wrongs done by defendants were aggravated by the kind of malice, fraud, and grossly negligent disregard for the rights of others, the public, and Plaintiff for which the law would allow, and which Plaintiff will seek at the appropriate time under governing law for the imposition of exemplary damages, in that Defendants' conduct, including the failure to comply with applicable Federal standards: was specifically intended to cause substantial injury to Plaintiff; or when viewed objectively from Defendants' standpoint at the time of the conduct, involved an extreme degree of risk, considering the probability and magnitude of the potential harm to others, and Defendants were actually, subjectively aware of the risk involved, but nevertheless proceeded with conscious indifference to the rights, safety, or welfare of others; or included a material representation that was false, with Defendants, knowing that it was false or with reckless disregard as to its truth and as a positive assertion, with the intent that the representation is acted on by Plaintiff.

166. Plaintiff relied on the representation and suffered injury as a proximate result of this reliance.

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

168. Defendants carelessly and negligently manufactured, designed, developed, tested, labeled, marketed and sold the Defendants' ST Bard Mesh to Plaintiff.

169. Defendants carelessly and negligently concealed the harmful effects of the Defendants' ST Bard Mesh from Plaintiff individually and/or Plaintiff's physician on multiple occasions and continue to do so to this day.

170. Defendants carelessly and negligently misrepresented the quality, safety and efficacy of the ST Bard Mesh to Plaintiff individually and/or Plaintiff's physician on multiple occasions and continue to do so to this day.

171. Plaintiff was directly impacted by Defendants' carelessness and negligence, in that Plaintiff has sustained and will continue to sustain emotional distress, severe physical injuries, economic losses, and other damages as a direct result of the decision to purchase the ST Bard Mesh sold and distributed by Defendants.

172. Defendants continued to carelessly and negligently misrepresent the quality, safety, efficacy, dangers and contraindications of the ST Bard Mesh to Plaintiff individually and/or Plaintiff's physician after Plaintiff sustained emotional distress, severe physical injuries, and economic loss.

173. Defendants continued to carelessly and negligently misrepresent the quality, safety, efficacy, dangers and contraindications of the ST Bard Mesh to Plaintiff individually and/or Plaintiff's physician knowing that doing so would cause the Plaintiff to suffer additional and continued emotional distress, severe physical injuries, and economic loss.

174. Defendants had a duty to accurately and truthfully represent to the medical and healthcare community, Plaintiff, and the public, that its ST Bard Mesh had not been adequately tested and found to be a safe and effective treatment. The representations made by Defendants were, in fact, false.

175. Defendants failed to exercise ordinary care in the representations concerning the Products while they were involved in their manufacture, sale, testing, quality assurance, quality control, and distribution in interstate commerce, because Defendants negligently misrepresented the ST Bard Mesh's high risk of unreasonable and dangerous adverse side effects.

176. Defendants breached their duty in representing that the Defendants' ST Bard Meshes have no serious side effects different from older generations of similar products and/or procedures to Plaintiff, Plaintiff's physicians, and the medical community.

177. As a foreseeable, direct, and proximate result of the negligent misrepresentation of Defendants, as set forth herein, Defendants knew, and had reason to know, that the ST Bard Mesh had been insufficiently tested, or had not been tested at all, and that they lacked adequate and accurate warnings, and that they created a high risk—and/or higher than acceptable risk, and/or higher than reported and represented risk—of adverse side effects, including, but not limited to, pain, graft rejection, graft migration, organ damage, complex seroma, fistula, sinus tract formation, delayed wound closure, infection, sepsis, and death.

FACTS COMMON TO ALL DEFENDANTS

178. The Mesh Products were designed, manufactured and distributed by Defendants who own the patent on their respective devices that were inserted into Plaintiff's body.

179. Defendants designed, manufactured and distributed the Mesh Products that were inserted into Plaintiff's body.

180. Defendants, through its agents, servants, and employees, participated in the manufacture and delivery of the Mesh Products that were inserted into Plaintiff's body.

181. At all relevant times, Defendants held themselves out to the public as being knowledgeable, skilled and experienced in the design, manufacture, production, assembly,

distribution and sale of medical devices used for hernia repair, including the polypropylene Mesh Products at issue.

182. Defendants had the requisite knowledge, skill and expertise to know that implanted devices, such as polypropylene mesh, must be chemically inert, non-carcinogenic, and able to withstand mechanical stress. Implanted devices, such as polypropylene mesh, must also not be physically modified by tissue fluids, not allow tissue infiltration, not incite an inflammatory or foreign body cell reaction, and not produce allergic reactions.

183. Polypropylene is not biologically inert in the human body, as it is known to expand as well as shrink, and can cause serious injury to patients, significantly impacting their quality of life.

184. Moreover, it is well known within the scientific and medical community that the polypropylene used for surgical treatment begins to degrade after implantation in the human body, which can lead to infection and irritation, and result in serious pain as the body tries to rid itself of the foreign material.

185. Scientific literature regarding the safety and effectiveness of these devices suggests that polypropylene mesh repair does not improve symptomatic results or quality of life over traditional non-mesh repair.

186. Defendants were fully aware of the dangers defective products they were placing into the stream of commerce posed to their customers, specifically the Mesh Products polypropylene mesh, which has been shown to pose an unreasonable risk of human body inflammation, granuloma formation, foreign body reaction, excessive scar tissue formation and long-term complications.

187. Despite the abundance of scientific and medical information available relating to the dangerous properties and serious risks of the Mesh Products, Defendants deliberately ignored these dangers and aggressively promoted the Mesh Products polypropylene mesh to healthcare providers and/or directly to consumers.

188. Defendants expressly warranted that the Mesh Products polypropylene mesh were safe and fit for use by consumers, that they were of merchantable quality, and they were adequately tested and fit for its intended use, even though they were not safe and had numerous side effects, many of which Defendants did not accurately warn about.

189. The Mesh Products, with its unusual design, were nothing more than a marketing ploy to capture the revenue stream from the lucrative hernia mesh market.

190. Defendants designed, developed, manufactured, assembled, distributed, tested, marketed, promoted and/or sold to the public, including Plaintiff, for profit, the at issue Mesh Products polypropylene mesh in a defective condition such that the Mesh Products polypropylene mesh failed and had to be surgically removed after numerous complications arose.

191. The Mesh Products that were implanted in Plaintiff were designed, manufactured, sold and distributed by Defendants to be used by surgeons for hernia repair surgeries and were further represented by Defendants to be an appropriate, cost-effective and suitable products for such purpose.

192. The polypropylene mesh used in the manufacture of the Mesh Products, which were implanted into Plaintiff is unreasonably dangerous, defective, and negligently designed in the following ways:

(a) The weave of the mesh produces very small interstices which allow bacteria to enter and hide from the host defenses designed to eliminate them. The bacteria

can secrete an encasing slime (biofilm) which further serves to protect them from destruction by white blood cells and macrophages

(b) Polypropylene is impure: there is no such thing as pure polypropylene (PP). PP contains about 15 additional compounds which are leached from the PP and are toxic to tissue which enhances the inflammatory reaction and the intensity of fibrosis.

(c) Mesh was shown to be not inert in 2003 with flaking and fissuring demonstrated by scanning electron microscopy which leads to degradation and release of toxic compounds. This enhances the inflammatory and fibrotic reactions.

(d) With loss of PP due to degradation, the surface area is greatly increased, thus providing greater areas for bacterial adherence and more elution of toxic compounds from the PP, and also the freed toxic PP itself, all of which increases the inflammatory reaction and intensity of fibrosis.

(e) By 1998 polypropylene mesh was known to shrink 30-50%.

(f) Heat begins the process of degradation.

(g) Predominate infection/inflammation was noted at least in 2007 in explanted samples.

(h) Allergic reactions occur with polypropylene after implantation.

(i) Polypropylene is subject to oxidation by acids produced during the inflammatory reaction which caused degradation and loss of compliance.

(j) 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 porosity of the pores is decreased.

(k) Observation of mesh under the scanning electron microscope reveals that very small interstices exist between the mesh fibrils, which are too small for a macrophage to enter to destroy incubating bacteria. Some bacteria are capable of degrading polypropylene.

(l) Polypropylene is known to depolymerize, cross-link, undergo oxidative degradation by free radicals, and stress crack after implantation in the human body.

(m) Polypropylene migrates to lymph nodes when there is a foreign body giant cell reaction.

(n) The large surface area promotes wicking of fluids and bacteria and is a "bacterial super highway" which provides a safe haven for bacteria.

(o) Common complications associated with PP include restriction of abdominal wall mobility and local wound disturbances. Often failures of PP include persistent and active inflammatory processes, irregular or low formation of scar tissue and unsatisfying integration of the mesh in the regenerative tissue area.

(p) Klosterhalfen published a series of 623 explanted mesh samples removed for pain, infection and recurrence. There are also reports of mesh migration and erosion into the sigmoid colon. Reduced mobility of the abdominal wall has also been found. Moreover, the rate of chronic pain after mesh hernia repair ranges from 4-40%. Thus, Defendants should have been aware of these issues with polypropylene.

193. A malfunction of this device can lead to bowel perforations and/or chronic intestinal fistulae (abdominal connections or passageways between the intestines and other organs), as well as other chronic and debilitating conditions

194. Upon information and belief Defendants failed to comply with the FDA application and reporting requirements.

195. Upon information and belief Defendants were aware of the high degree of complication and failure rate associated with the Mesh Products.

196. Upon information and belief Defendants were aware of the defects in the manufacture and design of the Mesh Products.

197. Upon information and belief, Defendants manipulated, altered, skewed, slanted, misrepresented, and/or falsified pre-clinical and/or clinical studies to bolster the perceived performance of the Mesh Products.

198. Upon information and belief, Defendants paid doctors, surgeons, physicians, and/or clinicians to promote the Mesh Products but did not readily disclose this information.

199. Defendants failed to properly investigate and disclose adverse event reports to the FDA and other regulatory agencies worldwide.

200. Defendants failed to implement adequate procedures and systems to report, track, and evaluate complaints and adverse events.

201. Defendants marketed the Mesh Products to the medical community and to patients as safe, effective, reliable, medical devices for the treatment of hernia repair, and as safer and more effective as compared to the traditional products and procedures for treatment, and other competing mesh products. Defendants did not undergo pre-market approval for the Mesh Products and are, therefore, prohibited by the FDA from asserting superiority claims.

202. Defendants failed to perform or rely on proper and adequate testing and research in order to determine and evaluate the risks and benefits of the Mesh Products.

203. Defendants failed to design and establish a safe, effective procedure for removal of the Mesh Products; therefore, in the event of a failure, injury, or complications it is difficult to safely remove the Mesh Products.

204. Defendants provided incomplete, insufficient, and misleading information to physicians in order to increase the number of physicians using the Mesh Products for the purpose of increasing their sales. By so doing, Defendants caused the dissemination of inadequate and misleading information to patients, including Plaintiff.

205. The Mesh Products were utilized and implanted in a manner foreseeable to Defendants.

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

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

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

ESTOPPEL AND TOLLING OF STATUTE OF LIMITATIONS

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

210. Given Defendants' affirmative actions of concealment by failing to disclose this known but non-public information about the defects—information over which Defendants had

exclusive control—and because Plaintiff could not reasonably have known the Mesh Products was defective, Defendants are estopped from relying on any statutes of limitations that might otherwise be applicable to the claims asserted in this Complaint.

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

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

CAUSES OF ACTION

COUNT I: STRICT LIABILITY – MANUFACTURING DEFECT

213. Plaintiff repeats, reiterates, and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

214. Defendants expected and intended the Mesh Products to reach users such as Plaintiff in the condition in which the products were sold.

215. The implantation of the Mesh Products in Plaintiff's body was medically reasonable and was a type of use that Defendants intended and foresaw when they designed, manufactured

and sold the products.

216. When the Mesh Products was implanted in Plaintiff's body it was defectively manufactured.

217. Defendants' poor quality control and general non-compliance resulted in the non-conformance of the Mesh Products implanted in Plaintiff. The implanted product did not conform to Defendants' intended manufacturing and design specifications.

218. Upon information and belief, Defendants utilized substandard and adulterated polypropylene and raw materials used to make the Mesh Products, which deviated from Defendants' material and supply specifications.

219. As a direct and proximate result of the defective manufacture of the Mesh Products, Plaintiff suffered injuries and damages as summarized in this Complaint.

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

221. Plaintiff has also incurred substantial medical bills and has suffered loss of other monies due to the Mesh Products that were implanted.

COUNT II: STRICT LIABILITY – DESIGN DEFECT

222. Plaintiff repeats, reiterates, and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

223. The Mesh Products were defectively designed and/or manufactured and were not reasonably safe for their intended use in hernia repair; and the risks of the design outweighed any potential benefits associated with them. As a result of the defective design and/or manufacture of the Mesh Products, there was an unreasonable risk of severe adverse reactions to the meshes or

their components including: chronic infections; chronic pain; recurrence of hernia; foreign body response; rejection; infection; scarification; improper wound healing; excessive and chronic inflammation; allergic reaction; adhesions to internal organs; erosion; abscess; fistula formation; granulomatous response; seroma formation; nerve damage; tumor formation, cancer, tissue damage and/or death; and other complications

224. When affixed to the body's tissue, the impermeable Mesh Products prevent fluid escape, which leads to seroma formation, and which in turn can cause infection or abscess formation and other complications.

225. The Mesh Products are defective in its design in part due to a material mismatch. This material mismatch results in the Mesh Products curling after implantation.

226. The multi-layer design of the Mesh Products results in ineffective sterilization more often than single layer mesh.

227. The Mesh Products are cytotoxic, immunogenic, and not biocompatible, which causes or contributes to complications such as delayed wound healing, inflammation, foreign body response, rejection, infection, and other complications.

228. These manufacturing and design defects associated with the product were directly and proximately related to the injuries Plaintiff suffered.

229. Neither Plaintiff nor Plaintiff's implanting physician were adequately warned or informed by Defendants of the defective and dangerous nature of the products. Moreover, neither Plaintiff nor Plaintiff's implanting physician were adequately warned or informed by Defendants of the risks associated with the Mesh Products.

230. The products implanted in Plaintiff failed to reasonably perform as intended. They caused serious injury and had to be removed via invasive surgery and necessitated additional

invasive surgeries to repair the hernia that the products were initially implanted to treat.

231. When the Mesh Products were implanted in Plaintiff's body, they were defectively designed. As described above, there was an unreasonable risk that the products would not perform safely and effectively for the purposes for which they were intended. Defendants failed to design against such dangers and failed to provide adequate warnings and instructions concerning the products' risks.

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

233. The implantation of the Mesh Products in Plaintiff's body was medically reasonable and was a type of use that Defendants intended and foresaw when they designed, manufactured and sold the products.

234. The risks of the products significantly outweigh any benefits that Defendants contend could be associated with it. Mesh Products incite an intense inflammatory response, leading to encapsulation, deformation, scarification and contraction, migration, erosion and rejection.

235. The polypropylene mesh was in itself dangerous and defective, particularly when used in the manner intended by Defendants. The polypropylene material used in the Mesh Products was substandard, adulterated and non-medical grade, and was unreasonably subject to oxidative degradation within the body, further exacerbating the adverse reactions caused by the product. The Mesh Products polypropylene mesh is unreasonably susceptible to adhesion, perforation or erosion, fistula formation and bowel strangulation or hernia incarceration, and other injuries.

236. The appropriate treatment for complications associated with the Mesh Products involves additional invasive surgery in an attempt to remove the mesh from the body, thus

eliminating any purported benefit that the products were intended to provide to the patient.

237. When the Mesh Products were implanted in Plaintiff, there were safer feasible alternative designs for hernia mesh products available.

238. The Mesh Products provides no benefit to consumers over other mesh types and increased the risks to patients implanted with these devices.

239. The Mesh Products implanted in Plaintiff failed to reasonably perform as intended and had to be surgically removed. Thus, further invasive surgery was necessary to repair the very problem that the products were intended to repair, providing only harm and no benefit to him.

240. As a direct and proximate result of the defective and unreasonably dangerous condition of the Mesh Products, Plaintiff suffered injuries and damages.

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

242. Plaintiff has also incurred substantial medical bills and has suffered loss of other monies due to the defective Mesh Products that were implanted.

COUNT III: STRICT LIABILITY – FAILURE TO WARN

243. Plaintiff repeats, reiterates, and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

244. When the Mesh Products were implanted in Plaintiff's body, the warnings and instructions provided by Defendants for the products were inadequate and defective. There was an unreasonable risk that the product would not perform safely and effectively for the purposes for which they were intended. Defendants failed to design and/or manufacture against such dangers and failed to provide adequate warnings and instructions concerning these risks.

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

246. Plaintiff and/or Plaintiff's physicians were unaware of the defects and dangers of the Mesh Products, and were unaware of the frequency, severity and duration of the risks associated with the products.

247. Defendants' Instructions for Use provided with the products expressly understate and misstate the risks known to be associated specifically with it. Defendants provided no warning to physicians about the risks or increased risks specifically associated with the unique design of the Mesh Products.

248. Defendants' Instructions for Use failed to adequately warn Plaintiff's physicians of numerous risks, which Defendants knew or should have known were associated with the Mesh Products, including the following: immunologic response, infection, pain, dehiscence, encapsulation, rejection, migration, scarification, contraction, erosion through adjacent tissue and viscera, adhesions, bowel obstruction, and tumor or cancer formation.

249. Defendants' Instructions for Use also failed to instruct physicians how much larger than the hernia defect the products needed to be for an effective repair.

250. As well, the Instructions for Use failed to disclose the extent the Mesh Products would shrink, or that they would even shrink at all.

251. Defendants failed to adequately warn Plaintiff and/or Plaintiff's physicians about the need for invasive surgical intervention in the event of complications or inform them of the treatment for such complications when they occurred.

252. Defendants failed to adequately warn Plaintiff and/or Plaintiff's physicians that the surgical removal of the Mesh Products, in the event of complications, would leave the hernia

unrepaired and the resulting hernia would be much larger than the original. Thus, more complicated medical treatment would be needed to attempt to repair the same hernia that the failed products were intended to treat.

253. Defendants failed to adequately warn Plaintiff and/or Plaintiff's physicians that in the event of complications, the products are more difficult to fully remove than other feasible hernia meshes that have been available at all material times.

254. Defendants failed to warn Plaintiff and/or Plaintiff's physicians that as a result of being implanted with the Mesh Products, he would be at a higher risk of infection for the remainder of his life.

255. With respect to the complications listed in Defendants' warnings, they provided no information or warning regarding the frequency, severity and duration of those complications, even though the complications associated with the Mesh Products were more frequent, more severe and longer lasting than those with safer feasible alternative hernia repair treatments.

256. If Plaintiff Plaintiff and/or Plaintiff's physicians had been properly warned of the defects and dangers of the Mesh Products, and of the frequency, severity and duration of the risks associated with the products, he would not have consented to allow the products to be implanted, and his physicians would not have implanted them.

257. As a direct and proximate result of the inadequate and defective warnings and instructions, Plaintiff suffered injuries and damages as summarized in this Complaint.

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

259. Plaintiff has also incurred substantial medical bills and have suffered loss of other monies due to the defective Mesh Products that were implanted.

COUNT IV: NEGLIGENCE

260. Plaintiff repeats, reiterates, and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

261. Defendants had a duty to use reasonable care in designing, testing, inspecting, manufacturing, packaging, labeling, marketing, distributing, and preparing written instructions and warnings for the Mesh Products, but failed to do so.

262. The negligence of the Defendants, their agents, servants, and/or employees, included but was not limited to the following acts and/or omissions:

(a) Manufacturing, producing, promoting, creating, and/or designing the Mesh Products without thoroughly testing them;

(b) Manufacturing, producing, promoting, creating, and/or designing the Mesh Products without adequately testing them;

(c) Not conducting sufficient testing programs to determine whether or not the Mesh Products were safe for use and/or implantation; in that Defendants herein knew or should have known that the Mesh Products were unsafe and unfit for use and/or implantation by reason of the dangers to its users;

(d) Selling the Mesh Products without making proper and sufficient tests to determine the dangers to its users;

(e) Negligently failing to adequately and correctly warn the Plaintiff, the public, and/or the medical and healthcare profession, and the FDA of the dangers of the Mesh Products;

(f) Negligently advertising and recommending the use of the Mesh Products without sufficient knowledge as to their dangerous and harmful properties;

(g) Negligently representing that the Mesh Products were safe for use for their intended purpose, when, in fact, they were unsafe and harmful;

(h) Negligently representing that the Mesh Products had equivalent safety and efficacy as other types of mesh products used in similar hernia repairs;

(i) Negligently designing the Mesh Products in a manner which were dangerous to their users;

(j) Negligently manufacturing the Mesh Products in a manner which were dangerous to their users;

(k) Negligently assembling the Mesh Products in a manner which were dangerous to their users;

(l) Concealing information from Plaintiff and/or implanting surgeons in knowing that the Mesh Products were unsafe and dangerous;

(m) Improperly concealing and/or misrepresenting information from Plaintiff and/or healthcare professionals, concerning the severity of risks and dangers of the Mesh Products compared to other hernia mesh devices used in similar hernia repairs.

263. Defendants knew, or in the exercise of reasonable care should have known, that the products were defectively and unreasonably designed and/or manufactured and were unreasonably dangerous and likely to injure patients in whom they were implanted. Defendants knew or should have known that Plaintiff and/or Plaintiff's physicians were unaware of the dangers and defects inherent in the products.

264. Defendants knew or should have known that the MSDS for the polypropylene used to manufacture the Mesh Products prohibited permanently implanting the polypropylene into the human body.

265. Defendants utilized non-medical grade polypropylene.

266. Defendants knew or should have known that the polypropylene component is not inert and would degrade, flake, chip, and disperse throughout the body once implanted.

267. Defendants knew or should have known that polypropylene incites a severe inflammatory response once implanted and continues to incite a severe inflammatory response indefinitely or until removed.

268. Defendants knew or should have known that every piece of polypropylene that flakes off and migrates throughout the body also incites its own chronic inflammatory response wherever it embeds.

269. Defendants knew or should have known that all subsequent operations carry a greater risk of infection after the patient has been implanted with the Mesh Products.

270. As a direct and proximate result of Defendants' negligence in designing, testing, inspecting, manufacturing, packaging, labeling, marketing, distributing, and preparing written instructions and warnings for the Mesh Products, Plaintiff suffered injuries and damages as summarized in this Complaint.

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

272. Plaintiff has also incurred substantial medical bills and has suffered loss of other monies due to the defective Mesh Products that were implanted.

COUNT V: BREACH OF IMPLIED WARRANTY

273. Plaintiff repeats, reiterates, and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

274. At all material times, Defendants manufactured, distributed, advertised, promoted, and sold their Mesh Products.

275. At all material times, Defendants intended for their products to be implanted for the purposes and in the manner that Plaintiff and/or Plaintiff's implanting physician in fact used them; and Defendants impliedly warranted that the products and their component parts were of merchantable quality, safe and fit for such use, and adequately tested.

276. Defendants were aware that consumers, including Plaintiff and/or Plaintiff's physician, would implant their products as directed by the Instructions for Use. Therefore, Plaintiff was a foreseeable user of Defendants' Mesh Products.

277. Defendants' Mesh Products were expected to reach, and did in fact reach consumers, including Plaintiff and/or Plaintiff's physician, without substantial change in the condition in which they were manufactured and sold by Defendants.

278. Defendants breached various implied warranties with respect to the Mesh Products, including the following:

(a) Defendants represented to Plaintiff and/or Plaintiff's physician and healthcare providers through labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that their products were safe. But at the same time, they fraudulently withheld and concealed information about the substantial risks of serious injury associated with using the products;

(b) Defendants represented to Plaintiff and/or Plaintiff's physician and healthcare providers that their products were safe and/or safer than other alternative procedures and devices. But at the same time, they fraudulently

concealed information demonstrating that the products were not safer than alternatives available on the market; and

(c) Defendants represented to Plaintiff and/or Plaintiff's physician and healthcare providers that their products were more efficacious than alternative procedures and/or devices. But at the same time, they fraudulently concealed information regarding the true efficacy of the Mesh Products.

279. In reliance upon Defendants' implied warranties, Plaintiff individually, and/or by and through his physician, used the Mesh Products as prescribed, and in the foreseeable manner normally intended, recommended, promoted, and marketed by Defendants.

280. Defendants breached their implied warranties to Plaintiff in that their products were not of merchantable quality, nor were they safe and fit for their intended use or adequately tested.

281. As a direct and proximate result of Defendants' breaches of the aforementioned implied warranties, Plaintiff was caused to suffer severe personal injuries, pain and suffering, severe emotional distress, financial or economic loss, including obligations for medical services and expenses, impairment of personal relationships, and other damages.

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

283. Plaintiff has also incurred substantial medical bills and has suffered loss of other monies due to the defective Mesh Products that were implanted.

COUNT VI: BREACH OF EXPRESS WARRANTY

284. Plaintiff repeats, reiterates, and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

285. At all relevant and material times, Defendants manufactured, marketed, sold, distributed and otherwise placed in to the stream of commerce the Mesh Products.

286. In advertising, marketing and otherwise promoting Mesh Products to physicians, hospitals and other healthcare providers, Defendants expressly warranted that their Mesh Products were safe for use and reasonably fit for their intended purposes. In advertising, marketing and otherwise promoting Mesh Products, Defendants' intended that physicians, hospitals and other healthcare providers rely upon their representations regarding safety and fitness in an effort to induce them to implant Mesh Products in their patients.

287. With respect to the Plaintiff, Defendants intended that Mesh Products be implanted by his treating surgeon in a reasonable and foreseeable manner in which they were implanted and in accordance with the instructions for use and product specifications provided by Defendants. The Plaintiff was in privity with Defendants.

288. Defendants expressly warranted to physicians, hospitals, other healthcare providers and the general public including Plaintiff that Mesh Products were safe and fit for use by consumers, that they were of merchantable quality, that its risks, side effects and potential complications were minimal and comparable to other hernia mesh products, that they was adequately researched and tested, and that they were fit for their intended use. Plaintiff and his physicians and healthcare providers reasonably relied upon Defendants' express representations and warranties, and consequently, Plaintiff was implanted with Defendants' Mesh Products.

289. The Mesh Products were manufactured from polypropylene, ePTFE, and PDO. The ePTFE was represented by the Defendants to decrease complications, but it did not. Instead, the ePTFE harbors and protects bacteria, resulting in a severe, chronic infection, which can take years to manifest.

290. Defendant breached these express warranties because the Mesh Products implanted in Plaintiff was unreasonably dangerous, defective, and not as Defendants had represented.

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

A. Defendants represented to Plaintiff and his physicians and healthcare provides through labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions among other ways that the Defendants' Mesh Products were safe, meanwhile Defendants fraudulently withheld and concealed information about the substantial risks of serious injury associated with using the Mesh Products.

B. Defendants represented to Plaintiff and his physicians and healthcare providers that the Defendants' Mesh Products were as safe and/or safer than other alternative procedures and devices on the market, meanwhile Defendants fraudulently concealed information that demonstrated that the Mesh Products were not safer than alternative therapies and products available on the market; and

C. Defendants represented to Plaintiff and his physicians and healthcare providers that the Defendants' Mesh Products were more efficacious than other alternative procedures, therapies and/or devices, meanwhile Defendants fraudulently concealed information, regarding the true efficacy of the Mesh Products.

292. Defendants' breach of their express warranties resulted in the implantation of unreasonably dangerous and defective products into the Plaintiff, placing his health and safety in jeopardy.

293. At the time of making such express warranties, Defendants knew or should have known that Defendants' Mesh Products do not conform to the express warranties and Defendants' acts were motivated by financial gain while the adverse consequences of Defendants' conduct was outrageous, fraudulent, oppressive, done with malice or gross negligence and evidenced reckless indifference to Plaintiff's rights, health and safety so as to warrant the imposition of punitive damages.

294. As a direct and proximate result of Defendants' breaches of the aforementioned express warranties, Plaintiff suffered injuries and damages as summarized in this Complaint. Plaintiff has suffered and will continue to suffer physical pain and suffering, as well as mental anguish and emotional distress. Plaintiff has also incurred substantial medical bills and has suffered loss of other monies due to the defective Mesh Products that were implanted.

COUNT VII: GROSS NEGLIGENCE

295. Plaintiff repeats, reiterates, and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

296. Defendants' wrongs were aggravated by the kind of malice, fraud, and grossly negligent disregard for the rights of others, the public, and Plaintiff, for which the law would allow, and for which Plaintiff will seek at the appropriate time, the imposition of exemplary damages. That is because Defendants' conduct, including the failure to comply with applicable federal standards was specifically intended to cause substantial injury to Plaintiff. Their conduct, when

viewed objectively from Defendants' standpoint at the time of the conduct, involved an extreme degree of risk, considering the probability and magnitude of the potential harm to others; and Defendants were actually, subjectively aware of the risk involved but nevertheless proceeded with conscious indifference to the rights, safety, or welfare of others; or included Defendants' false material representations, with their knowledge that it was false or with reckless disregard as to its truth and as a positive assertion, with the intent that Plaintiff would act upon their representation.

297. Plaintiff relied on the representation and suffered injury as a proximate result of this reliance.

298. Plaintiff therefore will seek to assert claims for exemplary damages at the appropriate time, in an amount within the jurisdictional limits of the Court.

299. Plaintiff also alleges that Defendants' acts and omissions, whether taken singularly or in combination with others, constitute gross negligence, proximately causing their injuries. In that regard, Plaintiff 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.

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

301. Plaintiff has also incurred substantial medical bills and has suffered loss of other monies due to the defective Mesh Products that were implanted.

COUNT VIII: NEGLIGENT INFLICTION OF EMOTIONAL DISTRESS

302. Plaintiff repeats, reiterates, and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

303. Defendants carelessly and negligently manufactured, designed, developed, tested,

labeled, marketed and sold the Mesh Products to Plaintiff.

304. Defendants carelessly and negligently concealed the harmful effects of the products from Plaintiff and/or Plaintiff's physician on multiple occasions and continue to do so to this day.

305. Defendants carelessly and negligently misrepresented the quality, safety and efficacy of the Mesh Products to Plaintiff and/or Plaintiff's physician on multiple occasions and continue to do so to this day.

306. Plaintiff were directly impacted by Defendants' carelessness and negligence, in that he has sustained, and will continue to sustain, emotional distress, severe physical injuries, economic losses, and other damages as a direct result of the decision to purchase the Mesh Products.

307. Defendants continued to carelessly and negligently misrepresent the quality, safety, efficacy, dangers and contraindications of the Mesh Products to Plaintiff and/or Plaintiff's physician, after he sustained emotional distress, severe physical injuries, and economic loss.

308. Defendants continued to carelessly and negligently misrepresent the quality, safety, efficacy, dangers and contraindications of the products to Plaintiff and/or Plaintiff's physician, knowing that doing so would cause him to suffer additional and continued emotional distress, severe physical injuries, and economic loss.

309. As a proximate result of Defendants' conduct, Plaintiff have been injured, sustained severe and permanent pain, suffering, anxiety, depression, disability, impairment, loss of enjoyment of life, loss of care, comfort, and economic damages.

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

311. Plaintiff has also incurred substantial medical bills and has suffered loss of other

monies due to the defective Mesh Products that were implanted.

COUNT IX: FRAUDULENT CONCEALMENT

312. Plaintiff repeats, reiterates, and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

313. At all material times Defendants knew or should have known that the Mesh Products caused large numbers of complications. Moreover, they knew or should have known that the surgical technique and training of implanting physicians was not the cause of the adverse events associated with these devices; the safety and efficacy of the Mesh Products had not been proven with respect to, among other things, the products, their components, their performance, and their method of insertion; and that the products were not safe and effective. Defendants continued to represent that it was safe and effective.

314. Although Defendants knew or should have known about the lack of safety and efficacy of the Mesh Products, they failed to disclose this information to Plaintiff, and/or the treating physicians, and/or the public at large.

315. At all material times, Defendants had the duty and obligation to disclose to Plaintiff and/or Plaintiff's physicians the true facts concerning the Mesh Products, i.e., their dangerous and defective nature, their lack of efficacy for their purported use and lack of safety in normal use, and their likelihood to cause serious consequences to users, including permanent and debilitating injuries. Defendants concealed these material facts before Plaintiff was implanted with the Mesh Products.

316. Defendants were under a duty to Plaintiff to disclose and warn them of the defective

nature of the products because:

(a) Defendants were in a superior position to know the products' true quality, safety, and efficacy;

(b) Defendants knowingly made false claims about the products' safety and quality in documents and marketing materials; and

(c) Defendants fraudulently and affirmatively concealed the defective nature of the products from Plaintiff.

317. The facts Defendants concealed and/or did not disclose to Plaintiff were material facts that a reasonable person would have considered important in deciding whether to purchase and/or use the Mesh Products.

318. At all material times, Defendants willfully, intentionally, and maliciously concealed facts from Plaintiff and/or Plaintiff's physician, with the intent to defraud.

319. Defendants intentionally concealed and/or failed to disclose the true defective nature of the Mesh Products so that Plaintiff would request and purchase the product; and his healthcare providers would dispense, prescribe, and recommend the product. Plaintiff justifiably acted or relied upon the concealed and/or non-disclosed facts to their detriment.

320. At all material times, neither Plaintiff and/or Plaintiff's physician were aware of the facts.

321. Had they been so aware, they would not have reasonably relied upon the representations of safety and efficacy and would not have utilized the Mesh Products. Defendants' failure to disclose this information was a substantial factor in Plaintiff's physician's selection of the Mesh Products. The failure to disclose also resulted in the provision of incorrect and incomplete information to Plaintiff as a patient.

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

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

324. Plaintiff has also incurred substantial medical bills and has suffered loss of other monies due to the defective Mesh Products that were implanted.

COUNT X: NEGLIGENT MISREPRESENTATION

325. Plaintiff repeats, reiterates, and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

326. Defendants had a duty to accurately and truthfully represent to the medical and healthcare community, Plaintiff and/or the public, that the Mesh Products had not been adequately tested and found to be a safe and effective treatment. Defendants' representations were in fact false.

327. Defendants failed to exercise ordinary care in their representations concerning the Mesh Products while involved in the manufacture, sale, testing, quality assurance, quality control, and distribution in interstate commerce of the products, because they negligently misrepresented the products' risk of unreasonable and dangerous adverse side effects.

328. Defendants breached their duty by representing to Plaintiff and/or Plaintiff's physician, and/or the medical community that the Mesh Products have no serious side effects different from older generations of similar products or procedures.

329. As a foreseeable, direct, and proximate result of Defendants' negligent misrepresentations, they knew, or had reason to know, that the Mesh Products had been insufficiently tested, or had not been tested at all; and that the products lacked adequate and

accurate warnings, and created a high risk—and/or higher than acceptable or reported and represented risk—of adverse side effects, including pain, graft rejection, graft migration, organ damage, complex seroma, fistula, sinus tract formation, dense adhesions, delayed wound closure, infection, sepsis, and death.

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

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

332. Plaintiff has also incurred substantial medical bills and has suffered loss of other monies due to the defective Mesh Products that were implanted.

PUNITIVE DAMAGES ALLEGATIONS

333. Plaintiff repeats, reiterates, and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

334. Defendants failed to adequately test and study the Mesh Products to determine and ensure that the products were safe and effective prior to releasing them for sale for permanent human implantation; and Defendants continued to manufacture and sell the products after obtaining knowledge and information that they was defective and unreasonably unsafe.

335. Defendants developed, designed and sold the products, and continue to do so, because they had a significantly higher profit margin than safer hernia repair products. Defendants were aware of the probable consequences of implantation of the dangerous and defective Mesh Products, including the risk of failure and serious injury, such as that suffered by Plaintiff.

336. At all material times, Defendants knew or should have known that the Mesh Products were inherently more dangerous with respect to the risk of foreign body response, allergic reaction, rejection, infection, failure, erosion, pain and suffering, organ perforation, dense adhesions, tumor or cancer formation, loss of life's enjoyment, remedial surgeries and treatments to attempt to cure the conditions related to use of the product, as well as the other severe and personal injuries that are permanent and lasting.

337. Defendants' misrepresentations include knowingly withholding material information from the medical community and/or the public, including Plaintiff, concerning the safety and efficacy of the Mesh Products, depriving Plaintiff and/or Plaintiff's implanting physicians of vitally necessary information with which to make a fully informed decision about whether to use the products.

338. At all material times, Defendants knew and recklessly and/or intentionally disregarded the fact that the Mesh Products can cause debilitating and potentially life-threatening side effects with greater frequency than safer alternative methods, products, procedures, and/or treatment.

339. At all material times, Defendants knew and recklessly and/or intentionally disregarded the fact that the Mesh Products can cause debilitating and potentially life-threatening side effects with greater frequency than safer alternative products and/or methods of treatment, and recklessly failed to advise the medical community and/or the general public, including Plaintiff, of those facts.

340. At all material times, Defendants intentionally misstated and misrepresented data; and continue to misrepresent data so as to minimize the perceived risk of injuries and the rate of complications caused by the Mesh Products.

341. Notwithstanding the foregoing and the growing body of knowledge and information regarding the true defective nature of the Mesh Products, and its increased risk of side effects and serious complications, Defendants continue to aggressively market the products to the medical community and/or to consumers without disclosing the true risk of such complications.

342. When Plaintiff was implanted with the Mesh Products, and since then, Defendants have known the products were defective and unreasonably dangerous. But they continued to manufacture, produce, assemble, market, distribute, and sell the products so as to maximize sales and profits at the expense of the health and safety of the public in a conscious, reckless and/or intentional disregard of the likely and foreseeable harm caused by the Mesh Products to members of the public, including Plaintiff.

343. At all material times, Defendants have concealed and/or failed to disclose to the public the serious risks and the potential complications associated with the Mesh Products, in order to ensure continued and increased sales and profits, to the detriment of the public, including Plaintiff.

344. Defendants' conduct, acts and omissions are of such character and nature so as to entitle Plaintiff to an award of punitive damages in accordance with applicable law. Defendants' conduct shows willful misconduct, malice, fraud, wantonness, oppression, or that entire want of care raising the presumption of conscious indifference to consequences, thereby justifying an award of punitive damages.

WHEREFORE, Plaintiff demands judgment against Defendants, individually, jointly, and severally, and in the alternative requests compensatory damages, punitive damages or enhanced compensatory damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

PRAYER FOR RELIEF

Plaintiff demands judgment against Defendants, individually, jointly and severally, and pray for the following relief in accordance with applicable law and equity:

i. Compensatory damages for past, present, and future damages, including but not limited to, pain and suffering for severe and permanent personal injuries sustained by Plaintiff, permanent impairment, mental pain and suffering, loss of enjoyment of life, health and medical care costs, economic damages, together with interest and costs as provided by law;

ii. Restitution and disgorgement of profits;

iii. Punitive or enhanced compensatory damages;

iv. Reasonable attorneys' fees as provided by law;

v. Costs of these proceedings, including past and future costs of the suit;

vi. All ascertainable economic damages;

vii. Prejudgment interest on all damages as allowed by law; and

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

DEMAND FOR TRIAL BY JURY

Plaintiff hereby demands a trial by jury to the full extent permitted by law.

Date: October 22, 2019

Respectfully submitted,

Brenes Law Group, P.C.

/s/ Jill M. Santiago
Jill M. Santiago (RI 9674)
623 Post Road
Warwick, RI 02888
(401) 384-0766
(401) 223-6791
jsantiago@breneslawgroup.com

Krause & Kinsman, LLC

/s/ Robert L. Kinsman
Robert L. Kinsman (MO #67427)
Adam W. Krause (MO #67462)
4717 Grand Ave., Suite 250
Kansas City, MO 64112
(816) 760-2700
(816) 760-2800 (fax)
robert@krauseandkinsman.com
adam@krauseandkinsman.com
www.krauseandkinsman.com

ATTORNEYS FOR PLAINTIFF