UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW MEXICO

MELVIN TODACHEENE, *Plaintiff,* vs. BG MEDICAL, LLC; ASPIDE MEDICAL d/b/a SURGIMESH; MEDICAL MURRAY, INC.; CHAMBERLAIN TECHNOLOGIES, LLC, *Defendants.*	)	Case No. **PLAINTIFF'S COMPLAINT and JURY DEMAND**

Plaintiff, by and through his undersigned counsel, brings this Complaint against Defendants, and in support thereof states the following:

1. This is a device tort action brought on behalf of the above-named Plaintiff arising out of the failure of Defendants' Surgimesh XB surgical mesh device ("Surgimesh" or "product"). As a result, Plaintiff MELVIN TODACHEENE suffered permanent injuries and significant pain and suffering, emotional distress, lost wages and earning capacity, and diminished quality of life. The Plaintiff respectfully seeks all damages to which he may be legally entitled.

I. PARTIES & JURISDICTION

2. Plaintiff Melvin Todacheene ("Plaintiff") is, and was, at all relevant times, a citizen and resident of New Mexico and the United States.

3. Defendant, BG MEDICAL, LLC (hereinafter "BG MEDICAL), now is, and at all times relevant to this action was, an Illinois Corporation which has its principal place of business and headquarters in the City of Chicago, County of Cook, and State of Illinois.

4. BG MEDICAL is exclusive distributor for Defendant, ASPIDE MEDICAL d/b/a SURGIMESH, and BG MEDICAL's product distribution is limited to ASPIDE MEDICAL products.

5. ASPIDE MEDICAL d/b/a SURGIMESH (hereinafter "ASPIDE") is a foreign corporation with its principal place of business located at 246 Allee Lavoisier, 42350 La Talaudiere, France.

6. CHAMBERLAIN TECHNOLOGIES, LLC ("CHAMBERLAIN") is an Illinois Limited Liability Company with its principal place of business in Deer Park, Illinois.

7. CHAMBERLAIN is the design and specification developer for all commercially available Surgimesh products, including the product at issue in this case.

8. MURRAY MEDICAL, INC. ("MURRAY") is the contract manufacturer for all commercially available Surgimesh Products, including the product at issue in this case.

9. Defendants BG MEDICAL, CHAMBERLAIN, MURRAY and ASPIDE MEDICAL (collectively "Defendants") have conducted business and derived substantial revenue from within New Mexico and have sufficient minimum contacts and purposefully avail themselves of the New Mexico Market so as to render the exercise of jurisdiction over them by the New Mexico courts consistent with the traditional notions of fair play and substantial justice.

10. ASPIDE and CHAMBERLAIN, through an exclusive distributorship with BG MEDICAL with respect to the product at issue in the case at bar, have made or performed contracts or promises substantially connected to New Mexico.

11. This Court has jurisdiction over all causes of action alleged in this Complaint pursuant to 28 U.S.C. § 1332 (a)(1) because complete diversity exists between the Plaintiff and all Defendants, and the amount in controversy exceeds seventy-five thousand dollars ($75,000.00),

excluding interest and costs.

12. Venue is proper in this Court, pursuant to 28 U.S.C. § 1391, as a substantial part of the events giving rise to the claim occurred within this judicial district and the Defendants regularly conduct business in this District, subjecting them to personal jurisdiction.

13. Plaintiff alleges that the corporate form of Defendants was a sham and should be disregarded because there exists and, at all times herein mentioned, there existed a unity of interest in ownership between and among these Defendants such that any individuality and separateness between these Defendants has ceased and/or never existed; in that these Defendants, and each of them are the alter-egos of one another and exerted direction and control over each other.

14. Adherence to the fiction of a separate and independent existence of Defendants, as separate entities distinct from one another will permit an abuse of the corporate privilege, sanction a fraud upon plaintiff and other recipients of the Surgimesh product, and promote injustice. Defendants, and each of them, encouraged, directed, condoned and ratified the negligent, willful, intentional, and wrongful acts, omissions, and conduct of each and all Defendants.

15. The following facts regarding the operations of the corporate Defendants support disregard of the corporate fiction: (1) corporate formalities for all of the wholly-owned subsidiaries were ignored and were not observed; (2) property was not kept separate and apart between the parent corporations and the wholly-owned subsidiaries; (3) direct deposits were made into bank accounts of subsidiaries which were controlled by the parent corporation and consolidated into the parent's deposit accounts; (4) the parent corporation at all times maintained 100% financial interest in all subsidiaries and maintained control over the subsidiaries on an operational basis both by appointing the chief operation officer of each subsidiary and by top down management; (5) the subsidiaries are used or established for the business purposes of the

parent, and are the means by which the parent corporation conducted its business; and (6) the subsidiary facilities were not reasonably capitalized in light of the nature and risk of their business.

16. Additionally, Plaintiff alleges that at all relevant times, the corporate Defendants have operated as a single business enterprise to achieve a common business purpose. Parent corporations and any wholly-owned subsidiaries were not operated as separate and individual entities, but rather integrated and commingled their resources to achieve a common business purpose and conducted their operations as follows: (1) a single and common board of directors and the same members existed between the parent and subsidiaries; (2) the same centralized and consolidated accounting and financial reporting was used by both the parent and the subsidiaries for both internal purposes and external purposes such as for the Internal Revenue Services and annual financial reports; (3) parent corporations paid the wages of all employees, agents, and representatives of the subsidiary corporation; (4) common business names are and were used by the parent and subsidiaries and the parent corporations' capital and credit lines are and were used to fund and operate the subsidiaries.

17. All of the subsidiaries of Defendant parent corporations were established simply as shells, instrumentalities, and conduits through which the parent conducted its business, and therefore, the corporate fiction must be disregarded to prevent fraud or injustice. Each constituent corporation may be held liable for the obligations incurred by the other component entities since these Defendants operated as a single business enterprise to achieve a common business purpose.

18. The Defendant parent corporations have intentionally operated all subsidiaries in a manner that left the subsidiaries without assets sufficient to satisfy the claims of the plaintiff and other claimants by taking complete control and possession of the subsidiaries' revenues and

receivables. All monies received as proceeds in the sales of products by the subsidiary corporations were maintained and received by the defendant parent corporations to fund their own operations and were not maintained at the subsidiary level.

19. At all times herein mentioned the Defendants, and each of them, were engaged in the business of or were successors in interest to, entities engaged in the business of developing, testing, designing, manufacturing, fabricating, inspecting, marketing, labeling, promoting, packaging, distributing and selling the Surgimesh product, which was implanted into Plaintiff.

II. STATEMENT OF FACTS

20. At all relevant times, each of the Defendants designed, developed, manufactured, licensed, marketed, distributed, sold and/or placed Surgimesh in the stream of commerce, deriving substantial revenue therefrom.

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

22. At all times hereinafter mentioned, upon information and belief, Defendants were and still are business entities actually doing business in the State of New Mexico.

23. At all times hereinafter mentioned, Defendants were engaged in the business of designing, manufacturing, advertising, marketing, and selling surgical mesh products including the Surgimesh XB, and in pursuit of this business, transacted business within the State of New Mexico and contracted to provide goods and services in the State of New Mexico.

24. At all times hereinafter mentioned, upon information and belief, Defendant committed tortious acts inside the State of New Mexico, which caused injury to Plaintiff.

25. At all times hereinafter mentioned, upon information and belief, Defendants expected or should reasonably expect its acts to have consequences in the State of New Mexico.

A. DEFENDANTS' SURGICAL MESH PRODUCT

26. Defendants obtained "clearance" to market the Surgimesh XB product under Section 510(k) of the Medical Device Amendments to the Food, Drug, and Cosmetic Act.

27. Section 510(k) permits the marketing of medical devices if the device is substantially equivalent to other legally marketed predicate devices without formal review for the safety or efficacy of the device. The FDA explained the difference between the 510(k) process and the more rigorous "premarket approval" ("PMA") process in its amicus brief filed with the Third Circuit in *Horn v. Thoratec Corp.*, which the court quoted from:

> A manufacturer can obtain an FDA findings of 'substantial equivalence' by submitting a premarket notification to the agency in accordance with section 510(k) of the [Food Drug and Cosmetic Act.] 21 U.S.C. § 360(k). A device found to be 'substantially equivalent' to a predicate device is said to be 'cleared' by the FDA (as opposed to "approved' by the agency under a PMA.

376. F.3d 163, 167 (3d. Cir. 2004). A pre-market notification submitted under 510(k) is thus entirely different from a PMA, which must include data sufficient to demonstrate that the produce involved is safe and effective.

28. In *Medtronic, Inc. v. Lohr*, the U.S. Supreme Court similarly described the 510(k) process, observing:

> If the FDA concludes on the basis of the [manufacturer's] § 510(k) notification that the device is 'substantially equivalent' to a pre-existing device, it can be marketed without further regulatory analysis…. The § 510(k) notification process is by no means comparable to the PMA process; in contrast to the 1,200 hours necessary to complete a PMA review, the § 510(k) review is completed in average of 20 hours …. As on commentator noted: "The attraction of substantial equivalence to manufacturers is clear. Section 510(k) notification required little information, rarely elicits a negative response form the FDA, and gets processed quickly.

518 U.S. 470, 478-79 (1996).

29. Pursuant to *Wyeth v. Levine*, 555 U.S. 555 (2009), once a product is cleared "the manufacturer remains under an obligation to investigate and report any adverse associated with the drug…and must periodically submit any new information that may affect the FDA's previous conclusions about the safety, effectiveness, or labeling …." This obligation extends to post-market monitoring of adverse events/complaints.

30. Surgimesh XB is a non-absorbable synthetic mesh, made of non-knitted, non-woven fibers of polypropylene, one surface of which is coated with silicone.

31. Defendants represent that the Surgimesh mesh provides reinforcement of soft tissues while the silicone layer on the opposite side minimized tissue attachment to the mesh.

32. Defendants did not timely or adequately apprise the public and physicians about the risks of using the Surgimesh mesh implanted in Plaintiff.

33. The polypropylene mesh used in the Surgimesh mesh implanted in patient was marketed by Defendants as superior to other implantable materials.

34. The available scientific evidence shows that the polypropylene material is biologically incompatible with human tissue and actually promotes deleterious immune responses in a large subset of the population.

35. These negative responses promote inflammation of the surrounding tissue and contribute to the development of severe adverse reactions to the mesh.

36. The polypropylene of which the Surgimesh is partially comprised is not stabilized with the types or amounts of anti-oxidants to permit it to resist material degradation *in vivo*.

37. Due to Defendants' design and manufacturing processes, the Surgimesh's polypropylene mesh component significantly degrades and weakens in the body, resulting in a variety of material failures.

38. The degradation of the polypropylene causes microscopic fissures to form on the

surfaces of the polypropylene filaments, creating a nidus for infection and biofilm.

39. Surface degradation also causes flaking of the polypropylene, which increases the surface area of host tissue exposed to the biomaterial and, in turn, increasing the host Foreign Body Response ("FBR") and accelerating the material degradation.

40. The polypropylene component is also prone to shrinking and contracting after being implanted in the human body, which results in multiple severe complications including but not limited to pain, hernia recurrence, organ perforation, device migration, and meshoma.

41. The silicone layer exacerbates the development of biofilms by creating an additional impediment to the human body's defenses to infection.

42. It is well-known in biomaterials research that permanently implanted products incorporating silicone-coated polypropylene increase the risk for erosion and wound dehiscence.

43. The Surgimesh mesh presents and constitutes an unreasonable risk of danger and injury in the following respects:

a. the mesh product was not properly manufactured;
b. the mesh product was defectively designed;
c. the mesh product did not perform as safely as an ordinary consumer/patient would expect;
d. the mesh product was inadequate or insufficient to maintain its integrity during normal use after implantation in the consumer/patient; and
e. such further and additional defects as discovery and the evidence reveal.

44. On August 28, 2017, Plaintiff was implanted with a Surgimesh XB product (reference # TINTRACK10; lot # F14098A) to repair multiple supraumbilical and umbilical ventral hernias.

45. The Surgimesh mesh implanted in Plaintiff was designed, manufactured, distributed, and sold by Defendants, and was intended to be used by surgeons for hernia repair

surgeries.

46. Defendants represented the product be appropriate and suitable products for such purposes.

47. Subsequently, as a direct result of the implanted Surgimesh mesh, Plaintiff experienced abdominal wall abscess, seroma, mesh infection, mesh disruption, mesh disincorporation, fistulae, seroma, and mesh migration and had to undergo removal surgery on or about August 23, 2018.

48. As a result of Defendants' actions and inactions, Plaintiff was injured due to Surgimesh product, which caused Plaintiff various injuries and damages. Plaintiff accordingly seeks damages associated with these injuries.

49. At all times herein mentioned, Defendants knew, or in the exercise of reasonable care should have known, that the Surgimesh mesh was not properly manufactured, tested, inspected, packaged, labeled, distributed, marketed, examined, sold, supplied, prepared and/or provided with proper warnings, was not suitable for the purpose it was intended and was unreasonably likely to injure the products' users.

50. Defendants ignored reports from patients and health care providers throughout the United States of the Surgimesh mesh's failure to perform as intended, which led to the severe and debilitating injuries suffered by Plaintiff and numerous other patients. Rather than doing adequate testing to determine the cause of these injuries or rule out the Surgimesh product's design as the cause of the injuries, Defendants continued to market Surgimesh mesh as a safer and more effective medical device as compared to other available alternative treatment for hernias.

51. Defendants did not timely or adequately apprise the public and physicians of the defects in Surgimesh product, despite Defendants' knowledge that it had failed due to the described

defects.

52. Before Plaintiff's implantation of Surgimesh, Defendants' sales representatives, agents, and employees knew of complications and/or other adverse events, including but not limited to:

a. Significantly increased rate, amount, and tenacity of adhesions;
b. Adherence of bacteria to the polypropylene material and silicone;
c. Significantly elevated risk of infection;
d. Extreme difficulty in removal;
e. Grave bodily injury associated with removal;
f. Significant mesh contracture;
g. Mesh rupture;
h. Severe inflammatory response;
i. Significantly increased rate of Fistula;
j. Significantly increased rate of Seroma;
k. Migration;
l. Organ perforation;
m. Sexual dysfunction;
n. Nerve injury;
o. Bowel obstruction;
p. Biofilms,
q. Erosion;
r. Wound dehiscence

53. In addition, Defendants knew or should have known of histopathological and other adverse reactions with the silicone coating used on its Surgimesh product.

54. Defendants' Surgimesh product was at all times utilized and implanted in a manner foreseeable to Defendants, as Defendants generated the instructions for use and created procedures for implanting the mesh.

55. Plaintiff and Plaintiff's physicians foreseeably used and implanted the Defendants' Surgimesh product, and did not misuse, or alter the Surgimesh mesh in an unforeseeable manner.

56. Feasible and suitable alternative procedures and instruments, as well as suitable alternative designs for implantation and treatment of hernias and soft tissue repair have existed at

all times relevant as compared to the Defendants' Surgimesh product.

57. Contrary to Defendants' representations, the Surgimesh product has a high rate of failure, injury, and complications associated with its intended use; the product fails to perform as intended resulting in debilitating subsequent revision surgeries for users of the medical device, including Plaintiff.

58. Despite their knowledge of this dangerous side effect that can result from Surgimesh use, Defendants refused to warn patients, physicians and the medical community about the risks.

59. Plaintiff and Plaintiff's physicians foreseeably used and implanted the Defendants' Surgimesh mesh, and did not misuse, or alter the Surgimesh mesh in an unforeseeable manner.

60. Consumers who have been implanted with Surgimesh, including Plaintiff, have several alternative safer products and biomaterials available for implantation and treatment of hernias, which have existed at all times relevant as compared to Defendants' product.

61. Defendants, through their affirmative misrepresentations and omissions, actively concealed from Plaintiff and his physicians the true and significant risks associated with long-term Surgimesh implantation.

62. Contrary to Defendants' representations, the Surgimesh mesh has a high rate of failure, injury, and complications associated with its intended use; the product fails to perform as intended resulting in debilitating subsequent revision surgeries for users of the medical device, including Plaintiff.

63. The Defendants' Surgimesh mesh implanted into the Plaintiff was in the same or substantially similar condition as when it left the possession of the Defendants, and in the condition directed by and expected by the Defendants.

64. Defendants advertised, promoted, marketed, sold, and distributed the Surgimesh mesh as a safe medical device when Defendants knew or should have known the Surgimesh mesh was not safe for its intended purposes and that the Surgimesh mesh could cause serious medical problems.

65. Defendants had sole access to material facts concerning the defective nature of the Surgimesh mesh and its propensity to cause serious and dangerous side effects.

66. Defendants under reported information about the propensity of the Surgimesh mesh to fail and cause injury and complications and have made unfounded representations regarding the efficacy and safety of the Surgimesh mesh.

67. In reliance on Defendants' representations, Plaintiff s doctors were induced to, and did use the Defendants' Surgimesh product.

68. As a direct and proximate cause of Defendants' conduct, Plaintiff has suffered injuries and will require continual monitoring and care.

69. As a result of Defendants' conduct, Plaintiff will incur future medical costs related to the Surgimesh product.

70. As a result of Defendants' actions, Plaintiff and his physicians were unaware, and could not have reasonably known or have learned through reasonable diligence, that Plaintiff would be exposed to the risks identified in this Complaint, and that those risks were the direct and proximate result of Defendants' conduct.

71. As a direct result of being implanted with Surgimesh mesh, Plaintiff has been permanently and severely injured.

72. Plaintiff requires and will in the future require ongoing medical care and treatment, including future surgeries.

73. Plaintiff, as a direct and proximate result of the Surgimesh, suffered severe mental and physical pain and suffering and has and will sustain permanent injuries and emotional distress, along with economic loss due to medical expenses, and living-related expenses due to his injuries.

74. Plaintiff's physicians would not have used Surgimesh mesh had Defendants properly disclosed the risks associated with its use.

B. STATEMENT OF CLAIM

COUNT I: NEGLIGENCE

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

76. At all relevant times, Defendants had a duty to exercise reasonable and ordinary care in the manufacture, design, labeling, instructions, warnings, sale, marketing, and distribution of the Defendants' Surgimesh product, and recruitment and training of physicians to implant the Surgimesh.

77. Defendants breached the duty of care to the Plaintiff, as aforesaid, in the manufacture, design, labeling, warnings, instructions, sale, marketing, distribution, and recruitment and training of physicians to implant the Surgimesh.

78. Defendants breached their duty by failing to comply with state and federal regulations concerning the study, testing, design, development, manufacture, inspection, production, advertisement, marketing, promotion, distribution, and/or sale of the Surgimesh.

79. As a direct and proximate result of the duties breached, the Surgimesh failed, resulting in much pain and suffering, mental anguish, doctor visits, subsequent procedures, and substantial medical bills.

80. As a direct and proximate result of Defendants' negligence, Plaintiff suffered severe pain, injuries and damages.

81. As a direct and proximate result of Defendants' conduct, Plaintiff has suffered and will continue to suffer severe pain and mental anguish.

82. Defendants' conduct in continuing to market, sell and distribute the Surgimesh after obtaining knowledge that the products were failing and not performing as represented and intended, showed complete indifference to or a conscious disregard for the safety of others, justifying an award of additional damages for aggravating circumstances in such a sum which will serve to deter Defendant and others from similar conduct in the future.

83. Defendants knew or should have known that its failure to exercise ordinary care in the manufacture, design, labeling, warnings, instructions, sale, marketing, distribution and recruitment and training of physicians to implant the Surgimesh would cause foreseeable harm, injuries and damages to individuals such as Plaintiff who are implanted with Surgimesh.

84. As a direct, proximate and foreseeable result of the Defendants' design, manufacture, labeling, marketing, sale, and distribution of the Surgimesh, Plaintiff has been injured, sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and consortium, and economic damages.

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

WHEREFORE, Plaintiff demands judgment against Defendants, and requests compensatory damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT II: STRICT LIABILITY – DESIGN DEFECT

86. Plaintiff re-alleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein and additionally or in the alternative, if same be necessary, allege as follows:

87. Defendants supplied, manufactured, sold, distributed and/or otherwise placed into the stream of commerce the Surgimesh implanted into Plaintiff. The product was defective in its design in that when it left the hands of Defendants, it was not safe for its anticipated use and safer, more reasonable alternative designs existed that could have been utilized by Defendants. A reasonably prudent medical device manufacturer would not have placed the Surgimesh with its defective design into the stream of commerce.

88. The Surgimesh was defectively designed when supplied, sold, distributed and/or otherwise placed into the stream of commerce and when it was implanted in Plaintiff.

89. The Surgimesh was unreasonably dangerous, taking into consideration the utility of said product and the risks involved in its use. The foreseeable risks associated with the design of the product were more dangerous than a reasonably prudent consumer such as Plaintiff and/or his physician would expect when the product was used for its normal and intended purpose.

90. The Surgimesh reached Plaintiff's implanting surgeon and was implanted in Plaintiff without any substantial change in the condition in which it was supplied, distributed, sold and/or otherwise placed into the stream of commerce.

91. The Surgimesh failed to perform as safely as an ordinary consumer and/or his physician would expect when used as intended or when used in a manner reasonably foreseeable by the manufacturer, and the risks and dangers of the Surgimesh outweigh its benefits. The design defects in the Surgimesh were not known, knowable and/or reasonably apparent to Plaintiff and/or

his physician or discoverable upon any reasonable examination. The Surgimesh was used and implanted in the manner in which it was intended to be used and implanted by Defendants pursuant to the instructions for use and the product specifications provided by Defendants.

92. The defective and unreasonably dangerous condition of the Surgimesh was the proximate cause of the damages and injuries complained of by Plaintiff.

93. As a direct and proximate result of the Surgimesh's aforementioned design defects, Plaintiff was caused and in the future will be caused to suffer severe personal injuries, pain and suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligations for medical services and expenses, and other damages.

94. Defendants are strictly liable to Plaintiff.

WHEREFORE, Plaintiff demands judgment against Defendants and requests compensatory damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT III: STRICT LIABILITY – MANUFACTURING DEFECT

95. Plaintiff re-alleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein and additionally or in the alternative, if same be necessary, allege as follows:

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

97. The Surgimesh as manufactured and constructed by Defendants was unreasonably dangerous to end consumers including Plaintiff and posed an unreasonable degree of risk, danger and harm to Plaintiff.

98. The Surgimesh was expected to reach and did reach Plaintiff's implanting surgeon and Plaintiff without substantial change in the condition in which it was manufactured, supplied, distributed sold and/or otherwise placed in the stream of commerce.

99. The manufacturing defect in the Surgimesh implanted in Plaintiff was not known, knowable or readily apparent to Plaintiff's physician or to Plaintiff. Nor was it discoverable upon any reasonable examination by Plaintiff's physician or Plaintiff. The Surgimesh was used and implanted in the very manner in which it was intended to be used and implanted by Defendant in accordance with the instructions for use and specifications provided by Defendants.

100. The Surgimesh implanted in Plaintiff was different from its intended design and failed to perform as safely as a product manufactured in accordance with the intended design would have performed.

101. The defective and unreasonably dangerous condition of the Surgimesh product was a proximate cause of damages and injuries suffered by Plaintiff.

102. As a direct and proximate result of the Surgimesh's aforementioned manufacturing defect, Plaintiff was caused and in the future will be caused to suffer severe personal injuries, pain and suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligations for medical services and expenses, and other damages.

103. Defendants are strictly liable to Plaintiff.

WHEREFORE, Plaintiff demands judgment against Defendants and requests compensatory damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT IV: STRICT LIABILITY – FAILURE TO WARN

104. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein and additionally or in the alternative, if same be necessary, allege as follows:

105. Defendants manufactured, designed, marketed, sold and/or otherwise placed into the stream of commerce their Surgimesh product.

106. The Defendants failed to properly and adequately warn and instruct Plaintiff and his treating physician that Surgimesh was designed and/or manufactured in a way that could cause injuries and damages including lasting and permanent injuries. Defendants further failed to inform and further warn Plaintiff and his treating physician with respect to the most effective proper technique and methods of implantation and/or the selection of appropriate candidates to receive Surgimesh.

107. The Defendants failed to properly and adequately warn and instruct Plaintiff and his treating physician as to the risks and benefits of the Defendants' Surgimesh. To the contrary, Defendants withheld information from Plaintiff and his treating physician regarding the true risks as relates to implantation of their Surgimesh.

108. The Defendants failed to properly and adequately warn and instruct Plaintiff and his treating physician that inadequate research and testing of the Surgimesh was done prior to Surgimesh being placed on the market and in the stream of commerce and that Defendants lacked a safe, effective procedure for removal of the Surgimesh once complications from same arise.

109. The Defendants intentionally, recklessly, and maliciously misrepresented the efficacy, safety, risks, and benefits of Surgimesh, understating the risks and exaggerating the benefits in order to advance its own financial interest, with wanton and willful disregard for the rights, safety and health of Plaintiff.

110. The dangerous and defective conditions in the Surgimesh existed at the time they were delivered by the manufacturer to the distributor. At the time Plaintiff had his implant surgery, the Surgimesh was in the same condition as when manufactured, distributed and sold.

111. Plaintiff did not know at the time of surgery that the Surgimesh placed during Plaintiff's surgery or at any time prior thereto, of the existence of the defects or dangerous propensities in the Surgimesh.

112. As a direct and proximate result of the Defendants' design, manufacture, marketing, sale, and distribution of the Surgimesh, Plaintiff has been injured and sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and economic damages.

113. The Defendants are strictly liable in tort to the Plaintiff for their wrongful conduct in failing to properly warn Plaintiff.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory damages, interest, attorneys' fees, costs of suit, and such further relief as the Court deems equitable and just.

COUNT V: BREACH OF EXPRESS WARRANTY

114. Plaintiff re-alleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein and additionally or in the alternative, if same be necessary, allege as follows:

115. At all relevant and material times, Defendants manufactured, marketed, sold, distributed and otherwise placed into the stream of commerce the Surgimesh product.

116. In advertising, marketing and otherwise promoting Surgimesh to physicians, hospitals and other healthcare providers, Defendants' expressly warranted that their Surgimesh was safe for use. In advertising, marketing and otherwise promoting Surgimesh, Defendant intended that physicians, hospitals, and other healthcare providers rely upon their representations in an effort to induce them to use Surgimesh for their patients.

117. The Plaintiff was a person whom the defendants could reasonably have expected to use, consume, or be affected by the Defendants' Surgimesh product, as the Defendants specifically designed the Surgimesh for implantation in patients requiring reinforcement of abdominal wall defects such as Plaintiff.

118. With respect to Plaintiff, Defendants intended that Surgimesh be implanted in Plaintiff by his treating surgeon in the reasonable and foreseeable manner in which it was implanted and in accordance with the instructions for use and product specifications provided by Defendants. Plaintiff was in privity with Defendants.

119. Defendants expressly warranted to physicians, hospitals, other healthcare providers and the general public including Plaintiff that Surgimesh was safe and fit for use by consumers including Plaintiff, that it was of merchantable quality, that its risks, side effects and potential complications are minimal and are comparable to other Hernia Mesh Devices, that it was adequately researched and tested and was fit for its intended use. Plaintiff and his physicians and healthcare providers relied upon these express representations and warranties made by Defendants and consequently, Plaintiff was implanted with Defendants' Surgimesh.

120. Defendants breached express representations and warranties made to Plaintiff and his physicians and healthcare providers with respect to the Surgimesh implanted in Plaintiff including the following particulars:

a) Defendants represented to Plaintiff and his physicians and healthcare providers through labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions among other ways that the Defendants' Surgimesh was safe, meanwhile Defendant fraudulently withheld and concealed information about the substantial risks of serious injury associated with using Surgimesh;

b) Defendants represented to Plaintiff and his physicians and healthcare providers that the Defendants' Surgimesh was as safe and/or safer than other alternative procedures and devices then on the market, meanwhile Defendant fraudulently concealed information that demonstrated that Surgimesh was 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' Surgimesh was more efficacious than other alternative procedures, therapies and/or devices. Meanwhile Defendant fraudulently concealed information, regarding the true efficacy of Surgimesh.

121. At the time of making such express warranties, Defendants knew or should have known that Defendants' Surgimesh 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.

122. As a direct and proximate result of Defendants' breaches of the aforementioned express warranties, Plaintiff was caused and in the future will be caused to suffer severe personal injuries, pain and suffering, severe emotional distress, financial or economic loss, including, but

not limited to, obligations for medical services and expenses, impairment of personal relationships, and other damages.

WHEREFORE, Plaintiff demands judgment against Defendants and requests compensatory damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

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

123. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein and additionally or in the alternative, if same be necessary, allege as follows:

124. At all relevant and material times, Defendants manufactured, distributed, advertised, promoted, and sold the Defendants' Surgimesh.

125. At all relevant times, Defendants intended that its Surgimesh be implanted for the purposes and in the manner that Plaintiff's implanting surgeon did in fact implant it in accordance with the instructions for use and product specifications provided by Defendants and Defendants impliedly warranted that their Surgimesh was of merchantable quality, safe and fit for its intended use of implantation in Plaintiff and was properly and adequately tested prior to being placed in the stream of commerce.

126. When the Surgimesh was distributed into the stream of commerce and sold by Defendants, they were unsafe for their intended use, and not of merchantable quality, as warranted by Defendants, in that they had very dangerous propensities when used as intended and implanted into a patient's body and, as a result, could cause serious injury of harm or death to the end user.

127. The Plaintiff was a person whom the defendants could reasonably have expected to use, consume, or be affected by the Defendants' surgical mesh product, as the Defendants

specifically designed the Surgimesh for implantation in patients requiring reinforcement of abdominal wall defects such as Plaintiff.

128. Defendants were aware that consumers such as Plaintiff would be implanted with Surgimesh by their treating physicians in accordance with the instructions for use and product specifications provided by Defendants to Plaintiff's physicians. Plaintiff was a foreseeable user of Defendants' Surgimesh, and plaintiff was in privity with Defendants.

129. Defendants breached implied warranties with respect to the Surgimesh including the following particulars:

a) Defendants represented to Plaintiff and his physicians and healthcare providers through its labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that the Defendants' Surgimesh was of merchantable quality and safe when used for its intended purpose meanwhile Defendants fraudulently withheld and concealed information about the substantial risks of serious injury associated with using Surgimesh;

b) Defendants represented to Plaintiff and his physicians and healthcare providers that the Defendants' Surgimesh was safe, as safe as and/or safer than other alternative procedures and devices, meanwhile Defendants fraudulently concealed information, which demonstrated that the Surgimesh was not safe, as safe as or safer than alternatives and other products available on the market; and

c) Defendants represented to Plaintiff and his physicians and healthcare providers that the Defendants' Surgimesh were more efficacious than other alternative procedures and/or devices. Meanwhile Defendant fraudulently concealed information, regarding the true efficacy of Surgimesh.

130. In reliance upon Defendants' implied warranty, Plaintiff's implanting surgeon used Surgimesh to treat Plaintiff in the foreseeable manner normally intended, recommended, promoted, and marketed by Defendants and in accordance with the instructions for use and product specification provided by Defendants.

131. Defendants breached their implied warranty to Plaintiff in that the Defendants' Surgimesh was not of merchantable quality, safe and fit for its intended use nor was it adequately tested prior to being placed in the stream of commerce.

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

133. As a direct and proximate result of Defendants' breach of the aforementioned implied warranties, Plaintiff was caused and in the future will be caused to suffer severe personal injuries, pain and suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligations for medical services and expenses, impairment of personal relationships, and other damages.

WHEREFORE, Plaintiff demands judgment against Defendants and requests compensatory damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT VII: GROSS NEGLIGENCE AND INTENTIONAL CONDUCT

134. Plaintiff re-alleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein and additionally or in the alternative, if same be necessary, allege as follows:

135. The acts and omissions of Defendants as alleged herein are of a character and nature that is outrageous, fraudulent, oppressive, done with malice and evidenced reckless disregard for Plaintiff's rights, health and safety and constitute gross negligence and/or willful or intentional indifference or conduct.

136. The acts and omissions of Defendants, whether taken singularly or in combination with others, and committed by Defendants individually or through the cumulative conduct of employees and agents, constitute gross negligence or willful and/or intentional conduct that proximately caused injuries to Plaintiff.

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

COUNT VIII: UNJUST ENRICHMENT

137. Plaintiff re-alleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein and additionally or in the alternative, if same be necessary, allege as follows:

138. Defendants at all times was the manufacturer, seller, and/or supplier of Surgimesh.

139. Plaintiff was implanted with Defendants' Surgimesh for the purpose of treatment of hernia, and Defendants were paid for Plaintiffs use of said product.

140. Defendants have accepted payment by Plaintiff and/or by others on Plaintiff's behalf for the purchase of the Surgimesh with which Plaintiff was implanted.

141. Plaintiff was not implanted with nor did he receive the medical device that Defendants' represented and warranted to be safe, effective and efficacious and for which Plaintiff paid.

142. Equity demands that Defendants be required to disgorge any and all moneys, profits and/or any other thing of value received by Defendants on account of Plaintiff receiving a product that was substantially different than that which was represented and/or warranted and because of Defendants' conduct, acts and omissions as set out herein.

WHEREFORE, Plaintiff demands judgment against Defendants and requests compensatory damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT IX: VICARIOUS LIABILITY

143. Whenever in this complaint it is alleged that Defendant did or omitted to do any act, it is meant that Defendants' officers, agents, servants, employees, or representatives did or omitted to do such act and that at the time such act or omission was done, it was done with the full authorization or ratification of Defendants or was done in the normal and routine course and scope of employment of Defendants' officers, agents, servants, employees, and representatives.

COUNT X: EQUITABLE TOLLING OF THE APPLICABLE STATUTE OF LIMITATION

144. The running of any statute of limitation has been tolled by reason of the Defendants' fraudulent conduct. Defendants, through their affirmative misrepresentations and omissions, actively concealed from Plaintiff and Plaintiff's treating physicians the true risks associated with Surgimesh.

145. As a result of the Defendants' actions, Plaintiff and Plaintiff's treating physicians were unaware, and could not reasonably know or have learned through reasonable diligence that Plaintiff had been exposed to the risks alleged herein and that those risks were the direct and proximate result of Defendants' acts and omissions.

146. Furthermore, Defendants are estopped from relying on any statute of limitations defense because of their fraudulent concealment of the truth regarding the quality and nature of Surgimesh. Defendants had a duty to disclose the true character, quality and nature of Surgimesh because this was non-public information over which Defendant had and continued to have

exclusive control, and because Defendants knew that this information was not available to the Plaintiff, medical providers and/or to health facilities. Defendants are estopped from relying on any statute of limitation because of their intentional concealment of these facts.

147. The Plaintiff had no knowledge that Defendants were engaged in the wrongdoing alleged herein. Because of the fraudulent acts of concealment and wrongdoing by Defendants, Plaintiff could not have reasonably discovered the wrongdoing until less than the applicable limitations period prior to the filing of this action.

C. PRAYER FOR RELIEF

Plaintiff demands judgment against Defendant and prays for the following relief in accordance with applicable law and equity:

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

ii. Reasonable attorneys' fees as provided by law;

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

iv. Prejudgment interest on all damages as is allowed by law;

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

JURY TRIAL DEMANDED

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

Respectfully submitted,

DURHAM, PITTARD & SPALDING, LLP

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