Kristy M. Arevalo, State Bar No. 216308
MCCUNE·WRIGHT·AREVALO, LLP
3281 East Guasti Road, Suite 100
Ontario, California 91761
Telephone: (909) 557-1250
Facsimile: (909) 557-1275

Attorney for Plaintiff

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SHARI ANNETTE JORDEN, Plaintiff, v. COVIDIEN, LP., and MEDTRONIC, INC., Defendants.	Case No.: **COMPLAINT FOR MONEY DAMAGES** **1) STRICT LIABILITY – FAILURE TO WARN** **2) NEGLIGENCE** **JURY TRIAL DEMANDED**

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

1. This is a medical device tort action brought on behalf of the above-named Plaintiff arising out of the failure of Defendants' hernia mesh product, the Covidien Parietex Optimized Composite Mesh ("Parietex Optimized Composite Mesh"). As a result, Plaintiff Shari Annette Jorden ("Plaintiff") has suffered permanent injuries and significant pain and suffering, emotional distress, lost wages and earning capacity, and diminished quality of life. Plaintiff respectfully seeks all damages to which she may be legally entitled.

STATEMENT OF PARTIES

2. Plaintiff is, and was, at all relevant times, a citizen and resident of San Jose, California, Santa Clara County, and the United States.

3. Covidien, LP, ("Covidien") is a Limited Partnership organized under the laws of Delaware and has its principal place of business in Mansfield, Massachusetts. Covidien manufactures, distributes, and services medical devices, including medical devices known as the Parietex Optimized Composite Mesh, a medical device implanted to treat persons like Plaintiff for hernias. The general partner of Covidien is Covidien Holding Inc., a for-profit corporation organized under the laws of Delaware with its principal place of business in Mansfield, Massachusetts.

4. Medtronic, Inc. ("Medtronic") is incorporated in Minnesota and has its principal place of business in Minneapolis, Minnesota. Medtronic is a medical device company involved in the design, manufacturing, marketing, packaging, labeling, and sale of medical devices.

5. In January 2015, Medtronic acquired Covidien. From that point forward, Medtronic has been responsible for the actions of Covidien and exercised control over Covidien's functions specific to the oversight of and compliance with applicable safety standards relating to and including the Parietex Optimized Composite Mesh sold in the United States. In such capacity, Medtronic committed or allowed to be committed tortious and wrongful acts, including the violation of numerous safety standards relating to device manufacturing, quality assurance/control, and conformance with design and manufacturing specifications. Medtronic's misfeasance and malfeasance, including failure to warn the public of known problems with their products, caused Plaintiff to suffer injury and damages.

6. Covidien and Medtronic (collectively referred to as "Defendants") are individually, jointly and severally liable to Plaintiff for damages suffered by Plaintiff arising from their design, manufacturing, marketing, labeling, distribution, sale, and placement of the defective Parietex Optimized Composite Mesh at issue in this suit. All acts were effectuated directly and indirectly through Defendants' respective agents, servants, employees, officers, and owners, acting within the course and scope of their representative agencies, services, employments, and/or ownership.

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

VENUE AND JURISDICTION

8. This Court has diversity subject matter jurisdiction pursuant to 28 U.S.C. § 1332(a).

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

10. Defendants have conducted, and continue to conduct, substantial business in the State of California and in this District; distribute Covidien Products in this District; receive substantial compensation and profits from sales of Covidien Products in this District; and make material omissions and misrepresentations and breaches of warranties in this District, so as to subject them to personal jurisdiction in this District.

11. Covidien and Medtronic are registered to transact business in California.

FACTS COMMON TO ALL COUNTS

12. On or about December 17, 2014, Plaintiff underwent laparoscopic ventral hernia repair by Dr. Jong-Ping Lu at Kaiser Permanente Santa Clara Medical Center in Santa Clara, California. A piece of Parietex Optimized Composite Mesh, Cat. No. PCO3020X, Lot No. PNB0318 was implanted in Plaintiff during this repair.

13. Defendants manufactured, sold, and/or distributed the Parietex Optimized Composite Mesh to Plaintiff, through Plaintiff's physician, to be used for the treatment of hernia repair.

14. Plaintiff continued to suffer from abdominal pain after her hernia repair in December 2014.

15. On or about June 21, 2017, Plaintiff returned to Kaiser Permanente Santa Clara Medical Center with concerns that the hernia was recurring and requested to follow-up with Dr. Jong-Ping Lu.

16. Plaintiff returned to Kaiser Permanente Santa Clara Medical Center on or about May 16, 2018, again with concerns that the hernia was recurring and requested to follow-up with Dr. Jong-Ping Lu. Plaintiff reported that she had a lump in her abdomen, and she could not push it back in.

17. On or about July 5, 2018, Plaintiff returned to see Dr. Jong-Ping Lu. Upon examination, Dr. Jong-Ping Lu noted that Plaintiff did have a recurrent ventral hernia and scheduled a repair for Plaintiff's hernia.

18. On or about September 19, 2018, Plaintiff underwent repair of her recurrent ventral hernia and partial removal of the failed Parietex Optimized Composite Mesh at Kaiser Permanente Santa Clara Medical Center in Santa Clara, California by Dr. Jong-Ping Lu. During the procedure, Dr. Jong-Ping Lu noted "superior to the hernia was mesh that was divided. The omentum was noted to be adherent to the anterior abdominal wall and to the prior mesh which was well incorporated."

19. Even after the removal of the Parietex Optimized Composite Mesh, Plaintiff continues to suffer severe abdominal pain associated with the failed Parietex Optimized Composite Mesh.

20. Defendants' Parietex Optimized Composite Mesh is a two-sided composite mesh with an absorbable collagen barrier on the visceral side and a hydrophilic three-dimensional polyester textile on the parietal side used in the treatment of hernias such as laparoscopic ventral hernia repair.

21. Defendants claim that the Parietex Optimized Composite Mesh is coated with a protective absorbable collagen barrier to help prevent tissue attachment. However, the absorbable collagen barrier on the visceral side of the Parietex Optimized Composite Mesh fails to protect the body from the hydrophilic three-dimensional polyester textile on the parietal side because the absorbable collagen barrier breaks down after coming in contact with moisture.

22. Defendants claim that the Parietex Optimized Composite Mesh incites true tissue integration rather than inflammatory encapsulation and is optimized to minimize

shrinkage. However, the composition of polyester in the Parietex Optimized Composite Mesh is weak. It tears easily during handling and is known to unravel causing the polyester fibers to detach and travel to other parts of the body inciting an inflammatory response. Further, the Parietex Optimized Composite Mesh contracts over time causing tension to increase where secured by tacks and sutures resulting in tearing.

23. Contrary to the representations of Defendants, Parietex Optimized Composite Mesh has a high rate of failure, injury, and complication; fails to perform as intended; and causes severe and irreversible injuries like those suffered by Plaintiff.

24. Defendants applied for clearance from the United States Food and Drug Administration ("FDA") to market the Parietex Optimized Composite Mesh pursuant to Section 510(k) of the Food, Drug, and Cosmetic Act. The Section 510(k) process allowed Defendants to skip pre-market clinical studies and research intended to ensure the safety of the Parietex Optimized Composite Mesh. The approval of the Parietex Optimized Composite Mesh was based on a substantial equivalence to legally marketed predicate devices.

25. Defendants' predecessor product to the Parietex Optimized Composite Mesh, The Parietex Composite, is a polyester based hernia mesh with a delicate collagen film. In 2011, Defendants came out with the Parietex Optimized Composite Mesh. The Parietex Optimized Composite Mesh was intended to fix problems with the regular Parietex Composite. In the Parietex Optimized Composite Mesh 510(k) submitted to the FDA, Defendants explained that, the "Parietex Optimized Composite Mesh has been modified compared to the predicate devices as the knitting textile has been modified to obtain a higher mechanical resistance of the mesh and the collagen film formulation has been changed to get a film more resistant to handling." However, the Parietex Optimized Composite Mesh has the same problems and results in the same complications as the regular Parietex Composite. With both versions of the Parietex Composite hernia mesh, the collagen film is ineffective at protecting the bowel, the polyester tears easily, and the mesh doesn't properly incorporate into the abdominal wall. Defendants failed to warn

the public, including Plaintiff and her physician, of these known problems with the Parietex Optimized Composite Mesh.

26. During the Section 510(k) process, in the "Indications for Use", Defendants represented to the FDA and the public, including Plaintiff and her physician, that, "The PARIETEX Optimized Composite mesh is used for the reinforcement of tissues during surgical repair. It is indicated for the treatment of incisional hernias, abdominal wall repair and parietal (i.e. pertaining to the walls) reinforcement of tissues. The non-absorbable three-dimensional polyester mesh provides long term reinforcement of soft tissues. On the opposite side, the absorbable hydrophilic film minimizes tissue attachment to the mesh in case of direct contact with the viscera."

27. The FDA maintains a database of adverse incidents related to medical implants and devices and there are numerous reports documenting serious adverse events associated with the Parietex Optimized Composite Mesh. Defendants misrepresented the Parietex Optimized Composite Mesh as a safe and effective treatment for hernias; wrongly marketed the Parietex Optimized Composite Mesh as safer and more effective than other meshes or methods for hernia repair; failed to warn of known problems with the Parietex Optimized Composite Mesh; and improperly minimized the adverse effects of the Parietex Optimized Composite Mesh.

28. Defendants knew or should have known that Parietex Optimized Composite Mesh was not a safe and effective treatment for hernias. Defendants also knew or should have known that Parietex Optimized Composite Mesh was considerably more harmful and inadequate than other meshes or methods for hernia repair. Additionally, Defendants knew or should have known that the Parietex Optimized Composite Mesh was unreasonably dangerous as well as defective and likely to cause severe complications. Specifically, after known problems with the predecessor Parietex mesh and introduction of the Parietex Optimized Composite Mesh, Defendants knew and failed to warn the public about continued, similar problems with the revised Parietex Optimized Composite Mesh. Despite knowing that the newer Parietex mesh was causing the exact same

problems, in addition to mounting adverse events being reported on the FDA website, Defendants failed to warn the public, including Plaintiff and her physician, of the defects and problems with the Parietex Optimized Composite Mesh.

29. Defendants were responsible for the research, design, development, testing, manufacture, production, marketing, promotion, distribution, and sale of the Parietex Optimized Composite Mesh, including providing the warnings and instructions concerning the products.

30. Among the intended purposes for which Defendants designed, manufactured, and sold the Parietex Optimized Composite Mesh was use by surgeons for hernia repair surgeries. That is the purpose for which the Parietex Optimized Composite Mesh was implanted in Plaintiff.

31. Defendants represented to Plaintiff and Plaintiff's physicians that the Parietex Optimized Composite Mesh was a safe and effective product for hernia repair.

ESTOPPEL AND TOLLING OF STATUTE OF LIMITATIONS

32. Plaintiff incorporates the allegations in all prior paragraphs.

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

34. Plaintiff pleads that the discovery rule should be applied to toll the running of the statute until Plaintiff knew, or through the exercise of reasonable care and diligence should have known, of facts indicating her injury, the cause of the injury, and the tortious nature of the wrongdoing that caused the injury.

35. Despite diligent investigation by Plaintiff into the cause of her injuries, including consultations with Plaintiff's medical providers, the nature of the injuries and damages, and their relationship to the Parietex Optimized Composite Mesh, it was not discovered, and through reasonable care and diligence could not have been discovered, until a date within the applicable statute of limitations for filing Plaintiff's claims.

Therefore, under the appropriate application of the discovery rule, the action was filed well within the applicable statutory limitations period.

36. The running of the statute of limitations is tolled due to equitable tolling. Defendants are estopped from asserting a limitations defense due to their fraudulent concealment, through misrepresentations and omissions, from Plaintiff and Plaintiff's physicians of the true risks associated with the Parietex Optimized Composite Mesh. As a result of Defendants' fraudulent concealment, Plaintiff and her physicians were unaware, and could not have known or have learned through reasonable diligence, that Plaintiff had been exposed to the risks alleged in this Complaint, and that those risks were the direct and proximate result of Defendants' wrongful acts and omissions.

FIRST CAUSE OF ACTION

STRICT LIABILITY – FAILURE TO WARN

37. Plaintiff incorporates by reference the allegations in all prior paragraphs.

38. Defendants researched, developed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and otherwise released into the stream of commerce Parietex Optimized Composite Mesh and in the course of same, directly advertised or marketed the product to the FDA, healthcare professionals, consumers, and persons responsible for consumers, and therefore had a duty to warn of the risks associated with the use of the Parietex Optimized Composite Mesh.

39. Approximately a decade ago, the manufacturers of polypropylene based hernia meshes started to apply a coating to their meshes. Without conducting any human trials, the manufacturers launched the meshes claiming the coatings would protect the patient's underlying organs. The hernia mesh manufacturers were attempting to expand their markets. Less skilled surgeons could repair a hernia with mesh laparoscopically, but laparoscopic insertion required placing the mesh closer to the bowel. To keep up with its competitors, Defendants marketed the collagen film of the Parietex Optimized Composite Mesh as being an effective tissue barrier. However, the collagen film of the Parietex Optimized Composite Mesh undergoes contraction when it comes into contact

with fluids. Further, the instructions for use (IFU) for the Parietex Optimized Composite Mesh instruct surgeons to hydrate the Parietex Optimized Composite Mesh prior to implanting it. Not only does the collagen film contract, the protective collagen film easily tears while simply handling the mesh. The cheap, frail collagen film is tasked with the all-important duty of protecting a patient's vital organs. Defendants were aware of these problems, which is why they came out with the Parietex Optimized Composite Mesh in 2011, the mesh that was implanted into Plaintiff. The Parietex Optimized Composite Mesh 510(k) even admits that the new "collagen film formulation has been changed to get a film more resistant to handling." Unfortunately, the Parietex Optimized Composite Mesh still suffered from the same defects and caused the same injuries as its predecessor. Despite knowing this, Defendants failed to warn the public, including Plaintiff and her physicians, regarding these known problems.

40. Defendants' Parietex Optimized Composite Mesh is composed of a polyester material whose properties are designed to invite healthy tissue integration and mesh compliance. However, upon information and belief, Plaintiff alleges that the polyester used in the Parietex Optimized products is more likely to contract and cause severe inflammation than polypropylene, despite the coatings that have been applied. Additionally, Defendants knew or should have known that polyester is also less sturdy than polypropylene, creating difficulty during surgery.

41. Defendants' predecessor product to the Parietex Optimized Composite Mesh, The Parietex Composite mesh, is a polyester based hernia mesh with a delicate collagen film. In 2011, Defendants came out with the Parietex Optimized Composite Mesh. The Parietex Optimized Composite Mesh was intended to fix problems with the original Parietex Composite mesh. In the Parietex Optimized Composite Mesh 510(k) submitted to the FDA, Defendants explained that, the "Parietex Optimized Composite Mesh has been modified compared to the predicate devices as the knitting textile has been modified to obtain a higher mechanical resistance of the mesh and the collagen film formulation has been changed to get a film more resistant to handling." However, the

Parietex Optimized Composite Mesh has the same problems and results in the same complications as the regular Parietex Composite. With both versions of the Parietex Composite hernia mesh, the collagen film is ineffective at protecting the bowel, the polyester tears easily, the mesh contracts, and the mesh does not properly incorporate into the abdominal wall. Defendants failed to warn the public, including Plaintiff and her physicians, of these known problems with the Parietex Optimized Composite Mesh.

42. During the Section 510(k) process, in the "Indications for Use," Defendants represented to the FDA and the public, including Plaintiff and her physicians, that, "The PARIETEX Optimized Composite mesh is used for the reinforcement of tissues during surgical repair. It is indicated for the treatment of incisional hernias, abdominal wall repair and parietal (i.e. pertaining to the walls) reinforcement of tissues. The non-absorbable three-dimensional polyester mesh provides long term reinforcement of soft tissues. On the opposite side, the absorbable hydrophilic film minimizes tissue attachment to the mesh in case of direct contact with the viscera." Defendants failed to warn Plaintiff that it knew that the Parietex Optimized Composite Mesh did not, in fact, provide long term reinforcement of soft tissue while minimizing tissue attachment and performed in the opposite manner, causing a recurrent ventral hernia.

43. Moreover, Defendants were aware, and failed to warn, that Parietex Optimized Composite Mesh contracts over time, causing tension to increase where the tacks or sutures secure it. Eventually, the Parietex Optimized Composite Mesh will tear which is exactly what happened to Plaintiff's mesh and why she had to undergo a subsequent hernia repair surgery. Defendants were aware of this defect, which is why Defendants later came out with the Parietex ProGrip Mesh, which has "micro-hooks" so that tacks or sutures are no longer required.

44. The FDA maintains a database of adverse incidents related to medical implants and devices and there are numerous reports documenting serious adverse events associated with the Parietex Optimized Composite Mesh. Defendants misrepresented the Parietex Optimized Composite Mesh as a safe and effective treatment for hernias;

wrongly marketed the Parietex Optimized Composite Mesh as safer and more effective than other meshes or methods for hernia repair; failed to warn of known problems with the Parietex Optimized Composite Mesh; and improperly minimized the adverse effects of the Parietex Optimized Composite Mesh.

45. Defendants knew or should have known that Parietex Optimized Composite Mesh was not a safe and effective treatment for hernias. Defendants also knew or should have known that the Parietex Optimized Composite Mesh was considerably more harmful and inadequate than other meshes or methods for hernia repair. Additionally, Defendants knew or should have known that Parietex Optimized Composite Mesh was unreasonably dangerous as well as defective and likely to cause severe complications. Specifically, after known problems with the predecessor Parietex Composite mesh and introduction of the Parietex Optimized Composite Mesh, Defendants knew and failed to warn the public about continued, similar problems with the revised Parietex Optimized Composite Mesh, as well as the additional problems of contracture, separation, and tearing. Despite knowing that the newer Parietex Optimized Composite Mesh was causing the exact same problems, in addition to new problems, and mounting adverse events being reported on the FDA website, Defendants failed to warn the public, including Plaintiff and her physicians, of the defects and problems with the Parietex Optimized Composite Mesh.

46. On information and belief, Plaintiff alleges that Defendants failed to adequately warn healthcare professionals, including Plaintiff's surgeon, of the true risks of the Parietex Optimized Composite Mesh, including that the device had higher than normal rates of migration, contraction, and tearing, thus causing severe pain and injury and requiring further treatment, including surgical removal of the mesh.

47. When the Parietex Optimized Composite Mesh was implanted in Plaintiff's body, the warnings and instructions Defendants provided were inadequate and defective. As described above, there was an unreasonable risk that the product would not perform

safely and effectively for the purposes for which it was intended, and Defendants failed to provide adequate warnings and instructions concerning these risks.

48. Defendants expected and intended the Parietex Optimized Composite Mesh to reach users such as Plaintiff in the condition in which the product was sold.

49. Plaintiff and her physicians were unaware of the defects and dangers of the Parietex Optimized Composite Mesh and were unaware of the frequency, severity, and duration of the risks associated with the product.

50. Defendants provided no warning to physicians that the Parietex Optimized Composite Mesh's collagen barrier quickly disintegrates once implanted and then exposes bare polyester to any underlying organs. This results in dense adhesions to the bowel resulting in bowel obstructions, which are common with the Parietex Optimized Composite Mesh.

51. Defendants failed to adequately warn physicians that the Parietex Optimized Composite Mesh shrinks and contracts to a significant degree after it is implanted. The polyester fibers that create the Parietex are weaker than the titanium tacks or polypropylene sutures used to secure the mesh. Because of this, the polyester fibers will tear on the securing tacks or sutures after tension increases due to the mesh contracting. Once the mesh tears, the patient can re-herniate, and the mesh can migrate or ball up.

52. Defendants failed to adequately warn physicians of the significant risk of complications associated with mesh migration if the Parietex Optimized Composite Mesh is implanted in the abdomen to repair a hernia.

53. The Instructions for Use for the Parietex Optimized Composite Mesh also failed to adequately warn Plaintiff's physicians of numerous risks that Defendants knew or should have known were associated with the Parietex Optimized Composite Mesh, including migration, tearing, contraction, adhesions or bowel obstruction.

54. Defendants failed as well to adequately warn Plaintiff or Plaintiff's physicians about the necessity for invasive surgical intervention in the event of

complications with the Parietex Optimized Composite Mesh or train the physicians on the proper treatment of such complications when they occurred.

55. Defendants failed to adequately warn Plaintiff or her physicians that the surgical removal of the Parietex Optimized Composite Mesh in the event of complications would leave the hernia unrepaired; the resulting hernia would be much larger than the original; and further, more complicated medical treatment to attempt to repair the same hernia would be necessary.

56. With respect to the complications listed in their warnings, Defendants provided no information or warning regarding the frequency, severity, and duration of those complications, although the complications associated with the Parietex Optimized Composite Mesh were more frequent, more severe, and longer lasting than those in safer feasible alternative hernia repair treatments.

57. If Plaintiff and/or Plaintiff's physicians had been properly warned of the defects and dangers of the Parietex Optimized Composite Mesh, and of the frequency, severity, and duration of the risks associated with the products, Plaintiff would not have consented to allow the Parietex Optimized Composite Mesh to be implanted, and Plaintiff's surgeon would not have implanted Defendants' product in Plaintiff.

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

SECOND CAUSE OF ACTION

NEGLIGENCE

59. Plaintiff incorporates by reference the allegations in all prior paragraphs.

60. While the focus of Plaintiff's strict liability claims is on the condition of the product, the focus of Plaintiff's negligence claim is instead on Defendants' conduct.

61. Although Defendants had a duty to use reasonable care in designing, testing, inspecting, manufacturing, packaging, labeling, marketing, distributing, and preparing written instructions and warnings for the Parietex Optimized Composite Mesh, including

a duty to assure that their products did not pose a significantly increased risk of bodily harm and adverse events, and/or a duty to comply with federal regulations and requirements, they failed to do so.

62. At all relevant times herein, Defendants owed a duty and continue to owe a duty to Plaintiff to provide safely manufactured products, to notify her physicians, and the FDA of any flaws in the products, and to warn of the defective nature of the Parietex Optimized Composite Mesh.

63. Defendants breached their duty of reasonable care to Plaintiff by negligently failing to warn of the defects in the Parietex Optimized Composite Mesh, thereby causing her injuries and damages.

64. Defendants breached their duty of reasonable care to Plaintiff by manufacturing and assembling the Parietex Optimized Composite Mesh in such a manner that it was prone to fail and malfunction in a manner that exposed Plaintiff to severe and permanent personal injuries and damages.

65. Further, Defendants breached their duty of reasonable care to Plaintiff by failing to promptly and adequately notify the FDA and/or warn and instruct Plaintiff and Plaintiff's surgeon at the earliest possible date of known defects in the Parietex Optimized Composite Mesh.

66. Defendants breached their duty of reasonable care to Plaintiff by failing to exercise due care under the circumstances and failing to adequately test the Parietex Optimized Composite Mesh.

67. Defendants' conduct, as described within this Complaint, was negligent, careless, and reckless. Defendants were made aware of and disregarded substantial and unjustifiable risks that the Parietex Optimized Composite Mesh users, including Plaintiff, would suffer injuries as a result of Defendants' defective manufacture of the device as known or should have been known to Defendants, as well as Defendants' failure to warn of these defects.

68. Defendants misrepresented material facts regarding the safety, efficacy, and fitness for human use of the Parietex Optimized Composite Mesh by claiming the Parietex Optimized Composite Mesh would not contract and that the mesh's polyester material would invite healthy tissue integration and mesh compliance, when in fact the polyester material caused pain and additional surgeries.

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

70. Defendants knew or should have known that polyester should not be used for ventral hernia repair.

71. Defendants knew or should have known that the polyester used in the Parietex Optimized Composite Mesh is soft and flimsy compared to similar hernia products that are made of polypropylene.

72. Defendants knew or should have known that polyester is more likely to tear and cause a severe inflammatory response than polypropylene, despite the protective absorbable collagen barrier that has been applied to the Parietex Optimized Composite Mesh in order to prevent tissue attachment.

73. Defendants knew or should have known that the protective absorbable collagen barrier that has been applied to the Parietex Optimized Composite Mesh in order to prevent tissue attachment can cause an inflammatory response.

74. Defendants knew or should have known that the Parietex Optimized Composite Mesh will contract and rip or tear away from the required tacks and sutures.

75. Defendants knew or should have known that the unsealed edges of the Parietex Optimized Composite Mesh would cause the products to fray and disintegrate once they have been implanted.

76. Defendants knew or should have known of the significant risk of complications if the Parietex Optimized Composite Mesh is implanted into the abdomen to repair a ventral hernia. Nonetheless, Defendants marketed the Parietex Optimized Composite Mesh as being safe and effective for abdominal ventral hernia repairs.

77. Defendants knew or should have known that the Parietex Optimized Composite Mesh is more dangerous and less effective than other meshes or methods for hernia repair and cause injury.

78. Despite the aforementioned, Defendants continued to manufacture and market the Parietex Optimized Composite Mesh for use by consumers and continued to fail to comply with federal requirements.

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

PRAYER FOR RELIEF

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

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

ii. restitution and disgorgement of profits;

iii. reasonable attorneys' fees as provided by law;

iv. costs of these proceedings, including past and future costs of suit;

v. all ascertainable economic damages;

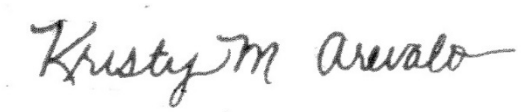
vi. prejudgment interest on all damages as allowed by law; and

vii. such other and further relief as this Court deems just and proper.

Respectfully submitted,

Date: September 11, 2019

MCCUNE·WRIGHT·AREVALO, LLP



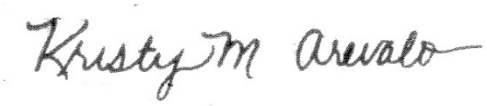
By: _____
Kristy M. Arevalo
Attorney for Plaintiff

DEMAND FOR JURY TRIAL

Plaintiff, Shari Annette Jorden, hereby demands a trial by jury on all issues so triable.

Date: September 11, 2019

MCCUNE·WRIGHT·AREVALO, LLP



By: _____
Kristy M. Arevalo
Attorney for Plaintiff