**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF NEW JERSEY**

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| LEDDA SELLARS<br><br>Plaintiff,<br><br>v.<br><br>LIFECELL CORPORATION; ALLERGAN, INC.; And ALLERGAN USA, INC.<br><br>Defendants. | Case No. _____<br><br>**PLAINTIFF DEMANDS TRIAL BY JURY** |

## COMPLAINT FOR DAMAGES AND JURY DEMAND

Plaintiff Ledda Sellars, by and through her undersigned attorneys, files this Complaint for Damages against Defendants LifeCell Corporation, Allergan, Inc., and Allergan USA, Inc., and alleges as follows.

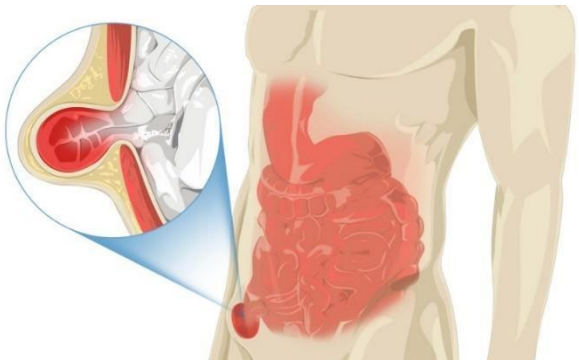
## INTRODUCTION

1. This case concerns a product known as hernia mesh.

2. Hernia mesh is a medical device.

3. Some surgeons use hernia mesh to repair hernias.

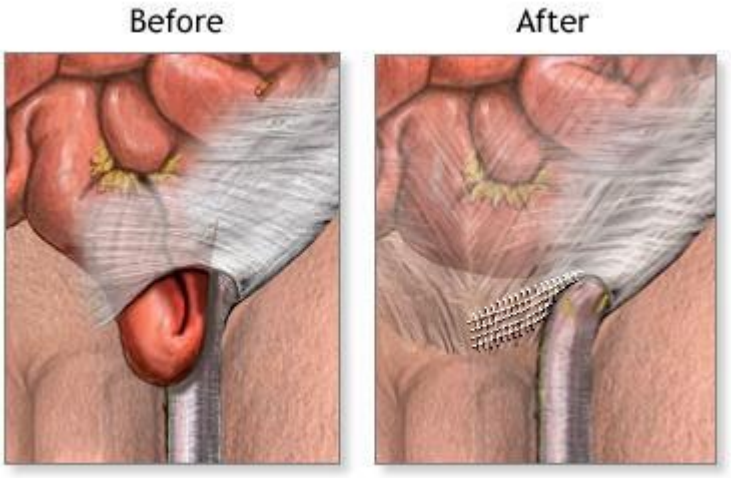
4. Hernias occur when an organ protrudes through an abnormal opening.



[1]

5. Hernias can occur in the abdomen, groin, or other parts of the body.

6. Doctors can treat hernias in several ways, including through surgery.




[2]

7. Some surgeons use a medical device, hernia mesh, to repair hernias.

8. Hernia mesh is a medical device because it is intended for the use in the diagnosis of disease or other conditions, for the cure, mitigation, treatment, or prevention of disease, and/or to affect the structure or function of the body.

9. Hernia mesh is a surgical mesh.

10. Surgical mesh is a metallic or polymeric screen implanted inside people to reinforce

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[1] Source: https://www.niddk.nih.gov/health-information/digestive-diseases/inguinal-hernia

[2] Source: https://medlineplus.gov/ency/presentations/100027_4.htm

soft tissue or bone where weakness exists.

11. Metallic or polymeric mesh for hernia repair is one kind of surgical mesh, but there are others.

12. Synthetic mesh is a common product used for surgical hernia repairs.

13. Synthetic mesh is made from materials such as nylon or plastic.

14. Some hernia mesh products are made from animal products.

15. Biologic graft implants are one such alternative to synthetic mesh.

16. Biologic grafts implants are made using material from animals.

17. Made from biological material, biologic mesh is supposed to become replaced by the patient's own tissue over time through a process known as remodeling.

18. The goal is to lower the human body's foreign body inflammatory response and biomechanical requirements of the repair.

19. Because biologic grafts are believed to cause less foreign body response, the use of biologic implants was believed to reduce the risks of adhesions and infections.

20. Biologic graft implants vary in design.

21. For example, biologic grafts can be made from either non-human animal tissue (xenograft) or from human tissue (allograft).

22. Additionally, biologic grafts can be either cross-linked or non-cross-linked.

23. "Cross-linking" refers to treating the biologic graft chemically to link together the proteins in the tissue.

24. This is believed to increase the strength of the graft.

25. Although cross-linking may increase the strength of a biologic graft, the process

can also increase the risk of foreign body response.

26. This could result in a higher risk of adhesions, scarring, and infection complications.

27. For this and other reasons, biological mesh present risks to patients.

28. Hernia mesh sometimes migrates, contracts, and fails for other reasons.

29. Hernia mesh also gets infected.

30. A surgeon may remove hernia mesh surgically (sometimes referred to as "explantation" or "removal" surgery) and repair the hernia with alternative methods.

31. Surgeons may adjust the mesh surgically (sometimes referred to as a "revision" surgery).

32. Plaintiff's surgeon implanted mesh in her.

33. The mesh failed.

34. Plaintiff's surgeon had to perform a revision surgery.

35. Defendants designed, made, and/or sold the mesh that Plaintiff's surgeon implanted into her body.

36. Defendants' hernia mesh products are biological mesh.

37. Defendants' biological mesh products are medical devices.

38. Defendants' hernia mesh products include human-based (allograft) tissue matrices.

39. Defendants' hernia mesh products, including the device at issue in this case, include xenograft devices.

40. Xenograft devices are made with tissue graft or organ transplant from different species.

41. Defendant's xenograft device at issue in this case is derived from a pig.

42. Defendants' xenograft hernia mesh products include human-based AlloDerm Regenerative Tissue Matrix ("AlloDerm") and animal-based (xenograft) tissue matrices, which included Strattice Reconstructive Tissue Matrix ("Strattice").

43. Defendants made Strattice available in various configurations.

44. Defendants intended for their mesh to be used as soft tissue patches to reinforce soft tissue where weakness exists and for the surgical repair of damaged or ruptured soft tissue membranes.

45. These products' indications for use include the repair of hernias and/or body wall defects that require the use of reinforcing or bridging material to obtain the desired surgical outcome.

46. The mesh is indicated for open or laparoscopic procedures.

47. An open repair procedure involves cutting into the human body to open the abdomen or groin with an incision.

48. A laparoscopic repair uses smaller incisions and can include robotic-assisted techniques.

49. These xenograft-based tissue matrices are made from porcine skin tissue.

50. The pig skin tissue in Defendants' products is supposedly processed with a supposed non-damaging proprietary processing technique that supposedly removes cells.

51. Defendants designed it to reduce significantly a component believed to play a major role in human's rejection response associated with xenogeneic tissue.

52. These matrices are also supposed to provide a versatile scaffold for remodeling into

the patient's tissues.

53. The clinical application of these xenograft tissue matrix products at issue here are challenging hernia repairs in the acute care setting.

54. In other words, Defendants' product was for patients presenting complex cases to surgeons.

**PARTIES, JURISIDCTION, & VENUE**

55. Plaintiff Ledda Sellars ("Plaintiff" or "Sellars") is a resident and citizen of Rosedale, Maryland Baltimore County.

56. At all relevant times, Plaintiff was a resident and citizen of Rosedale, Maryland Baltimore County.

57. Defendant LifeCell Corporation ("LifeCell") is a Delaware corporation and until August 1, 2021, had its principal place of business in New Jersey. Notwithstanding the presence of corporate officers located at 1 Waukegan Road, North Chicago, Lake County, Illinois as of August 2, 2021, LifeCell has and continues to regularly design, manufacture, and sell medical devices in the state of New Jersey. At or around both the time that the Strattice mesh was implanted and revised in Plaintiff, Defendant LifeCell's principal place of business was in New Jersey. Lifecell has also consented to the jurisdiction of this Court following the filing of other complaints regarding the same product at issue here. LifeCell maintains a registered service agent, Corporate Creations Network, at 181 New Road #304, Parsippany, NJ 07054. Accordingly, LifeCell is subject to the jurisdiction and venue of this Court.

58. LifeCell designs, manufactures, sells, and manages various medical products including skin/dermal products under brand names including, "Strattice." LifeCell holds itself out

as a global advanced wound care company committed to developing innovative healing solutions for customers and patients across the care continuum.

59. Acelity L.P. sold LifeCell to Defendant Allergan for $2.9 billion in cash in early 2017. Strattice net revenues, a component of "other" Regenerative Medicine, were $18.8 million in the first quarter of 201. Strattice net revenues in the second quarter of 2017, a component of "other" Regenerative Medicine, were $29.7 million. Strattice net revenues were $27.3 million in the fourth quarter of 2017.

60. Defendants Allergan, Inc. and Allergan USA, Inc. (collectively "Allergan") are Delaware corporations and, until August 1, 2021, had their principal places of business at 5 Giralda Farms, Madison, New Jersey. Notwithstanding the recent appointment of corporate officers located at 1 Waukegan Road, North Chicago, Lake County, Illinois as of August 1, 2021, Allergan has and continues to regularly design, manufacture, and sell, medical devices in the State of New Jersey. At or around both the time that the Strattice mesh was implanted and revised in Plaintiff, Defendant Allergan's principal place of business was in New Jersey. Both Allergan Defendants have also consented to the jurisdiction of this Court following the filing of other complaints regarding the same product at issue here. Allergan maintains a registered service agent, Corporate Creations Network, at 181 New Road #304, Parsippany, NJ 07054. Accordingly, Allergan is subject to the jurisdiction and venue of this Court.

61. Allergan claims it delivers life-enhancing innovations to help people live happier lives. Allergan sells many products in various therapeutic areas. At all relevant times, Allergan was the owner/operator of the LifeCell Corporation establishment.

62. Allergan agreed to acquire LifeCell from Acelity L.P. Inc. for $2.9 billion in cash

in December 2016 and completed the transaction in early 2017. Allergan anticipated LifeCell's assets would generate approximately $450 million in 2016 revenue, growing at a mid-single digit rate, approximately 75% gross margin and approximately 40% operating margin in 2016.

63. The majority of LifeCell's revenue was from challenging hernia repairs.

64. Allergan understood that LifeCell marketed Strattice, a pig-based tissue matrix used in complex abdominal wall repair and for the surgical repair of damaged or ruptured soft tissue.

65. Allergan believed Strattice was the industry standard for challenging hernia repair.

66. Promotional materials for Strattice mesh identify Allergan by name and reveal its involvement in the design, manufacture, and sale of the product.

67. For example, in materials related to the Reconstructive Tissue Matrix, RTM, the tissue processing process is described as an "Allergan proprietary tissue process."

68. Defendants represent in these materials that Strattice is an Allergan proprietary tissue process.

69. Additionally, "Allergan carefully selects the tissue suitable" for the product.

70. Allergan also instructs that it should be called at 800.367.5737 regarding any adverse reactions to Strattice mesh.

71. Defendants designed, manufactured, promoted, distributed, and/or warranted the hernia mesh medical device at issue.

72. This court has jurisdiction over this action pursuant to 28 U.S.C. §1332 because there is complete diversity of citizenship between the parties, and the amount in controversy exceeds $75,000.00, exclusive of interest and costs.

73. Venue in this district is appropriate under 28 U.S.C. §1391 because all Defendants were engaged in the research, development, manufacture, design, testing, sale and marketing of the devices, and introduced such products into interstate commerce with knowledge and intent that such products be sold in all States, including the State of New Jersey. Moreover, the events giving rise to the research, development, manufacture, design, testing, sale, and marketing of the devices occurred in the State of New Jersey and the related witnesses are located therein.

## NATURE OF THE ACTION

74. Plaintiff had hernia repair surgery on or about March 30, 2015.

75. Plaintiff was 39-years old at the time.

76. During Plaintiff's hernia repair surgery, Plaintiff's surgeon implanted a Strattice mesh.

77. The records indicate this is a LifeCell Strattice mesh.

78. This mesh is a medical device.

79. After surgery, because of Defendants' product, Plaintiff returned to the hospital on or around April 2015 with pain and an abdominal wall abscess.

80. Plaintiff was eventually diagnosed with intraabdominal mesh infection.

81. On or about July 13, 2015, Plaintiff underwent a removal of infected mesh with primary closure to the abdominal wall and dissection of adhesions.

82. As a result, Plaintiff has suffered and will suffer physical injury, pain and suffering, loss of enjoyment of life, disfigurement, and economic and non-economic losses.

83. This lawsuit therefore seeks recovery for Plaintiff's damages.

84. In support, Plaintiff asserts claims for negligence, strict products liability for design defect, strict products liability for failure to warn, breach of express and implied warranties, negligent misrepresentation, fraud, consumer fraud act violations, survival action, and punitive damages against Defendants.

85. Defendants designed, manufactured, marketed, promoted, sold, and post-market managed the product to Plaintiff's health care providers.

86. Defendants designed and marketed Strattice for patients with comorbidities.

87. Defendants designed and marketed, promoted, sold the product for patients with complex medical histories and surgical cases.

88. Defendants failed to design, manufacture, market, promote, and manage the product post-market in a reasonable, safe manner.

89. Defendants knew or should have known the product was dangerous and would injure patients, including in the ways Plaintiff was injured.

90. Defendants knew or should have known of the defective nature of its product, the need for and existence of a feasible, practical, and safer alternative design, and the need for additional information regarding it and its safe usage by:

a. Conducting appropriate tests and studies, which they failed to do;

b. Performing adequate post-marketing surveillance activities including monitoring complaints, adverse event reports, and scientific literature, which they failed to do;

c. Following industry standards, from which they deviated; and

d. Adhering to risk management principles, which they neglected.

91. For example, Defendants received medical device reports ("MDR") regarding their mesh products.

92. In February 2010, a surgeon removed an infected mesh and used Defendants' mesh for a repair.

93. A week later, the device had dissolved and was no longer apparent.

94. Defendants reported this event to FDA in March of 2010.

95. In another MDR in 2010, a post-operative visit indicated an infection that the doctor reported required emphatically removed in early 2011.

96. There are at last 450 MDRs from September 1, 1990 through September 30, 2020 involving Strattice.

97. Six reports involve death.

98. Over 340 of those reports are injury reports.

99. At least another 107 were characterized as malfunction reports.

100. These reports include peer-reviewed studies reported in scientific journals.

101. Defendants identified some of these articles while conducting literature reviews later in the product lifecycle.

102. Had Defendants conducted proper pre and post market testing, designed, manufactured, promoted, marketed, and managed the product properly, Plaintiff would not have been injured.

## STRATTICE MESH HISTORY

103. LifeCell was the designer, manufacturer, marketer, distributor, supplier, and manager of the Strattice hernia mesh product at all times.

104. For the most part, to sell medical devices in America, companies must go through the FDA.

105. Congress created two pathways for the FDA to regulate medical devices – the premarket approval process and what is commonly referred to as the 510(k)-clearance process.

106. The latter generally requires less time, effort, and testing, whereas the former is more rigorous.

107. LifeCell presented its LTM Surgical Mesh to the FDA via the 510(k) process in February 2007.

108. FDA cleared the device on June 11, 2007, under K070560.

109. The LTM Surgical Mesh was intended for use as a soft tissue patch to reinforce soft tissue where weakness exists and for the surgical repair of damaged or ruptured soft tissue membranes.

110. Its indications for use included the repair of hernias and/or body wall defects which require the use of reinforcing or bridging material to obtain the desired surgical outcome.

111. In October of that same year, FDA cleared the LifeCell Tissue Matrix-Rotator Cuff (LTM-RC) Surgical Mesh as K071986.

112. The LTM-RC Surgical Mesh is intended for use as a soft tissue patch to reinforce soft tissue where weakness exists and for the surgical repair of damaged or ruptured soft tissue membranes.

113. The implant is intended for the reinforcement of soft tissues repaired by sutures or suture anchors, during rotator cuff surgery. Indications for use also include the repair of hernias and/or body wall defects which require the use of reinforcing or bridging material to obtain the

desired surgical outcome.

114. LifeCell first brought Strattice to the market in 2008.

115. Again, Strattice is a surgical mesh that is made from pig skin.

116. Strattice is processed and preserved in a phosphate buffered aqueous solution containing matrix stabilizers.

117. Defendants designed it to perform as a surgical mesh for soft tissue repair while presenting a scaffold to the patient.

118. The structural properties were supposed to minimize tissue attachment to the mesh.

119. It was supposed to minimize patient rejection.

120. It was supposed to enable the tissue matrices to ultimately transition into host tissue for strong, natural repair.

121. It was supposed to support tissue regeneration without scar formation.

122. It was supposed to allow for rapid revascularization, white cell migration and cell repopulation.

123. This was supposed to lead to increased resistance to infection at the surgical site.

124. The foregoing was supposed to be a key differentiator for the products as compared to other competitive offerings.

125. Defendants understood that surgeons were using Strattice to reinforce tissue where weakness exists, including hernia and body wall defects with multiple comorbidities and prior hernia repair surgeries.

126. Defendants failed to disclose that its product did not meet these needs as expected.

127. FDA inspected LifeCell in Somerville, New Jersey between June 10, 2008 and

September 3, 2008.

128. FDA's inspection revealed that the Strattice/LTM device was adulterated within the meaning of section 501(h) of the Act, 21 U.S.C. § 351(h).

129. This was because the methods used in, or the facilities or controls used for, its manufacture, packing, storage, or installation were not in conformity with the Current Good Manufacturing Practice (cGMP) requirements of the Quality System (QS) regulation found at Title 21, Code of Federal Regulations (C.F.R.), Part 820.

130. FDA determined LifeCell failed to sufficiently monitor for products that might be out of specification.

131. FDA determined LifeCell failed to conduct root causes analyses.

132. FDA determined LifeCell failed to implement corrective actions.

133. FDA determined LifeCell failed to verify or validate corrective and preventive actions to ensure that such actions are effective and do not adversely affect the finished device, as required by 21 C.F.R. § 820.100(a)(4).

134. FDA determined LifeCell failed to implement and record changes in methods and procedures needed to correct and prevent identified quality problems as required by 21 C.F.R. § 820.100(a)(5).

135. FDA determined Strattice devices had failed mechanical testing.

136. FDA determined LifeCell failed to identify and address the root cause of the mechanical testing failures and assess the training needs of your operators.

137. FDA determined LifeCell had sealing problems.

138. FDA determined LifeCell did not resolve those issues properly.

139. FDA determined LifeCell failed to establish procedures for identifying training needs and to ensure that all personnel are trained to adequately perform their assigned responsibilities, as required by 21 C.F.R. § 820.25(b).

140. FDA determined LifeCell failed to establish and maintain procedures to adequately control environmental conditions that could reasonably be expected to have an adverse effect on product quality, as required by 21 C.F.R. § 820.70(c).

141. FDA determined LifeCell failed to establish and maintain procedures for analyzing reports from all sources of quality data to identify existing and potential causes of nonconforming product or other quality problems, as required by 21 C.F.R. § 820.100(a)(1).

142. FDA determined lots (as in units) of Strattice devices failed endotoxin testing.

143. FDA determined LifeCell failed to establish and maintain procedures for adequately inspecting, testing, or otherwise verifying incoming product as conforming to specified requirements, as required by 21 C.F.R. § 820.80(b).

144. LifeCell continued marketing its devices after this inspection.

145. For the full year of 2009, Regenerative Medicine revenue increased 18%, compared to the prior year on a pro forma basis.

146. Total Strattice sales in the fourth quarter of 2009 increased $12.1 million, or 80%, from the same period one year ago.

147. In March 2010, LifeCell started a study, "A Multicenter, Prospective, Single-Blind, Randomized, Controlled Study of the Repair of Challenging Abdominal Wall Defects: Strattice (TM) TM in Abdominal Wall Repair."

148. The purpose was to compare the incidence of post-repair wound related

complications, including hernia occurrence/recurrence, between challenging abdominal wall defects repaired with Strattice Reconstructive Tissue Matrix and those managed by standard repair.

149. It was hypothesized that the use of Strattice TM to reinforce the repair would reduce the incidence of these post-repair complications.

150. It was a prospective, multicenter, single-blind, randomized, longitudinal, cross-over evaluation of the repair of challenging abdominal wall defects using Strattice TM or standard surgical repair.

151. The abdominal wall defects could be acute or chronic, and include midline, transverse (including flank) as well as Pfannenstiel incisions.

152. Hernia occurrence was to be assessed by clinical evaluation.

153. At the 12$^{th}$ month and at any time during the study if hernia occurrence was clinically suspected, a magnetic resonance image (MRI) would be obtained.

154. Patients with a need of surgical intervention for repair of (potentially) contaminated abdominal wall defect of >3cm and <22cm in length, where the viscera have not been exposed for more than 15 days in case of open abdomen (skin and fascia open) could be included in the study.

155. Patients with severe systemic sepsis, frank pus in the wound, a fistula that will not be closed at the time of surgery or intra-abdominal abscess in surgical area, ongoing necrotizing pancreatitis, on chronic immunosuppressive therapy, or other medication that influences wound healing, requiring only short-term temporary closure, requiring a synthetic, non-absorbable mesh to close the abdominal wall defect, undergo general anesthesia, that had other major organ system dysfunction or disorder that would jeopardize subject completing the 24 month study, and that were unable to undergo an MRI scan were to be excluded.

156. Results were published in 2013.

157. The study was terminated, allegedly because "surgical practice evolution changed acceptable standard of care and lead to potential enrollment bias."

158. FDA inspected LifeCell Corporation again from November 2, 2010, to November 12, 2010.

159. The purpose of that inspection was to determine whether LifeCell's activities as sponsor of the clinical study "A Prospective, Multicenter, Randomized, Controlled, Third Party-Blinded Study of Strattice Fascial Inlay to Prevent Parastomal Hernia Formation in Patients Undergoing Surgery for Permanent Abdominal Wall Ostomies (PriSm)" complied with applicable federal regulations.

160. The inspection was conducted under a program designed to ensure that data and information contained in requests for Investigational Device Exemptions (IDE), Premarket Approval (PMA) applications, and Premarket Notification submissions (510(k)) are scientifically valid and accurate.

161. Another objective of the program is to ensure that human subjects are protected from undue hazard or risk during the course of scientific investigations.

162. The inspection revealed serious violations of Title 21, Code of Federal Regulations (21 CFR) Part 812--Investigational Device Exemptions, and Section 520(g) (21 U.S.C. 360j(g)) of the Food, Drug, and Cosmetic Act.

163. LifeCell began using human beings as research subjects without first submitting an application to FDA.

164. The issue was that FDA cleared the product to reinforce soft tissue weakness, and

that the indications for use were for only the repair of hernias and/or body wall defects which require the use of reinforcing or bridging material to obtain the desired surgical outcome.

165. By comparison, Defendants were studying "the device was being studied for use to prevent (not reinforce) parastomal hernias, and for cases where use of a bridging or reinforcing material is not required (unlike the FDA-cleared indications for use where use of a bridging or reinforcing material is required)."

166. To the extent Defendants promoted the product in this way, it constitutes off label marketing.

167. LifeCell initiated a Class 3 recall of Strattice Reconstructive Tissue Matrix on July 12, 2010, just three years after it was introduced and months after FDA's inspection.

168. In its description of the product in its recall, LifeCell noted that "Strattice is intended for use as a foil tissue patch to reinforce soft tissue where weakness exists and for the surgical repair of damaged or ruptured soft tissue membranes. It is used for repair of hernias and/or body wall defects which require the use of reinforcing or bridging material to obtain the desired surgical outcome."

169. LifeCell represented that the recall was due to employee error.

170. Specifically, one lot of the product was labeled as 8 cm x 8 cm when in fact it was actually cut using a 6 cm x 6 cm template.

171. On May 9, 2011, LifeCell Corporation received a warning letter from FDA dated May 5, 2011.

172. The warning letter was a result of the November 2010 inspection.

173. The warning letter related to a failure to submit required documentation to the FDA

prior to conducting certain clinical studies.

174. The FDA also identified certain observed non-compliance with FDA regulations covering the promotion of LifeCell's Strattice/LTM product in relation to these studies.

175. A written response to the FDA on May 31, 2011, updated the FDA regarding corrective actions supposedly undertaken.

176. As part of these corrective actions, a clinical study Investigational Device Exemption (IDE) was filed with the FDA.

177. LifeCell initiated a Class 2 recall of the Strattice Reconstructive Tissue Matrix for Stoma Reinforcement on July 13, 2011, a year after the first recall.

178. LifeCell described the product in its recall as "intended for use as a soft tissue patch to reinforce soft tissue where weakness exists and for the surgical repair or damaged or ruptured soft tissue membranes."

179. This was a notification to users of potential off label use.

180. Specifically, the use of Strattice for stoma reinforcement at the time of stoma creation is not within the product's cleared indications for use in the U.S. market.

181. To market for that use, LifeCell would need to submit a PMA (pre-market approval) application.

182. Defendants never submitted a PMA for their hernia mesh products.

183. LifeCell began notifying their customers by phone on July 13, 2011.

184. Recall Notice Letters and return response forms dated July 12, 2011, were sent out on the same day.

185. If customers had product affected by the recall, they were to contact Customer

Solutions at 1-866-423-2433 to arrange for return of the product to LifeCell.

186. A Recall Notification form should have been completed and returned.

187. In September 2013, a company called LifeNet Health sued LifeCell in the U.S. District Court for the Eastern District of Virginia, Norfolk Division.

188. LifeNet alleged that Strattice infringed on its U.S. Patent No. 6,569,200, or the '200 Patent.

189. On November 18, 2014, a jury found that the '200 Patent was valid and was infringed.

190. The jury awarded LifeNet $34.7 million in damages.

191. Through the foregoing experiences, and through the exercise of reasonable care, including by adherence to industry standards, in the design, manufacture, marketing, and post market management such as post market surveillance, of the product, Defendants knew or should have known of the risks and limitations of Strattice.

192. Defendants knew or should have known that Strattice could, would, and did injure people.

193. Defendants knew or should have known that Strattice did not perform as well as safer alternative products.

194. Defendants knew or should have known that the product may create a significant inflammatory reaction, an inability to infiltrate the mesh, and resultant encapsulation.

195. Defendants knew or should have known that the product is prone to cell infiltration, degradation, and replacement by scar.

196. Scar, over time presents a higher risk to the formation of elastin which results in

stretching.

197. As a result, this leads to bulging and ultimately hernia recurrence.

198. Defendants' product's design, consisting of biologic materials, increased the susceptibility for this complication.

199. Defendants knew or should have known that the product had a high susceptibility to fluid accumulation and inflammation significantly raising the risk for infection.

200. Fluid accumulation prevents also the ingrowth and incorporation of the mesh.

201. This rendered Defendants' biologic mesh useless.

202. As a result, the patient will be as if no repair surgery occurred.

203. Defendants knew or should have known that the product creates an environment for greater susceptibility for infections, which increases the rate, severity, and duration of said infections requiring further surgery and/or removal of the product.

204. Defendants knew or should have known that the product causes significant tissue ingrowth into the organs of the abdominal cavity which then leads for a significant risk of adhesions.

205. Adhesions result in bowel obstructions, bowel resections, organ damage, infections, severe and chronic pain, and the need for more complicated future surgeries.

206. Defendants knew or should have known the product does not perform at any higher an efficacy rate for hernia repair than that of suture.

207. Defendants knew or should have known the product compares unfavorably to synthetic meshes.

208. Defendants knew or should have known that the product would elicit an

inflammatory response.

209. Before placing the product into the marketplace, Defendants were required to mitigate, including any element of its design that could render the device ineffective, increased bacterial adherence to the device, decrease the body's ability to properly clear toxins, or increase or prolong inflammation once the device is implanted, which would result in an increase in adhesion formation, scar tissue formation, pain, wound complications, bowel complications, seromas, hernia recurrence, fluid accumulation, infection, and/or the need for early surgical revision.

210. Defendants designed, manufactured, and marketed the product despite a lack of data, testing and warnings properly describing the true effects of biologic mesh on patients in a clinical setting, which if done would show an increase of a myriad of complications, including, but not limited to, infection, adhesions, tumor formation, chronic pain, mesh shrinkage, bowel obstruction, and early hernia recurrence.

211. Moreover, available data to Defendants demonstrated over several years the increased risk of the use of biologic mesh with little efficacy over traditional suture repair.

212. Defendants made several representations about the product's safety.

213. Defendants claimed for example that Strattice was "The industry leader for biological tissue matrices in complex abdominal wall reconstruction."

214. Defendants avowed Strattice is an acellular reconstructive tissue matrix derived from pig skin, which undergoes allegedly non-damaging proprietary processing to remove cells and significantly reduces the key component believed to play a major role in the xenogeneic rejection response.

215. Defendants stated Strattice has an internal matrix that "behaves like a natural scaffold for tissue remodeling by the host until it is completely substituted by the host's mature and newly formed tissue, theoretically making it more physiologic than synthetic prostheses."

216. Defendants represented that it was suitable for transplantation into a human, when in fact it was not suitable for many people.

217. Defendants claimed the Strattice Extra Thick mesh was the strongest Strattice Tissue Matrix when it was the newest member of the LifeCell abdominal wall portfolio.

218. Defendants averred further that the extra thick mesh has the same biologic response as Strattice.

219. Defendants stated, "The LifeCell process minimizes damage to the tissue matrix in order to support tissue regeneration and retain the tissue's native properties out of the package."

220. Regarding Tissue Matrix Laparoscopic (TML), Defendants claimed that "Because ease of use, strength, and performance all matter in a laparoscopic biological mesh, [they] developed Strattice Tissue Matrix Laparoscopic (TML) for laparoscopic ventral hernia repair. Prepared with the same proprietary processing as Strattice Tissue Matrix, Strattice TML provides the same regenerative benefits with a thickness more suitable for laparoscopic handling."

221. Defendants declared that the Strattice Perforated mesh, Reconstructive Tissue Matrix (RTM) Perforated[,] delivers the regenerative performance you have come to expect from Strattice Tissue Matrix, and is now perforated to help meet your surgical needs."

222. Defendants maintained further that the RTM Perforated mesh was manufactured using the same proprietary LifeCell tissue processing technology as Strattice Tissue Matrix, a process that retains the integrity of the matrix to support tissue regeneration, as shown in an animal

study."

223. Defendants did not disclose all studies known or knowable to them.

224. Defendants did not disclose their failure to study the product thoroughly.

225. Defendants did not disclose the lack and/or inadequacy of human clinical studies and findings.

226. Defendants withheld information about the risks associated with Strattice and its lack of comparative efficacy.

**COUNT ONE – DESIGN DEFECT AGAINST ALL DEFENDANTS**

227. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

228. Defendants' Strattice product is inherently dangerous and defective, unfit and unsafe for its intended and reasonably foreseeable use, and does not meet or perform to the expectations of consumers.

229. Strattice's design creates risks to the health and safety of the consumers that are far more significant and devastating than the risks posed by other products on the market.

230. There are practical, feasible, and reasonable alternative designs.

231. Defendants have intentionally and recklessly designed, marketed, labeled, sold and distributed the product with wanton and willful disregard for the rights and health of Plaintiff and others, and with malice, placing their economic interests above the health and safety of Plaintiff and others similarly situated.

232. Defendants expected the product to, and it did in fact, reach physicians and patients, including Plaintiff and Plaintiff's physicians, without substantial alteration, change or modification

in its condition.

233. The Strattice product Plaintiff's surgeon used reached Plaintiff without substantial change in its condition.

234. Defendants knew hernia repair involves a complex patient population.

235. The product was marketed specifically for difficult cases.

236. The goal was to provide patients with the best repair the first time to prevent subsequent complex issues.

237. However, biologic mesh such as the product at issue suffers from various design flaws including, but not limited to:

a. Lack of strength or durability;

b. Vulnerability to laxity and stretching;

c. Susceptibility to infection;

d. Difficulty in surgeon handling; and

e. Difficulty in robot surgery/LAP

238. Studies recognize a significant recurrence rate within a year or two.

239. For example, one study found 22% and 33% recurrence rates at 12 and 24 months follow up.

240. Strattice mesh has a particularly high recurrence rate that is many times the rate of other products.

241. Indeed, as reported by others, the table below presents recurrence data for biological matrix and resorbable synthetic mesh products used in ventral repairs.

| Product Name | Tissue Reinforcement Material | Hernia Recurrence Rate[1] | Number of Hernia Recurrence[1] | Number of Patients who Completed Follow-up[1] | Follow-up Period in Months |
|---|---|---|---|---|---|
| Phasix[1] | Resorbable Synthetic Mesh | 5% | 5 | 95 | 12 |
| Phasix[1] | Resorbable Synthetic Mesh | 12% | 11 | 95 | 18 |
| Phasix[1] | Resorbable Synthetic Mesh | 23% | 19 | 82 | 36 |
| Strattice[1] | Biologic Matrix | 22% | 15 | 69 | 12 |
| Strattice[1] | Biologic Matrix | 33% | 22 | 67 | 24 |

242. The dangers associated with Strattice outweigh any supposed benefits of the way it was designed and marketed.

243. Strattice is defective and unreasonably dangerous in light of its utility and its risks.

244. Strattice is defective and unreasonably dangerous in light of the expectations of consumers, including Plaintiff.

245. Strattice was designed defectively when it was implanted into Plaintiff's body.

246. Strattice is designed defectively today.

247. Strattice is designed defectively in part because it was:

a. Designed to absorb into the body and incorporate and fails to do so when used in clinical settings as described in the IFU and promoted by Defendants;

b. Designed in such a way that led to greater risk of seromas and fluid collection;

c. Designed in such a way that could cause infection; and

d. Designed in such a way that the mesh could grow into the patient's skin, causing scar tissue and becoming either unremovable or requiring the need for removal.

248. Strattice is also defective and unreasonably dangerous for the following reasons:

a. Failing to be reasonably safe as intended to be and/or was used;

b. Having an inadequate design for the purpose of hernia repair in general, and for this specific patient population;

c. Containing unreasonably dangerous design defects, including the use of biologic material which does not properly support hernia repair nor absorb as intended without complications;

d. Using biologic materials, which leads to fluid collection, scar tissue formation, inflammation, adhesions, and tissue ingrowth;

e. Employing biologic materials that act as an incubator and growth source for the formation of fluid collection, bacteria and infection of the Strattice;

f. Including biologic materials, which, due to overly aggressive tissue ingrowth leading to organ and tissue attachment or adhesions – adhesions that may then lead to bowel obstruction and perforation resulting in pain and/or removal and revision;

g. Being inappropriately and/or inadequately tested pre and post market; and

h. Having a high propensity for adhesion formation, hernia recurrence, chronic pain, bowel complications, seroma formation, hematoma formation, infection, absence of proper incorporation, and extrusion.

249. At the time of Strattice's design, manufacture, marketing, and sale, technically feasible, practical, alternative, safer designs were known, knowable, and available.

250. Defendants had the ability to eliminate the unsafe character of the product without impairing its usefulness.

251. When the product left Defendants' control, the foreseeable risk of harm from the use of the product exceeded or outweighed the benefit or utility a consumer would expect, and/or it failed to comply with federal requirements for these medical devices.

252. Defendants had the ability to provide adequate, complete, and adequate information and to inform healthcare providers of the problems related to the product in many ways, including, but not limited to devices through e-mails, letters, recalls, warnings in product inserts, and/or through its product representatives, who work directly with surgeons.

253. Strattice mesh carries many additional risks and potential adverse reactions that safer alternatively designed meshes do not, such as an increased likelihood of infection, greater formation of scar tissue and issues with incorporation and aggressive ingrowth.

254. Additionally, the design choice by Defendants to use biologic instead of a synthetic material created greater risk in Strattice mesh for the rate of infection, adhesion formation, chronic pain, seroma formation, scar tissue formation, hematomas, bowel obstruction, hernia recurrence, foreign body response, extrusion, and other additional injuries.

255. Defendants knew or reasonably should have known about the following and that as a result, the product was unreasonably dangerous and defective when used as directed and designed.

256. The product was used for its intended purpose.

257. Defendants, as designer, manufacturer, distributor, promoter, marketer, and/or seller of medical devices, were experts in their field.

258. Defendants had superior knowledge about the product.

259. Defendants should have known that the product was unsuited to repair a hernia in Plaintiff.

260. Defendants have intentionally and recklessly designed, manufactured, marketed, labeled, sold and distributed the product with wanton and willful disregard for the rights and health of Plaintiff and others, and with malice, placing their economic interests above the health and safety of Plaintiff and others similarly situated.

261. Each product defect was a substantial and/or contributing factor to the Plaintiff's injuries and damages.

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

263. Defendants are strictly liable in tort to Plaintiff for their wrongful conduct

**COUNT TWO - FAILURE TO WARN AGAINST ALL DEFENDANTS**

264. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

265. At all pertinent times, the product was defective because it lacked appropriate and necessary warnings and instructions.

266. Plaintiff and/or Plaintiff's physicians used the product according to its intended or reasonably foreseeable purpose.

267. At the time Plaintiff and/or Plaintiff's physicians used the product, it had not been substantially altered since it left Defendants' control.

268. At all pertinent times, including at the time of sale and consumption, the product, when put to its reasonably foreseeable use, was in an unreasonably dangerous and defective condition because it failed to contain adequate and proper warnings and/or instructions regarding, among other things, the serious risk of bodily harm posed by the incompatibility of the material used to make the mesh and human blood and tissue or the serious risk of infection or serious scarring.

269. At all pertinent times, Defendants failed to provide the kind of warning or instruction which a reasonably prudent manufacturer or seller in the same or similar circumstance would have provided to people intended to use the product including Plaintiff and Plaintiff's healthcare providers.

270. At all pertinent times, Defendants' warnings or instructions failed to communicate sufficient information on the dangers of the product and how to use the product safely.

271. Defendants failed to adequately and properly warn and instruct Plaintiff and Plaintiff's physicians as to the risks and benefits of the product, including the following:

a. that the product is no more effective in repairing hernias than suture repair and carried a significantly higher risks for infection, scar tissue formation, recurrence, bowel obstruction and other serious risks leading to the need for revision and repair;

b. that the product creates fluid collection, inflammation, which results in seroma formation, potentiating infections;

c. that the biologic materials used in Strattice mesh created significant tissue ingrowth and adhesions leading to bowel complications, significant pain and the need for revision and repair;

d. that the product may create significant scar tissue resulting in elastin creation which results in bulging and recurrence of hernias;

e. that for patients who have more complicated comorbidities or higher risk surgeries, biologic mesh is inferior to synthetic mesh in hernia repair, as opposed to how they promoted it as more effective for that patient population;

f. that Defendants did not adequately study and/or test the product and/or its labeling, including the lack of clinical trials concerning its safety; and

g. that the product was ineffective at preventing adhesions; the biologic materials would create a greater risk for fluid collection and inflammation thus leading to infections.

272. Defendants failed to warn and instruct health care professionals and the public, including Plaintiff and Plaintiff's implanting physician, adequately of the true risks, problems associated with, and proper safe uses of the product.

273. Defendants failed to and warn of and instruct about material facts regarding the safety, efficacy, and proper usage of the product.

274. Defendants failed to provide adequate instructions and training concerning the safe and effective use of the product timely, reasonably, and adequately.

275. Had Defendants provided adequate warnings or instructions, those warnings would have been heeded and Plaintiff would not have received the product.

276. The product was defective due to inadequate post-marketing warnings and/or instructions because Defendants knew or should have known that there was reasonable evidence of an association between the product and infections, dense adhesion formation, seromas, fluid collection, scar tissue formation, and hernia recurrence, causing serious injury and pain.

277. Defendants knew or should have known that the product was also defective due to inadequate post-marketing warnings and/or instruction regarding the increased risk of failure resulting in revision/removal surgery, or an inability to perform such surgery because of the attendant risks.

278. The Strattice mesh IFU has a section for 'Warnings' and 'Precautions', which fail to mention any of the significant risks of using biologic mesh products.

279. Not all possible adverse reactions are listed.

280. Defendants' labeling provided inadequate information about the product. Defendant's label offered only the following "precautions":

a. Discard these products if mishandling has caused possible damage or contamination, or the products are past their expiration date.

b. Ensure these products are placed in a sterile basin and covered with room temperature sterile saline or room temperature sterile lactated Ringer's solution for a minimum of 2 minutes prior to implantation in the body.

c. Place these products in maximum possible contact with healthy, well-vascularized tissue to promote cell ingrowth and tissue remodeling.

d. These products should be hydrated and moist when the package is opened. If the surgical mesh is dry, do not use.

281. The label noted further that certain considerations should be used when performing surgical procedures using a surgical mesh product:

a. Consider the risk/benefit balance of use in patients with significant co-morbidities; including but not limited to, obesity, smoking, diabetes, immunosuppression, malnourishment, poor tissue oxygenation (such as COPD), and pre- or post-operative radiation.

b. Bioburden-reducing techniques should be utilized in significantly contaminated or infected cases to minimize contamination levels at the surgical site, including, but not limited to, appropriate drainage, debridement, negative pressure therapy, and/or antimicrobial therapy prior and in addition to implantation of the surgical mesh. In large abdominal wall defect cases where midline fascial closure cannot be obtained, with or without separation of components techniques, utilization of the surgical mesh in a bridged fashion is associated with a higher risk of hernia recurrence than when used to reinforce fascial closure.

c. For Strattice RTM Perforated, if a tissue punch-out piece is visible, remove using aseptic technique before implantation. For Strattice RTM

Laparoscopic, refrain from using excessive force if inserting the mesh through the trocar."

282. Defendants currently provide five-step instructions for preparing the product:

**PREPARATION INSTRUCTIONS**

1. Open the carton and remove the foil package.
2. Peel open the outer foil package and remove the inner foil pouch using aseptic technique. The inner foil pouch is sterile and may be placed directly into the sterile field.
3. Open the inner pouch carefully and aseptically remove the surgical mesh. Always use sterile gloved hands or forceps when handling the surgical mesh.
4. Soak the device for a **minimum of 2 minutes** using a sterile basin and sufficient room temperature sterile saline or room temperature sterile lactated Ringer's solution to cover the surgical mesh.
5. Store the surgical mesh in the room temperature sterile solution until ready for implantation. Device can be stored in sterile solution for a maximum of 4 hours.

283. Defendants currently provide six-step instructions for implanting the product:

**IMPLANTATION INSTRUCTIONS**

1. Prepare the surgical site using standard techniques. As with any surgical implant, careful aseptic technique should be practiced and contact of the mesh with patient's skin should be minimized.
2. The surgical mesh may be folded, trimmed or cut as required to fit the surgical site using aseptic technique, ensuring allowance for overlap.
3. Transfer the surgical mesh to the surgical site using sterile gloved hands or forceps.
4. Suture the surgical mesh into place.

**NOTE:** Tension and suture placement are application dependent. For hernia repair applications, surgical experience with soft tissue implants indicates that suturing STRATTICE™ TM under physiologic tension with a minimum of 3cm–5cm overlap or as much as required to reach healthy adjacent tissues, may produce improved outcomes. Use of permanent sutures is recommended.

5. Complete the standard surgical procedure.
6. Discard any unused portions of the surgical mesh as per institutional procedures.

284. The foregoing has been in place since July 2017.

285. Defendants also sell the Strattice BPS Reconstructive Tissue Matrix.

286. Strattice BPS Reconstructive Tissue Matrix ("Strattice BPS" or "the surgical mesh") is a surgical mesh that is derived from porcine skin and is processed and preserved in a patented phosphate buffered aqueous solution containing matrix stabilizers. This device is designed to perform as a surgical mesh for soft tissue repair while presenting a scaffold for cellular and microvascular ingrowth. Strattice BPS consists of terminally sterilized sheet of processed porcine dermal matrix provided in a prescribed geometric configuration and packaged in a double pouch configuration. Use of Strattice BPS provides for an implant that is strong and biocompatible for its intended use and which will incorporate into the recipient tissue with associated cellular and microvascular in-growth. Animal studies show a low incidence in adhesion to the Strattice BPS surgical mesh based on observation of minimal visceral tissue attachment.

287. The product's indications for use state that the Strattice BPS is intended for use as a soft tissue patch to reinforce soft tissue where weakness exists and for the surgical repair of damaged or ruptured soft tissue membranes. The implant is intended for reinforcement of soft tissue in plastic and reconstructive surgery.

288. Only patients with a known sensitivity to porcine material or Polysorbate 20 are contraindicated.

289. The label warns only against resterilizing and against use if the package was opened or damaged, the seal was broken or compromised, or the temperature monitoring device does not display "OK."

290. Additionally, the label states, "[d]o not reuse once the surgical mesh has been removed from the packaging and/or is in contact with a patient. This increases risk of patient-to-patient contamination and subsequent infection."

291. The product contains the following "precautions":

a. Discard the surgical mesh if mishandling has caused possible damage or contamination.

b. Discard if the surgical mesh is past its expiration date.

c. Ensure that the surgical mesh is placed in a sterile basin and covered with room temperature sterile saline or room temperature sterile lactated Ringer's solution for a minimum of 2 minutes prior to implantation in the body.

d. Place the surgical mesh in maximum possible contact with healthy, well-vascularized tissue to promote cell ingrowth and tissue remodeling.

e. The surgical mesh should be hydrated and moist when the package is opened. If the surgical mesh is dry, do not use.

f. Certain considerations should be used when performing surgical procedures using a surgical mesh product: – Consider the risk/benefit balance of use in patients with significant co-morbidities; including but not limited to, obesity, smoking, diabetes, immunosuppression, malnourishment, poor tissue oxygenation (such as COPD), and pre- or postoperative radiation. – As standard practice, bioburden-reducing techniques should be utilized in significantly contaminated or infected cases to minimize contamination

levels at the surgical site, including, but not limited to, appropriate drainage, debridement, negative pressure therapy, and/or antimicrobial therapy prior and in addition to implantation of the surgical mesh.

292. Defendants provide five-step instructions for preparing the product.

**PREPARATION INSTRUCTIONS**

1. Open the carton and remove the foil package.
2. Peel open the outer foil package and remove the inner foil pouch using aseptic technique. The inner foil pouch is sterile and may be placed directly into the sterile field.
3. Open the inner pouch carefully and aseptically remove the surgical mesh. Always use sterile gloved hands or forceps when handling the surgical mesh.
4. Soak the device for a **minimum of 2 minutes** using a sterile basin and sufficient room temperature sterile saline or room temperature sterile lactated Ringer's solution to cover the surgical mesh.
5. Store the surgical mesh in the room temperature sterile solution until ready for implantation. Device can be stored in sterile solution for a maximum of 4 hours.

293. Defendants provide six-step instructions for implanting the product:

**IMPLANTATION INSTRUCTIONS**

1. Prepare the surgical site using standard techniques. As with any surgical implant, careful aseptic technique should be practiced and contact of the mesh with the patient's skin should be minimized.
2. The surgical mesh may be folded, trimmed or cut as required to fit the surgical site using aseptic technique, ensuring allowance for overlap.
3. Transfer the surgical mesh to the surgical site using sterile gloved hands or forceps.
4. Secure the surgical mesh into place.
5. The surgical mesh should be placed in good approximation with healthy adjacent tissues without leaving potential spaces for fluid accumulation between the mesh and the adjacent tissues. Care should be taken to avoid placing the mesh adjacent to ischemic or poorly vascularized tissues whenever possible.
6. Complete the standard surgical procedure.
7. Discard any unused portions of the surgical mesh as per institutional procedures.

294. Unique to this model, Defendants produce two post-op care recommendations.

295. First, "[p]roper post-operative care may include the use of appropriate drainage and negative pressure therapy.

296. Second, "[a]s with any post-operative care, aseptic technique should be practiced when required to minimize contamination to the surgical wound."

297. The foregoing has been in place since July 2017.

298. A third type of Strattice mesh is the Strattice Reconstructive Tissue Matrix Extra Thick.

299. The Reconstructive Tissue Matrix Extra Thick is also made from pig skin and is processed and preserved in a patented phosphate buffered aqueous solution containing matrix stabilizers.

300. This device is designed to perform as a surgical mesh for soft tissue repair while presenting a scaffold to the patient.

301. The structural properties minimize tissue attachment to the mesh.

302. This product consists of a terminally sterilized sheet of processed porcine dermal matrix.

303. This device is provided in prescribed geometric configurations and packaged in a double pouch configuration.

304. Defendants claim that use of Strattice provides for an implant that is strong, biocompatible and will incorporate into the recipient tissue with associated cell and microvascular ingrowth.

305. Defendants represent that animal studies show a low incidence in adhesion to the Strattice surgical mesh based on observation of minimal visceral tissue attachment.

306. Defendants present the indications as use as "intended for use as a soft tissue patch to reinforce soft tissue where weakness exists and for the surgical repair of damaged or ruptured

soft tissue membranes. Indications for use include the repair of hernias and/or body wall defects which require the use of reinforcing or bridging material to obtain the desired surgical outcome."

307. Defendants contraindicated the product for patients with known sensitivity to pig material or Polysorbate 20.

308. The only warnings are:

a. Do not resterilize. Discard all open and unused portions of the device.

b. Do not use if the package is opened or damaged.

c. Do not use if seal is broken or compromised.

d. Do not use if the temperature monitoring device does not display "OK".

e. Do not reuse once the surgical mesh has been removed from the packaging and/or is in contact with a patient because this allegedly increases risk of patient-to-patient contamination and subsequent infection.

309. Defendants presented the following "precautions":

a. Discard the surgical mesh if mishandling has caused possible damage or contamination.

b. Discard if the surgical mesh is past its expiration date.

c. Ensure that the surgical mesh is placed in a sterile basin and covered with room temperature sterile saline or room temperature sterile lactated Ringer's solution for a minimum of 2 minutes prior to implantation in the body.

d. Place the surgical mesh in maximum possible contact with healthy, well-vascularized tissue to promote cell ingrowth and tissue remodeling.

e. The surgical mesh should be hydrated and moist when the package is opened. If the surgical mesh is dry, do not use.

f. Certain considerations should be used when performing surgical procedures using a surgical mesh product: – Consider the risk/benefit balance of use in patients with significant co-morbidities; including but not limited to, obesity, smoking, diabetes, immunosuppression, malnourishment, poor tissue oxygenation (such as COPD), and pre- or postoperative radiation. – As standard practice, bioburden-reducing techniques should be utilized in significantly contaminated or infected cases to minimize contamination levels at the surgical site, including, but not limited to, appropriate drainage, debridement, negative pressure therapy, and/or antimicrobial therapy prior and in addition to implantation of the surgical mesh. – In large abdominal wall defect cases where midline fascial closure cannot be obtained, with or without separation of components techniques, utilization of the surgical mesh in a bridged fashion is associated with a higher risk of hernia recurrence than when used to reinforce fascial closure.

310. Defendants provide five preparation instructions:

**PREPARATION INSTRUCTIONS**

1. Open the carton and remove the foil package.
2. Peel open the outer foil package and remove the inner foil pouch using aseptic technique. The inner foil pouch is sterile and may be placed directly into the sterile field.
3. Open the inner pouch carefully and aseptically remove the surgical mesh. Always use sterile gloved hands or forceps when handling the surgical mesh.
4. Soak the device for a **minimum of 2 minutes** using a sterile basin and sufficient room temperature sterile saline or room temperature sterile lactated Ringer's solution to cover the surgical mesh.
5. Store the surgical mesh in the room temperature sterile solution until ready for implantation. Device can be stored in sterile solution for a maximum of 4 hours.

311. Defendants provide the following implantation instructions

**IMPLANTATION INSTRUCTIONS**

1. Prepare the surgical site using standard techniques. As with any surgical implant, careful aseptic technique should be practiced and contact of the mesh with patient's skin should be minimized.
2. The surgical mesh may be folded, trimmed or cut as required to fit the surgical site using aseptic technique, ensuring allowance for overlap.
3. Transfer the surgical mesh to the surgical site using sterile gloved hands or forceps.
4. Suture the surgical mesh into place.

**NOTE:** Tension and suture placement are application dependent. For hernia repair applications, surgical experience with soft tissue implants indicates that suturing STRATTICE™ TM under physiologic tension with a minimum of 3cm–5cm overlap or as much as required to reach healthy adjacent tissues, may produce improved outcomes. Use of permanent sutures is recommended.

5. Complete the standard surgical procedure.
6. Discard any unused portions of the surgical mesh as per institutional procedures.

312. The foregoing has been in place since July 2017.

313. The fourth type of Strattice mesh currently available is the Reconstructive Tissue Matrix Laparoscopic.

314. It is a surgical mesh that is derived from porcine skin and is processed and preserved in a patented phosphate buffered aqueous solution containing matrix stabilizers.

315. The product was designed to perform as a surgical mesh for soft tissue repair while presenting a scaffold to the patient.

316. The structural properties supposedly minimize tissue attachment to the mesh.

317. Defendants explained that Strattice consists of a terminally sterilized sheet of processed porcine dermal matrix. This device is provided in prescribed geometric configurations and packaged in a double pouch configuration.

318. Defendants represented that, use of Strattice provides for an implant that is strong, biocompatible and will incorporate into the recipient tissue with associated cell and microvascular ingrowth.

319. Defendants averred that animal studies show a low incidence in adhesion to the Strattice surgical mesh based on observation of minimal visceral tissue attachment.

320. The indications for use state that it is intended for use as a soft tissue patch to reinforce soft tissue where weakness exists and for the surgical repair of damaged or ruptured soft tissue membranes. Indications for use include the repair of hernias and/or body wall defects which require the use of reinforcing or bridging material to obtain the desired surgical outcome during open or laparoscopic procedures.

321. Defendants contraindicated the product for patients with known sensitivity to pig material or Polysorbate 20.

322. The current label contains only the following “warnings:”

## WARNINGS

- **Do not resterilize.** Discard all open and unused portions of the device.
- **Do not use** if the package is opened or damaged.
- **Do not use** if seal is broken or compromised.
- **Do not use** if the temperature monitoring device does not display "OK".
- **Do not reuse** once the surgical mesh has been removed from the packaging and/or is in contact with a patient. This increases risk of patient-to-patient contamination and subsequent infection.
- After use, handle and dispose of all unused product and packaging in accordance with accepted medical practice and applicable local, state and federal laws and regulations.

323. The current label contains the following "precautions":

## PRECAUTIONS

- Discard the surgical mesh if mishandling has caused possible damage or contamination.
- Discard if the surgical mesh is past its expiration date.
- Ensure that the surgical mesh is placed in a sterile basin and covered with room temperature sterile saline or room temperature sterile lactated Ringer's solution for a **minimum of 2 minutes** prior to implantation in the body.
- Place the surgical mesh in maximum possible contact with healthy, well-vascularized tissue to promote cell ingrowth and tissue remodeling.
- The surgical mesh should be hydrated and moist when the package is opened. If the surgical mesh is dry, do not use.
- Certain considerations should be used when performing surgical procedures using a surgical mesh product:
  - Consider the risk/benefit balance of use in patients with significant co-morbidities; including but not limited to, obesity, smoking, diabetes, immunosuppression, malnourishment, poor tissue oxygenation (such as COPD), and pre- or post-operative radiation.
  - As standard practice, bioburden-reducing techniques should be utilized in significantly contaminated or infected cases to minimize contamination levels at the surgical site, including, but not limited to, appropriate drainage, debridement, negative pressure therapy, and/or antimicrobial therapy prior and in addition to implantation of the surgical mesh.
  - In large abdominal wall defect cases where midline fascial closure cannot be obtained, with or without separation of components techniques, utilization of the surgical mesh in a bridged fashion is associated with a higher risk of hernia recurrence than when used to reinforce fascial closure.
  - Refrain from using excessive force if inserting through the trocar.

324. Defendants identified the following five-step instructions for preparation.

**PREPARATION INSTRUCTIONS**

1. Open the carton and remove the foil package.
2. Peel open the outer foil package and remove the inner foil pouch using aseptic technique. The inner foil pouch is sterile and may be placed directly into the sterile field.
3. Open the inner pouch carefully and aseptically remove the surgical mesh. Always use sterile gloved hands or forceps when handling the surgical mesh.
4. Soak the device for a **minimum of 2 minutes** using a sterile basin and sufficient room temperature sterile saline or room temperature sterile lactated Ringer's solution to cover the surgical mesh.
5. Store the surgical mesh in the room temperature sterile solution until ready for implantation. Device can be stored in sterile solution for a maximum of 4 hours.

325. Defendants identified the following six-step instructions for implantation.

**IMPLANTATION INSTRUCTIONS**

1. Prepare the surgical site using standard techniques. As with any surgical implant, careful aseptic technique should be practiced and contact of the mesh with patient's skin should be minimized.
2. The surgical mesh may be folded, trimmed or cut as required to fit the surgical site using aseptic technique, ensuring allowance for overlap.
3. Transfer the surgical mesh to the surgical site using sterile gloved hands or forceps.
4. Suture and/or tack the surgical mesh into place.

**NOTE:** Tension and suture placement are application dependent. For hernia repair applications, surgical experience with soft tissue implants indicates that suturing STRATTICE™ TM under physiologic tension with a minimum of 3cm–5cm overlap or as much as required to reach healthy adjacent tissues, may produce improved outcomes. Use of permanent sutures is recommended. The choice of fixation device and fixation method should be determined by surgeon preference and the nature of the reconstruction to provide for adequate tissue fixation.

5. Complete the standard surgical procedure.
6. Discard any unused portions of the surgical mesh as per institutional procedures.

326. The foregoing has been in place since July 2017.

327. The fifth Strattice mesh is the Reconstructive Tissue Matrix Perforated ("TM").

328. It is a surgical mesh that is derived from porcine skin and is processed and preserved in a patented phosphate buffered aqueous solution containing matrix stabilizers.

329. It allegedly consists of a terminally sterilized sheet of processed porcine dermal matrix.

330. This device is designed to perform as a surgical mesh for soft tissue repair while presenting a scaffold to the patient.

331. Defendants claim the structural properties minimize tissue attachment to the mesh.

332. This device is provided in prescribed geometric configurations and packaged in a double pouch configuration.

333. Defendants claim that use of Strattice provides for an implant that is strong, biocompatible and will incorporate into the recipient tissue with associated cell and microvascular ingrowth.

334. Defendants represent that animal studies show a low incidence in adhesion to the Strattice surgical mesh based on observation of minimal visceral tissue attachment.

335. The indications for use state that it is intended for use as a soft tissue patch to reinforce soft tissue where weakness exists and for the surgical repair of damaged or ruptured soft tissue membranes. Indications for use include the repair of hernias and/or body wall defects which require the use of reinforcing or bridging material to obtain the desired surgical outcome.

336. The current only contraindication is against patients with a known sensitivity to porcine material and/or Polysorbate 20.

337. The current label contains only the following warnings:

## WARNINGS

- **Do not resterilize.** Discard all open and unused portions of the device.
- **Do not use** if the package is opened or damaged.
- **Do not use** if seal is broken or compromised.
- **Do not use** if the temperature monitoring device does not display "OK".
- **Do not reuse** once the surgical mesh has been removed from the packaging and/or is in contact with a patient. This increases risk of patient-to-patient contamination and subsequent infection.
- After use, handle and dispose of all unused product and packaging in accordance with accepted medical practice and applicable local, state and federal laws and regulations.

338. The current label contains the following "precautions":

## PRECAUTIONS

- Discard the surgical mesh if mishandling has caused possible damage or contamination.
- Discard if the surgical mesh is past its expiration date.
- Ensure that the surgical mesh is placed in a sterile basin and covered with room temperature sterile saline or room temperature sterile lactated Ringer's solution for a **minimum of 2 minutes** prior to implantation in the body.
- Place the surgical mesh in maximum possible contact with healthy, well-vascularized tissue to promote cell ingrowth and tissue remodeling.
- The surgical mesh should be hydrated and moist when the package is opened. If the surgical mesh is dry, do not use.
- Certain considerations should be used when performing surgical procedures using a surgical mesh product:
  - Consider the risk/benefit balance of use in patients with significant co-morbidities; including but not limited to, obesity, smoking, diabetes, immunosuppression, malnourishment, poor tissue oxygenation (such as COPD), and pre- or post-operative radiation.
  - As standard practice, bioburden-reducing techniques should be utilized in significantly contaminated or infected cases to minimize contamination levels at the surgical site, including, but not limited to, appropriate drainage, debridement, negative pressure therapy, and/or antimicrobial therapy prior and in addition to implantation of the surgical mesh.
  - In large abdominal wall defect cases where midline fascial closure cannot be obtained, with or without separation of components techniques, utilization of the surgical mesh in a bridged fashion is associated with a higher risk of hernia recurrence than when used to reinforce fascial closure.

339. Defendants identified the following five-step instructions for preparation.

**PREPARATION INSTRUCTIONS**

1. Open the carton and remove the foil package.
2. Peel open the outer foil package and remove the inner foil pouch using aseptic technique. The inner foil pouch is sterile and may be placed directly into the sterile field.
3. Open the inner pouch carefully and aseptically remove the surgical mesh. Always use sterile gloved hands or forceps when handling the surgical mesh.
4. Soak the device for a **minimum of 2 minutes** using a sterile basin and sufficient room temperature sterile saline or room temperature sterile lactated Ringer's solution to cover the surgical mesh.
5. Store the surgical mesh in the room temperature sterile solution until ready for implantation. Device can be stored in sterile solution for a maximum of 4 hours.

340. Defendants identified the following six-step instructions for implantation.

**IMPLANTATION INSTRUCTIONS**

1. Prepare the surgical site using standard techniques. As with any surgical implant, careful aseptic technique should be practiced and contact of the mesh with patient's skin should be minimized.
2. The surgical mesh may be folded, trimmed or cut as required to fit the surgical site using aseptic technique, ensuring allowance for overlap.
3. Transfer the surgical mesh to the surgical site using sterile gloved hands or forceps.
4. Suture the surgical mesh into place.

**NOTE:** Tension and suture placement are application dependent. For hernia repair applications, surgical experience with soft tissue implants indicates that suturing STRATTICE™ TM under physiologic tension with a minimum of 3cm–5cm overlap or as much as required to reach healthy adjacent tissues, may produce improved outcomes. Use of permanent sutures is recommended.

5. Complete the standard surgical procedure.
6. Discard any unused portions of the surgical mesh as per institutional procedures.

341. Defendant's labeling omits material information about the product and its usage.

342. Each product defect was a substantial and/or contributing factor to the Plaintiff's injuries and damages.

343. Had the Defendants disclosed that the use of the product would have significantly increased Plaintiff's risk of injuries, Plaintiff would not have received the Strattice mesh.

344. As a proximate result of Defendants' design, manufacture, marketing, sale, and distribution of the product, Plaintiff has suffered severe and permanent injuries, pain, suffering, loss of enjoyment of life, loss of care, comfort, and economic damages.

345. The development of Plaintiff's injuries were the direct and proximate result of the unreasonably dangerous condition of the product at the time of sale and consumption, including the lack of warnings; Plaintiff has suffered injuries and damages, including but not limited to severe and debilitating injuries, economic loss, medical damages, conscious pain and suffering, and other damages.

346. Defendants' product was defective because it failed to contain warnings and/or instructions, and breached express warranties and/or failed to conform to other express factual representation upon which the Plaintiff and Plaintiff's healthcare providers justifiably relied in electing to use the product.

347. The defect or defects made the product unreasonably dangerous to those persons, such as Plaintiff and Plaintiff's healthcare providers, who could reasonably be expected to use and rely upon the product.

348. As a result, the defect or defects, including the Defendants' failure to adequately warn or instruct, were a proximate cause of the Plaintiff's injuries and damages.

349. At all relevant times, Defendants' product failed to contain adequate warnings and/or instructions.

350. Defendants continue to market, advertise, and expressly represent to the general public that it is safe for healthcare providers, users, and consumers to use their product.

351. Defendants are liable to Plaintiff for their wrongful conduct under the doctrine of Strict Liability in Tort.

**COUNT THREE – NEGLIGENCE AGAINST ALL DEFENDANTS**

352. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

353. Plaintiff and Plaintiff's healthcare providers used the product in a foreseeable manner.

354. At all pertinent times, Defendants had a duty to exercise reasonable care to consumers and users, including Plaintiff and Plaintiff's healthcare providers, in the design, development, manufacture, testing, inspection, packaging, promotion, marketing, distribution, labeling and/or sale of the product, pre and post-marketing.

355. At all relevant times, Defendants had a duty to exercise reasonable care in the risk management of the product.

356. This required Defendants to adhere to an iterative process of identifying risks, controlling risks, and measuring the efficacy of those controls throughout the product lifecycle.

357. This required Defendants to conduct market surveillance, proactively.

358. This required Defendants to follow design controls.

359. This required Defendants to test the product, uses of it, and assess product users through human factors testing and other means.

360. This required Defendants to follow industry standards.

361. LifeCell's unique product gave rise to additional duties, including because of representations Defendants made about the product, including that it was intended for particularly difficult hernias and patient populations.

362. Standard risk management practices required Defendants to identify and eliminate risks, including of injuries from the product, failure of the product, and problems using the product safely.

363. To identify risks, Defendants had to study the product and its intended users, test the product, and identify, obtain, and monitor information about the product throughout its product lifecycle, including post-market.

364. In doing the foregoing, Defendants had to identify and follow industry standards in the design, research, development, manufacture, inspection, labeling, marketing, promotion, and post-market management of the product.

365. Standard risk management practices required Defendants to identify and eliminate risks, including of injuries from the product, failure of the product, and problems using the product safely.

366. For example, proper testing and/or a reasonably careful search and review of the scientific and medical literature, and other information, would have indicated the following:

a. implanting materials next to the bowel and other organs which fails to incorporate results in fluid collection and an inflammatory response;

b. bacteria can easily reside and feed on the biologic materials used in Strattice mesh;

c. biologic mesh is associated with higher rates of severe infections, especially when used in high-risk patients;

d. biologic mesh creates an environment that bacteria feeds on;

e. once biologic mesh is infected, it must be removed;

f. adhesions form as a result of overly aggressive tissue ingrowth;

g. biologic mesh has no better efficacy than suture repair when used in clinical patients and carries increased risks as compared to many synthetic meshes;

h. all subsequent operations carry a greater risk of infection after the patient has been infected as a result of Strattice mesh; and

i. biologic materials used in Strattice mesh leads to inflammation, fluid collection, seromas and scar tissue formation all of which increase the risk for the need for unnecessary revision and removal.

367. Being a medical device product intended to be implanted in human beings without any expiration period, Defendants also had specific, widely accepted duties.

368. Defendants had a duty to individuals, including Plaintiff, to use reasonable care throughout each of the stages in the continuous lifecycle of the product.

369. Defendants had a duty to report information it had about its product, including problems using it, failures, and injuries associated with it.

370. Defendants had to conduct testing and study controls designed to control risks or issues associated with use of the product.

371. Defendants had to change the design of the product, which includes its labeling, a broad term that includes more than just its label.

372. Defendants breached the aforementioned duties by failing to undertake a reasonable risk management program that assured safe design, manufacture, marketing, labeling, packaging, and/or use of the product.

373. Defendants breached their duties by failing to warn of the risks, dangers, and proper uses of the product.

374. Defendants breached their duties by failing to modify the design of the product, including to employ safer alternative designs.

375. Defendants breached their duties by failing to instruct users regarding how to use the product safely and properly.

376. Defendants breached their duties by failing to disclose shortcomings in the product's efficacy.

377. Defendants breached their duties by failing to heed calls for at least a national, if not international, registry of patients to monitor risks.

378. Defendants failed to test the product and use of it.

379. Had Defendants properly and adequately tested the product, they would have discovered that:

a. the biologic mesh was ineffective at preventing adhesion formation;

b. the biologic materials comprising the mesh lead to fluid collection, inflammation and risk of infection and thus the design of Strattice increases the risk of infection and adverse outcomes;

c. the Strattice mesh creates the risk for significant scar tissue formation that leads to potential for bowel obstruction and other complications necessitating removal or reconstruction; and

d. the Strattice mesh may fail to incorporate and absorb properly into the body correctly leading to complications and a lack of support, whereby its efficacy rate is no better than that of suture repair; and these defects result in bowel obstructions, seromas, fistulas, infections, erosion, extrusion and a pronounced foreign body response, among other complications.

380. Defendants failed to perform or otherwise facilitate studying and testing of the product and did not reveal and/or concealed testing and research data and/or the lack thereof, in part by revealing available data selectively and misleadingly.

381. Defendants breached their duties by failing to warn of the risks, dangers, and proper uses of the product.

382. At all pertinent times, Defendants knew or should have known that the product is unreasonably dangerous and defective when put to its reasonably anticipated use.

383. Defendants knew or reasonably should have known that the product:

a. carried a significantly higher rate and severity of infections compared to other available and feasible alternatives;

b. would incite a severe and chronic inflammatory response if placed near the bowel;

c. is susceptible to a greater rate of adhesion to surrounding organs and lack of incorporation;

d. may not properly absorb into the body;

e. does not provide adequate reinforcement compared to synthetic mesh;

f. presented a greatest risk for complications;

g. was not as efficacious as alternative products; and

h. would require removal, which would necessitate further future medical care.

384. Defendants were negligent in marketing, designing, manufacturing, producing, supplying, inspecting, testing, selling and/or distributing the product in one or more of the following respects:

a. By failing to warn and instruct Plaintiff, Plaintiff's healthcare providers, and the public of the risks, dangers, and proper uses of the product;

b. By failing to modify the design of the product, including to employ safer alternative designs;

c. By failing to conduct testing and study controls designed to control risks or issues associated with use of the product;

d. By failing to change the design of the product, which includes its labeling, which is a broad term that includes more than just its label;

e. By failing to undertake a reasonable risk management program that assured safe design, manufacture, marketing, labeling, packaging, and/or use of the product, including through implementation of corrective and prevention actions and adequate risk controls;

f. By failing to heed calls for at least a national, if not international, registry of patients to monitor risks;

g. By failing to remove the product from the market with the Defendants knew or should have known the product was defective;

h. By failing to properly test the product to determine adequacy and effectiveness of safety measures, if any, prior to releasing the product for consumer use;

i. By failing to properly test the product to determine the increase risk of harm to users and consumers such as Plaintiff during the normal and/or intended use of the product; and

j. By failing to act like a reasonably prudent medical device company under similar circumstances.

385. Each and all of these acts and omissions, taken singularly or in combination, were a proximate cause of the injuries and damages sustained by Plaintiff.

386. It was feasible for Defendants to add additional information about the product to its label, change the product design, or employ a safer alternative design.

387. Instead, Defendants put profits above patient safety.

388. The acts and omissions were substantial and/or contributing factors to the Plaintiff's injuries and damages.

389. Without Defendants' product, and as a direct result of it, Plaintiff was injured.

390. As a direct and proximate result of the Defendants' negligence, Plaintiff and Plaintiff's healthcare providers used the product that directly and proximately caused his injuries.

391. As a direct and proximate result of the Defendants' negligence, Plaintiff was permanently injured and was caused to incur medical bills, conscious pain and suffering, economic loss, and loss of enjoyment of life.

392. As a direct and proximate result of the Defendants' negligence in one or more of the aforementioned ways, Plaintiff requires future medical care and will incur future medical bills and costs.

**COUNT FOUR - NEGLIGENT MISREPRESENTATION AGAINST ALL DEFENDANTS**

393. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

394. Defendants made material misrepresentations to Plaintiff's physician in written and oral form, through materials and representatives.

395. Reassurances of product safety were made through Defendants' labeling, selling, sales representatives and distributors, word-of-mouth from Defendants' agents and/or users influenced by the foregoing, and/or through promotional materials, advertising, and/or marketing efforts.

396. This occurred directly and indirectly through word of mouth originating with Defendants.

397. Defendants had a duty to accurately and truthfully represent to the medical and healthcare community, Plaintiff, and the public, that the product had been tested and found to be safe and effective for its intended and ordinary use. The representations made by Defendants, in fact, were false.

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

399. Defendants breached their duty in misrepresenting the product's risks, efficacy, and proper/appropriate uses.

400. As a foreseeable, direct and proximate result of the negligent misrepresentation of Defendants as set forth herein, Defendants knew or should have known that the product had be insufficiently tested, or had not been tested at all, and that the product lacked adequate and accurate warning, and that it created a high risk, and/or higher than acceptable risk, and/or higher than reported and represented risk, of adverse side effects.

401. Defendants represented negligently and omitted material facts concerning the product.

402. Defendants knew or should have known that their misrepresentations were false and that their omissions were misleading.

403. Defendants failed to exercise reasonable care in obtaining and communicating truthful, complete, and accurate information.

404. The foregoing occurred with the intent to encourage and/or with the effect of encouraging use of the product and to profit.

405. Plaintiff and/or Plaintiff's physicians justifiably relied on the misrepresentations and concealments.

406. As a direct and proximate result of Defendants' conduct, Plaintiff has been injured and suffered and will continue to suffer injuries, pain, suffering, loss of enjoyment of life, economic damages, and other losses.

**COUNT FIVE – FRAUD AGAINST ALL DEFENDANTS**

407. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

408. As alleged in this Complaint, Defendants' agents knowingly, intentionally, directly, and/or impliedly materially misrepresented that the product was safe for permanent implantation and effective for the use to which it was put. Defendants also omitted information regarding these matters.

409. Specifically, Defendants' sales representatives detailed Plaintiff's implanting surgeon prior to Plaintiff's surgery in 2018, and orally in writing represented that the Strattice mesh was safe, superior to the alternative products available at the time, and appropriate for specific uses, including in challenging and other specific kinds of cases.

410. At the same time, Defendants and their representatives fraudulently omitted material facts regarding the risks Defendants knew or should have known were associated with Strattice mesh.

411. When Defendants made these material representations and omissions, they knew those representations and/or omissions were false, deceptive, and misleading.

412. Defendants made these material misrepresentations with the intent that Plaintiff, Plaintiff's healthcare providers, and the public would rely on them.

413. Plaintiff, Plaintiff's healthcare providers, and the public reasonably and justifiably relied upon the misrepresentations and/or omissions reasonably believing the information they had was complete and accurate, and relying, justifiably, upon these misrepresentations and/or the absence of necessary information.

414. Defendants are liable for their agents' conduct and/or omissions, including, but not limited to, their employees and servants.

415. As a direct and proximate result of Defendants' fraud and fraudulent conduct, Plaintiff suffered and will continue to suffer injuries, damages, and losses as alleged herein.

**COUNT SIX – BREACH OF EXPRESS WARRANTY AGAINST ALL DEFENDANTS**

416. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

417. Defendants expressly warranted and made assurances described herein that the product was safe and effective for reasonably anticipated uses, including but not limited to the following:

a. The product was superior to other products.

b. The product was more effective than synthetic mesh; and

c. The product was effective for difficult hernia mesh cases.

418. The product did not conform to these express representations because it causes the injuries as alleged herein.

419. Plaintiff and/or his health care providers chose the product based upon Defendants' warranties and representations regarding the safety and fitness of its product.

420. Plaintiff individually and/or by and through his health care providers, reasonably relied upon Defendants' express warranties and guarantees that the product was safe, merchantable, and reasonably fit for its intended purposes and for the uses to which it was applied.

421. Defendants breached these express warranties because the product was unreasonably dangerous and defective as described herein and failed to perform as Defendants represented.

422. Defendants' breach of its express warranties resulted in the implantation of an unreasonably dangerous and defective product.

423. As a direct and proximate result of the Defendants' breach of warranty, Plaintiff and/or his health care providers purchased and used, as aforesaid, the product that directly and proximately caused his injuries as alleged herein and Plaintiff was caused to incur past and future medical expenses, lost wages, conscious pain and suffering, and other damages.

**COUNT SEVEN – BREACH OF IMPLIED WARRANTIES AGAINST ALL DEFENDANTS**

424. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

425. At the time the Defendants manufactured, marketed, labeled, promoted, distributed and/or sold the product, the Defendants knew of the uses for which the product was intended and impliedly warranted the product to be of merchantable quality and safe for such use.

426. Defendants breached their implied warranties of the product because it was not fit for its common, ordinary and intended purpose and uses.

427. Defendants impliedly warranted that the subject mesh was merchantable and was fit for the ordinary purposes for which it was intended.

428. When the mesh was implanted in Plaintiff to treat a hernia, the products were being used for the ordinary purpose for which they were intended.

429. Plaintiff, individually and/or by and through Plaintiff's healthcare providers, relied upon Defendants' implied warranties of merchantability in consenting to have the subject mesh implanted.

430. Defendants breached these implied warranties of merchantability because the product was neither merchantable nor suited for its intended uses as warranted.

431. Defendants' breach of their implied warranties resulted in the implantation of an unreasonably dangerous and defective product that placed Plaintiff's health and safety in jeopardy.

432. As a direct and proximate result of the Defendants' breach of implied warranties, Plaintiff and/or Plaintiff's health care providers purchased and used, as aforesaid, the product that directly and proximately caused Plaintiff's injuries as alleged herein and Plaintiff was caused to incur past and future medical expenses, economic damages, conscious pain and suffering, and other damages.

**COUNT EIGHT – VIOLATION OF CONSUMER PROTECTION LAWS AGAINST ALL DEFENDANTS**

433. 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:

434. Plaintiff and/or Plaintiff's physicians purchased and used the Defendants' product. Plaintiff thereby suffered ascertainable losses as a result of Defendants' actions in violation of the consumer protection laws.

435. Had Defendants not engaged in the deceptive conduct described herein, Plaintiff would not have purchased and/or received the product, and would not have incurred related medical costs and injuries.

436. Defendants engaged in wrongful conduct while at the same time obtaining, under false pretenses, money from Plaintiff for the product that would not have been used had Defendants not engaged in unfair and deceptive conduct.

437. Defendants' unfair methods of competition and/or deceptive acts or illegal practices include but are not limited to the following:

a. Representing that the product had characteristics, materials, uses, benefits, and/or qualities that it did not have;

b. Advertising the product with the intent not to sell it as advertised; and

c. Engaging in fraudulent or deceptive conduct that created a likelihood of confusion and/or misunderstanding.

438. Plaintiff was injured by the cumulative and indivisible nature of Defendants' conduct.

439. The cumulative effect of Defendants' conduct directed at patients, physicians, and consumers created demand for and ultimately caused the sale of the product. Each aspect of Defendants' conduct combined to artificially create sales of the product.

440. Defendants have a statutory duty to refrain from unfair or deceptive acts or trade practices in the design, labeling, development, manufacture, promotion, and sale of the product.

441. Defendants' deceptive, unconscionable, or fraudulent representations and material omissions to patients, physicians and consumers, including Plaintiff, constituted unfair and deceptive acts and trade practices in violation of the state consumer protection statutes listed.

442. Defendants' actions and/or omissions, as complained of herein, constitute unfair competition or unfair, unconscionable, deceptive or fraudulent acts, or trade practices in violation of state consumer protection statues.

443. Defendants have engaged in unfair competition or unfair or deceptive acts or trade practices or have made false representations in violation of applicable consumer protection laws.

444. Under these statutes, Defendants are the suppliers, manufacturers, advertisers, and sellers, who are subject to liability under such legislation for unfair, deceptive, fraudulent and unconscionable consumer sales practices.

445. Defendants violated the statutes that were enacted to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising, by knowingly and falsely representing that the product was fit to be used for the purpose for which it was intended, when in fact it was defective and dangerous, and by other acts alleged herein.

446. Defendants knowingly and falsely representing that the Defendants' Hernia Mesh Products were fit to be used for the purpose for which they were intended, when in fact they were defective and dangerous, and by other acts alleged herein. These representations were made in marketing and promotional materials.

447. Defendants had actual knowledge of the defective and dangerous condition of the product and failed to take any action to cure such defective and dangerous conditions.

448. Plaintiff and the medical community relied upon Defendants' misrepresentations and omissions in determining which product and/or procedure to undergo and/or perform, if any.

449. Defendants' deceptive, unconscionable or fraudulent representations and material omissions to patients, physicians and consumers, constituted unfair and deceptive acts and practices.

450. Had Defendants not engaged in the deceptive conduct described above, Plaintiff would have been exposed to the product.

451. The actions and omissions of Defendants alleged herein are uncured or incurable deceptive acts under the statues enacted in the states to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising.

452. By reason of the unlawful acts engaged in by Defendants, and as a direct and proximate result thereof, Plaintiff has suffered ascertainable losses and damages.

453. As a direct and proximate result of Defendants' violations of consumer protection laws, Plaintiff sustained economic losses and other damages, and therefore is entitled to statutory and compensatory damages in an amount to be proven at trial.

454. Plaintiff pleads a common law cause of action for consumer fraud.

**COUNT NINE – PUNITIVE DAMAGES AGAINST ALL DEFENDANTS**

455. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

456. Plaintiff is entitled to punitive damages because Defendants' wrongful acts and/or omissions were wanton or in conscious disregard of the rights of others. Defendants misled both the medical community and the public at large, including Plaintiff, by making false representations

about the safety and utility of the product and by failing to provide adequate warnings or instructions concerning its use.

457. The Defendants have acted willfully, wantonly, with an evil motive, and recklessly in one or more of the following ways as alleged herein.

458. Defendants knew of the unreasonably high risk of injury posed by the product before manufacturing, marketing, distributing, and/or selling the product, yet purposefully proceeded with such action.

459. Despite Defendants' knowledge of the high risks associated with the product as outlined in this Complaint, Defendants affirmatively minimized this risk through marketing and labeling.

460. Through the actions outlined in this Complaint, Defendants expressed a reckless indifference to the safety of users of the Product and the Plaintiff. Defendants' conduct, as described herein, knowing the dangers and risks of the product, yet concealing and/or omitting this information, was outrageous because of Defendants' evil motive or a reckless indifference to the safety of users of the product.

461. The Defendants' conduct was a conscious disregard for the rights, safety and welfare of the medical community and others including Plaintiff. The Defendants acted with willful and wanton disregard for the safety of the Plaintiff. The Defendants' conduct constitutes gross negligence. Defendants ' gross negligence was a proximate cause of Plaintiff's injuries, and as such the Defendants are liable for exemplary and punitive damages.

462. Defendants' failure to investigate and/or warn about the harm caused by the product has resulted in hundreds, if not thousands of unnecessary injuries. The number and scope of those

injured by Defendants' reckless disregard for human life is hard to quantify, because Defendants have actively concealed those injuries.

463. Defendants had actual and subjective awareness of the risk involved, but nevertheless proceeded to market the product with conscious indifference to the rights, safety or welfare of others, including Plaintiff.

464. Throughout the course of Defendants' its acts and omissions, Defendants served only its own interest, having reason to know and consciously disregarding a substantial risk that their conduct might significantly injure Plaintiff.

465. Defendants consciously pursued a course of conduct knowing that it created a substantial risk of significant bodily harm to Plaintiff and other patients.

466. Defendants' failure to identify and control risks associated with the product and its conscious decision to not test the product and its usage, and to withhold information about the product, reflected a wanton and willful disregard of persons who would foreseeably be harmed.

467. Defendants intentionally misrepresented its product, intentionally failed to follow basic risk management practices to keep patients safe, and intentionally refused to modify the design, limit its usage, and convey compete and accurate information in their labeling.

468. Defendants acted and failed to act knowing there was a high degree of probability of harm to another and reckless indifference to the consequences of such act or omission.

469. Even if Defendants' conduct was not extremely dangerous, which it was, it knew, or as a reasonable company should have known, that their actions and inactions were dangerous.

470. Defendants knew, or through the exercise of due care, including through simple study and testing, that there was a likelihood at the relevant time that their conduct would result in serious harm.

471. Even after learning of the risks, Defendants failed to act. Indeed, the issues persist to this very day.

472. Defendants acted with deliberate indifference of a substantial risk of significant harm to Plaintiff.

473. Defendants acted with an evil mind in the ways described above and in the following ways, among others:

a. Using surgeons and patients as unwitting guinea pigs by promoting the product at issue for permanent human implantation, close to vital organs, without disclosing that insufficient scientific studies had been done to determine their safety for such uses;

b. Ignoring complaints and/or adverse event reports revealing safety risks;

c. Representing the product was effective for difficult hernia cases when in fact it is no more efficacious than synthetic mesh;

d. Refusing to prevent scores of patients from developing significant complications by failing to notify users regarding the risks posed by the product;

e. Pursuing profits by selling additional product despite the known dangers; and

f. Maintaining a defective design despite feasible safer alternative designs;

474. The above listed ways indicate a pattern and practice of the Defendants, to place corporate profits over health and well-being of users and consumers such as Plaintiff. Such a pattern and practice has been followed by the Defendants regarding the product.

475. As a direct and proximate result of the malicious, willful, wanton, evilly motivated and/or reckless conduct of the Defendants, the Plaintiff has sustained damages as set forth above.

**TOLLING PRESCRIPTION**

476. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

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

478. The discovery rule applies to this case.

479. The running of any statute of limitations has been equitably tolled by reason of Defendants' fraudulent concealment and conduct.

480. Through their affirmative misrepresentations and omissions, Defendants actively concealed from Plaintiff the true risks associated with its product.

481. As a result of Defendants' actions, Plaintiff and Plaintiff's prescribing 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.

482. Defendants are estopped from relying on any statute of limitations because of their concealment of the truth regarding the safety of Strattice mesh. Defendants were under a duty to

disclose the true character, quality and nature of the product because this was non-public information over which they continue to have exclusive control. Defendants knew that this information was not available to Plaintiff, medical providers and/or health facilities, yet they failed to disclose the information to the public.

483. Defendants had the ability to and did spend enormous amounts of money in furtherance of their purposes of marketing and promoting profitable products, notwithstanding the known or reasonably knowable risks. Plaintiff and medical professionals could not have afforded to and could not have possibly conducted studies to determine the nature, extent, and identity of related health risks, and they were forced to rely on Defendants' representations.

## PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for relief as follows:

1) Compensatory damages in excess of the jurisdictional requirements of this Court;
2) Economic damages in the form of medical, incidental, and hospital expenses, out of pocket expenses, lost wages, and other economic damages in an amount to be determined at trial of this action;
3) For a full refund of all purchase's costs Plaintiff paid for the device;
4) Punitive damages in an amount in excess of any jurisdictional minimum of this Court and in an amount sufficient to impress upon Defendants the seriousness of its conduct and to deter similar conduct in the future;
5) Attorneys' fees, expenses, and costs of the action; and
6) Such further relief as the Court deems necessary, just, and proper.

## DEMAND FOR TRIAL BY JURY

Plaintiff demands a trial by jury as to all issues so triable.

DATED this 10th day of February, 2022.

Respectfully Submitted,

/s/ Derek T. Braslow, Esq.
Derek T. Braslow, Esq.
Brian Ketterer, Esq. (*pro hac vice to be filed)*
Justin Brown, Esq. (*pro hac vice to be filed)*
Robert E. Price, Esq. (*pro hac vice to be filed)*
Whitney Butcher, Esq. (*pro hac vice to be filed)*
**KETTERER, BROWNE & ASSOCIATES**
336 S. Main Street
Bel Air, MD 21014
Phone: 850-805-7011
brian@kbaattorneys.com
justin@kbaattorneys.com
robert@kbaattorneys.com
whitney@kbaattorneys.com

Chad Ihrig, Esq. (*pro hac vice to be filed)*
**NIX PATTERSON, LLP**
3600 N. Capital of Texas Highway
Suite B350
Austin, TX 78746
Phone: 512-328-5333
cihrig@nixlaw.com

Edward "Ned" Mulligan, Esq. (*pro hac vice to be filed)*
Jonathan A. Knoll, Esq. (*pro hac vice to be filed)*
**COHEN & MALAD, LLP**
One Indiana Square; Suite 1400
Indianapolis, IN 46204
Phone: 317-636-6481
Fax: 317-636-2593
nmulligan@cohenandmalad.com
jknoll@cohenandmalad.com