IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW MEXICO

JESUSITA AGUIRRE,

Plaintiff,

vs.

Case No.

ATRIUM MEDICAL CORPORATION,
GETINGE GROUP, GETINGE USA, INC.,
MAQUET CARDIOVASCULAR, LLC.,

Defendants.

COMPLAINT FOR DAMAGES FOR PERSONAL

INJURY RESULTING FROM NEGLIGENCE, STRICT LIABILITY

AND BREACH OF WARRANTIES

1. Plaintiff, Jesusita Aguirre ("Plaintiff"), by and through her attorney, Jason S. Montclare, Esq., brings this complaint for damages for personal injury caused by the Defendant Atrium Medical Corporation, who sold a surgical polypropylene mesh product (the Product) which was inserted into the body of Plaintiff to treat medical conditions, including but not limited to an abdominal hernia. The Product caused and continues to cause significant injury to the Plaintiff, as described below, while she resided and resides in the state of New Mexico.

2. This case involves a synthetic polypropylene mesh medical device which was implanted in plaintiff. The polypropylene mesh device was manufactured, promoted, marketed, distributed and sold by the Defendant Atrium Medical Corporation for use in hernia repair.

3. Defendants misrepresented that polypropylene mesh is a safe and effective medical device for hernia repair. In fact, polypropylene mesh causes a litany of serious medical problems and complications, including, but not limited to, mesh shrinkage, expansion, deformation, cracking, foreign body reaction, chronic inflammation, migration, organ damage, nerve damage, chronic pain and sexual dysfunction.

4. Polypropylene mesh was never approved as safe and effective by the FDA. Most medical devices, including mesh devices used for hernia repair, are "cleared" for marketing by the FDA under the 510(k) process of the Federal Food, Drug and Cosmetic Act. This process requires only that the manufacturer claim that the new device is "substantially equivalent" to another legally marketed predicate device—a device that itself was never reviewed for safety and efficacy. Under the United States Supreme Court decision in *Medtronic Inc. v. Lohr*, 518 U.S. 470 (1996), the preemption doctrine does not apply to devices cleared for marketing under the 510(k) process.

5. Plaintiff brings this action to recover damages for injuries resulting from negligence, strict liability and breach of warranties by Defendants in the manufacture, promotion, marketing, distribution and sale of polypropylene mesh.

6. Plaintiff Jesusita Aguirre is a resident of Alamogordo, New Mexico, and underwent hernia repair surgery on or about October 25, 1994, in the County of Otero, State of New Mexico, with polypropylene mesh manufactured, marketed, promoted, distributed and sold by Defendants.

7. Defendant Atrium Medical Corporation ("Atrium") is a Delaware corporation headquartered at 5 Wentworth Drive, Hudson, New Hampshire. Atrium is a pharmaceutical company involved in the research, development, testing, manufacture,

production, distribution, marketing, promotion and/or sale of medical devices used for hernia repair, including polypropylene mesh.

8. Defendant Getinge Group ("Getinge") is a Swedish corporation doing business in the United States. Getinge is a pharmaceutical company involved in the research, development, testing, manufacture, production, distribution, marketing, promotion and/or sale of medical devices used for hernia repair, including polypropylene mesh.

9. Defendant Getinge USA, Inc. ("Getinge USA") is a Delaware corporation headquartered at 1777 East Henrietta Road, Rochester, New York. Getinge USA is a pharmaceutical company involved in the research, development, testing, manufacture, production, distribution, marketing, promotion and/or sale of medical devices used for hernia repair, including polypropylene mesh.

10. Defendant Maquet Cardiovascular LLC ("Maquet") is a German corporation doing business in California with corporate offices located at 170 Baytech Drive, San Jose, California.

11. Maquet is a pharmaceutical company involved in the research, development, testing, manufacture, production, distribution, marketing, promotion and/or sale of medical devices used for hernia repair, including polypropylene mesh.

12. In October 2011, Atrium announced that it had signed an agreement to be acquired by Getinge and its subsidiary, Maquet. The true names and capacities, whether individual, corporate, associate or otherwise, of Defendants DOES 1 through 20, are unknown to Plaintiff who therefore sues these Defendants by such fictitious names. Plaintiff will amend this Complaint when the true names and capacities of these fictitiously named Defendants are ascertained. Plaintiff is informed and believe, and thereon allege, that

each fictitiously named defendant, whether as a supplier, manufacturer, distributor, marketer or seller, is responsible, strictly, negligently, in warranty, fraudulently or otherwise, for the occurrences alleged in this Complaint, and caused the injuries and damages sustained by Plaintiff as herein alleged.

13. At all times herein mentioned, each of the Defendants was the agent, servant, employee, co-conspirator and/or joint venturer of the other Defendants, and each of them, and was acting in the course and scope of that agency, service, employment, conspiracy and/or joint venture.

14. Hernia, a condition affecting thousands of men and women in the United States each year, is the protrusion or projection of an organ or tissue through the wall that normally contains it.

15. Until 1958, abdominal wall hernias were repaired without mesh. In 1958, Dr. Frances Usher published a medical journal article entitled *Marlex mesh, a new plastic mesh for replacing tissue defects*. Dr. Usher used polypropylene mesh in experimental canine work for abdominal repair. Polypropylene is a petroleum-based plastic initially used in the Hula-Hoop and for kitchen storage applications. Heavily promoted by the medical device manufacturers, including Defendants, hernia mesh, typically made wholly or partly of polypropylene, is frequently used in hernia repair surgery. About one million hernia repair surgeries with mesh are performed world-wide each year. Despite the marketing push by mesh manufacturers, including Defendants, to persuade doctors to use mesh in hernia repair, many doctors steer away from polypropylene mesh and use the Shouldice technique for hernia repair.

16. The Shouldice technique, used for decades, is a mesh-free hernia repair method. It has been known since 1953 that any implanted device must not be physically modified by tissue fluids, be chemically inert, not incite an inflammatory or foreign body cell reaction, be non-carcinogenic, not produce allergic reactions, and be able to withstand mechanical stress. D. Ostergard, *Degradation, Infection and Heat Effects on Polypropylene Mesh for Pelvic Implantation: What Was Known and When it Was Known*, 22 INT'L UROGYNECOLOGY J. 771-774 (2011).

17. Polypropylene is not biologically inert in the human body, and can cause serious injuries. A typical response to mesh implanted in the human body is inflammation, granuloma formation and a foreign body reaction. Scar tissue forms around the implant and causes contraction of the mesh up to 50%. This inflammation, foreign body response and scar tissue formation is a permanent condition and can result in long-term complications. U. Klinge et al., *Foreign Body Reaction to Meshes Used for the Repair of Abdominal Wall Hernias*, 165 EUR. J. SURGERY 665-73 (1999).

18. Despite the promotion of mesh as safe and effective by Defendants, the published medical literature contradicts this unsupported belief. One author observed that "[t]he literature suggests otherwise with reports of various degrees of degradation, including depolymerization, cross-linking, oxidative degradation by free radicals, additive leaching, hydrolysis, stress cracking and mesh shrinkage along with infection, chronic inflammation and the stimulation of sclerosis." The author concluded, "Based on available evidence the polypropylene used for surgical treatment of various structural defects is not inert after implantation in the human body." G. Sternschuss et al., *Post-implantation Alterations of Polypropylene in the Human*, 188 J. UROL. 27-32 (2012).

19. As the mesh degrades in the human body, small flakes of polypropylene can lead to infection and irritation, and resultant serious pain, as the body tries to rid itself of the foreign material. Once implanted, mesh contracts as well as cracks substantially in the human body. In one study, a contracture rate of 30% to 50% was found four weeks after implantation. Another study reported an 85% contracture rate after eight years. Nerve fibers are entrapped in the contracted tissue causing severe pain. A debilitating consequence of hernia repair with mesh is inguinodynia, or chronic groin pain. This condition results from nerves, such as the ilioinguinal, iliohypogastric and genitofemoral nerves, coming into contact with mesh, after its degradation and deformation in the body following implantation, and from the persistent and permanent foreign body reaction to the implantation of mesh. It has been reported that hernia repair with mesh results in an extraordinarily high rate of inguinodynia—in some reports approaching 50%. *See, e.g.*, J.E. Fischer, *Hernia Repair: Why Do We Continue to Perform Mesh Repair in the Face of Human Toll of Inguinodynia?* 206 AMER. J. SURG. 619-23 (2013).

20. Other studies have found an even higher rate of chronic pain after hernia repair with mesh. One study found that approximately 75% of patients had pain one year after hernia repair at rest, and 78% had pain when moving. B. Page, *Pain From Primary Inguinal Hernia and the Effect of Repair on Pain*, 89 BRIT. J. SURG. 1315-18 (2002).

21. Despite the abundance of scientific and medical information published in the literature relating to the dangerous properties and serious risks of polypropylene mesh, Defendants made a deliberate decision to ignore these dangers and to aggressively promote polypropylene mesh to healthcare providers and consumers. Defendants

misrepresented and concealed from Plaintiff, her physician and consumers, the serious risks, dangers and defects enumerated in this Complaint.

22. The hernia mesh implanted in Plaintiff was polypropylene mesh manufactured, promoted, marketed, distributed and sold by Defendants. The polypropylene mesh caused Plaintiff to suffer permanent injuries, substantial pain and suffering, emotional distress, medical expenses, lost wages and earning capacity, and diminished quality of life. Before Plaintiff underwent hernia repair surgery with polypropylene mesh, she had no history of these physical and emotional injuries. Plaintiff filed this lawsuit within the applicable limitations period of first suspecting polypropylene mesh caused the harm and injuries suffered by Plaintiff. Plaintiff could not, by the exercise of reasonable diligence, have discovered the wrongful cause of her injuries at an earlier time because the injuries were caused without perceptible trauma or harm, and when the injuries were discovered, their cause was unknown to Plaintiff. Plaintiff did not suspect, nor did Plaintiff have reason to suspect, that she had been injured, the cause of the injuries, or the wrongful nature of the conduct causing the injuries, until less than the applicable limitations period before the filing of this Complaint. Moreover, Plaintiff was prevented from discovering this information sooner because Defendants misrepresented and concealed, and continue to misrepresent and conceal to the public and the medical profession, the dangers of polypropylene mesh, as well as the true facts that could have led Plaintiff to discover a cause of action against Defendants for their wrongful conduct.

23. The following is a description of Ms. Aguirre's experience with the mesh in her own words. On October 25, 1994, I was in the hospital at Gerald Champion Memorial Hospital on Ninth Street in Alamogordo because I had given birth to my youngest

daughter. After her birth, I had surgery to repair an umbilical hernia. The following year in July of 1995, I had a repeat surgery to repair the previous hernia surgery at the same hospital. This past year on Tuesday February 17, 2015 at approximately 7:00pm I became very ill. I had excruciating lower stomach pains and I thought that I had become ill with food poisoning. The pain was so immense that it hurt to breathe, stand, sit or lie down. The pain became unbearable and I contacted my oldest daughter at approximately 10:00 pm to go to my house to pick me up and to take me to the Emergency Room at Gerald Champion Regional Medical Center in Alamogordo. Upon arrival to the hospital, I was taken into a room back in the Emergency Room and was examined by a Doctor and the Nursing Staff. They were surprised by the condition I was in. My hands and fingers had started to turn blue because I was not breathing right and basically my body was lacking Oxygen. It hurt so much that it literally hurt to breathe. The ER Doctor ordered X-Rays and then Dr. William Pollard was called to come in to see me. He told my daughter that the Mesh covered Hernia had embedded itself into a section of my bowls and had caused an obstruction and had twisted my intestines. He said that if I don't have immediate surgery, the obstruction will burst and I would die. He explained to her that the pain I was feeling was because that section of my bowl was not receiving blood and oxygen and basically it was dead and needed to be removed as soon as possible. A Surgical Team was brought in and I was taken into Emergency Surgery at 2:30 am on Wednesday, February 18, 2015. He had to remove that section of my bowl that the Mesh and Hernia had destroyed and I remained in the Intensive Care Unit until my release on Saturday, February 21, 2015. My incision was the type of incision that could not be closed surgically or stapled and it remained opened and had to close on its own from the inside

out. I had to have a Nurse go to my house for the next six weeks every day to cleanse my incision and monitor it's healing. I was out of work and on bed rest with strict limitations as to what I could do and remained on bed rest during that time period. My youngest daughter had to quit her job to stay home and take care of me. Dr. Pollard had advised me that I would need another surgery once I was healed to repair the Hernia. He said that he basically stabilized me from this medical emergency.

On November 4, 2015, I had a subsequent Hernia repair surgery performed by Dr. William Pollard at Gerald Champion Regional Medical Center in Alamogordo to repair the Hernia with a Metal Mesh after eight months of healing. I again had to miss work for another four weeks.

24. The Plaintiff is a citizen of New Mexico.

25. Defendants are responsible for the conduct complained of herein.

26. Defendants derived substantial revenue from sales directed at and occurring within the State of New Mexico, including from the Product, the subject of the present action.

27. At all relevant times, Defendants designed, manufactured, tested, analyzed, distributed, recommended, merchandised, advertised, promoted, supplied and sold to distributors, physicians, hospitals and medical practitioners, certain hernia surgical repair products to be surgically implanted in patients throughout the United States, including the State of New Mexico.

28. Defendants sold the Product, which was designed to fix such hernias as the medical condition suffered by Plaintiff.

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

30. Federal subject matter jurisdiction in this action is based upon 28 U.S.C. § 1332(a), in that in this action there is complete diversity among the Plaintiff and Defendants and the amount in controversy exceeds $75,000 as to each cause of action alleged in this complaint.

31. Venue is proper pursuant to 28 U.S. Code § 1391(b)(2) because a substantial part of the events and omissions giving rise to the claims occurred in this judicial district.

32. Defendants have significant contacts with the federal judicial district of New Mexico such that it is subject to the personal jurisdiction of the court in said district. Such contacts include but are not limited to selling the Product to patients that would not only forseeably live within the state of New Mexico, but would also potentially suffer injury caused by the Product within the state of New Mexico.

33. A substantial part of the events and omissions giving rise to Plaintiff's causes of action occurred in the federal judicial district of New Mexico. Such events and omissions include but are not limited to the significant injuries caused by the Product and sustained by Plaintiff while she resided within the state of New Mexico. Pursuant to 28 U.S.C. § 1391(a), venue is proper in the federal judicial district of New Mexico.

34. The Product sold and distributed by the Defendant may be properly identified as Atrium Polypropylene Mesh 12" x 12" 1001212-00 M503707822.

35. Defendants designed, manufactured, packaged, labeled, marketed, sold, and distributed the Product, including that which was implanted in the Plaintiff.

36. A hernia is a medical condition caused by the penetration of fatty tissue, intestine, or organs through a weakened or compromised location in the muscle of connective tissue.

37. The most common types of hernias are: inguinal, hiatal, umbilical, ventral, incisional, and femoral hernias, most occurring near the abdominal wall.

38. Hernias sometimes manifest as visibly observable protrusions or bulges, and can cause the patient pain, discomfort, and decreased mobility.

39. Hernias can be treated surgically, either by laparoscopic or open repair surgical procedures.

40. Hernia repairs are common surgeries, and are performed more than one-million times per year in the U.S. 18. The surgical mesh used to execute hernia repairs to damaged tissue can be constructed from synthetic or biologic materials and tissue. Synthetic surgical mesh is made of knitted or non-knitted sheets that can be absorbable, non-porous, or a combination of absorbable and nonabsorbent in composition.

41. Hernias have a high propensity for recurrence. Because of the propensity to require additional surgeries or revisions, surgical mesh can be introduced to the hernia site to strengthen the repair, in hopes of reducing the likelihood of recurrence.

42. Hernia mesh made from animal byproduct is usually derived from animal tissue sourced from skin or intestine, and is designed to be absorbed into the human body upon use.

43. Non-absorbable mesh, made from synthetic materials, is intended to remain within the body permanently.

44. The most common injuries caused by hernia surgeries using hernia mesh are: pain, infection, recurrence of hernia, adhesion of scar tissue sticking together, blockages that obstruct intestines, internal bleeding, fistula between organs (abnormal organ connection or fusion), serenoma or fluid build-up at site, and perforation of other organs.

45. The hernia mesh introduced to the body can cause serious injuries, including migration of the mesh and mesh shrinkage or contraction as well as the aforementioned conditions.

46. Additional defects and known side effects of hernia mesh, as used for reinforcement and strengthening of hernia repairs, include:

a. Mesh materials, as used, react to human tissues, organs and other body contents adversely.

b. Mesh materials can harbor or cultivate infections, which can affect surrounding areas, tissues, and organs.

c. Mesh material abrades bodily tissue, and can cause erosion of tissue and organs surrounding the placement of the mesh implant.

d. Mesh components routinely fail, malfunction or lose efficacy, resulting in serious adverse health implications, often requiring subsequent revision or removal surgery.

e. Mesh material causes significant injury, extending to perforation of surrounding tissue and/or organs, adhesion to other tissue and/or organs, and nerve damage.

f. Mesh material is intended to be rounded and reinforced to be safely cut, but when mesh is defective, it can become frayed, sharp, and protruding.

g. Unreasonable risk of malfunction, injury and health consequences, such as: severe chronic pain, infection, recurrence of hernia, adhesion, intestinal blockages, migration of mesh, contraction/shrinkage of mesh, and requirement of repeat surgical intervention.

47. In April of 2016, the FDA wrote and published an article on hernia mesh implants; "Many complications related to hernia repair with surgical mesh that have been reported to the FDA have been associated with recalled mesh products that are no longer on the market. Pain, infection, recurrence, adhesion, obstruction, and perforation are the most common complications associated with recalled mesh."

48. Safer and more effective alternatives to hernia mesh exist and have existed since the introduction of hernia mesh products into the market. These include the Shouldice Repair, McVay Repair, Bassini Repair, and Desarda Repair.

49. Defendant should have known of this serious risk and warned physicians and patients.

50. Defendant omitted and downplayed the risks, dangers, defects, and disadvantages of the Product, and advertised, promoted, marketed, sold and distributed the Product as a safe medical device when Defendant knew or should have known that the Product was not safe for its intended purposes, and that the Product would cause, and did cause, serious medical problems, and in some patients, including the Plaintiff named in the Complaint, catastrophic injuries. Further, while some of the problems associated with the Product were made known to physicians, the magnitude and frequency of these problems were not disclosed and were hidden from physicians.

51. Contrary to Defendant's representations and marketing to the medical community and to the patients themselves, the Product and other similar products made by the Defendant

have high rates of failure, injury, and complications, fail to perform as intended, require frequent and often debilitating re-operations, and have caused severe and irreversible injuries, conditions, and damage to a significant number of women, including the female Plaintiff named in the Complaint, making them defective under the law.

52. Such defects caused the Plaintiff to undergo additional surgeries which otherwise would not have been necessary.

53. The specific nature of the Product's defects, each which of which caused injuries to the Plaintiff, includes, but is not limited to, the following:

1. a) On information and belief, the design of the Product to be inserted into and through an area of the body with high levels of bacteria that can adhere to the mesh causes immune reactions and subsequent tissue breakdown and adverse reactions and injuries;
2. b) Biomechanical issues with the design of the Product, including, but not limited to, the propensity of the Product because of its physical characteristics to cause trauma to the body and bowel obstruction, that in turn cause surrounding tissue to be inflamed and/or decompose, resulting in injury;
3. c) The propensity of the Product to change shape and move within the body;
4. d) The adverse tissue reactions caused by the Product, which are causally related to infection, as the mesh is a foreign material;
5. e) The creation of a non-anatomic condition in the abdomen leading to chronic pain and functional disabilities when the mesh is implanting according to the manufacturer's instructions.

54. The Product is also defective due to Defendants' failure to adequately warn or instruct the female Plaintiff and/or her health care providers of subjects including, but not limited to, the following issues personally experienced by the Plaintiff: ;

1. a) The Product's propensities for degradation, fragmentation and/or creep;
2. b) The frequency and manner of mesh erosion or extrusion; ;
3. c) The risk of chronic infections resulting from the Product; ;
4. d) The risk of recurrent, intractable pain and other pain resulting from the Product;
5. e) The need for corrective or revision surgery to adjust or remove the Product;
6. f) The severity of complications that could arise as a result of implantation of the Product;
7. g) The hazards associated with the Product;
8. h) The Product's defects described herein;
9. i) Treatment of abdominal hernia with the Product is no more effective than feasible available alternatives;
10. j) Treatment of abdominal hernia with the Product exposes patients to greater risk than feasible available alternatives;
11. k) Treatment of abdominal hernia with the Product makes future surgical repair more difficult than feasible available alternatives;
12. l) Use of the Product puts the patient at greater risk of requiring additional surgery than feasible available alternatives;
13. m) Removal of the product due to complications may involve multiple surgeries and may significantly impair the patient's quality of life.

55. Defendant underreported and continues to underreport information about the propensity of the Product to fail and cause injury and complications, such as those personally experienced by the Plaintiff, and have made unfounded representations regarding the efficacy and safety of the Product through various means and media.

56. Defendant failed to perform proper and adequate testing and research in order to determine and evaluate the nature, magnitude and frequency of the risks attendant to the Product.

57. Defendant failed to design and establish a safe, effective procedure for removal of the Product, or to determine if a safe, effective procedure for removal of the Product exists.

58. Feasible and suitable alternatives to the Product have existed at all times relevant that do not present the same frequency or severity of risks as do the Product.

59. The Product was at all times utilized and implanted in a manner foreseeable to Defendant, as Defendant generated the instructions for use, created the procedures for implanting the device, and trained the implanting physician.

60. Defendant knowingly provided incomplete and insufficient training and information to physicians regarding the use of the Product and the aftercare of patients implanted with the Product. The training and information were deficient because they failed to describe the risks of the product.

61. The Product implanted in the Plaintiff was in the same or substantially similar condition as it was when it left Defendant's possession, and in the condition directed by and expected by Defendant. The product was substantially unchanged when it reached Ms. Aguirre.

62. The injuries, conditions, and complications suffered by numerous patients around the

world who have been implanted with the Product and other products like it made by the Defendant include, but are not limited to, the changing of shape, moving within the body, infection, inflammation, scar tissue, and pain, death of abdominal tissue, bowel obstruction \, all of which have been experienced by the Plaintiff to a significant degree.

63. In many cases, including the Plaintiff, patients have been forced to undergo extensive medical treatment including, but not limited to, operations to locate and remove mesh, tissue, the use of pain control and other medications, injections into various areas of the abdomen and operations.

64. The medical and scientific literature studying the effects of such mesh, like that of the Product implanted in Plaintiff, has concluded that such mesh is dangerous.

65. Removal of eroded and/or infected mesh can require multiple surgical interventions for removal of mesh and results in scarring on fragile compromised tissue and muscles. Due to the Product's defects, the Plaintiff had to undergo such multiple surgical interventions.

66. At all relevant times herein, Defendants continued to promote the Products as safe and effective.

67. In doing so, Defendant failed to disclose the known risks and failed to warn of known or scientifically knowable dangers and risks associated with the Product, including the magnitude and frequency of these risks.

68. At all relevant times herein, Defendants failed to provide sufficient warnings and instructions that would have put the Plaintiff and the general public on notice of the dangers and adverse effects caused by implantation of the Product.

69. The Product which is designed, manufactured, distributed, sold and/or supplied by Defendant is defective as marketed due to inadequate warnings, instructions, labeling and/or inadequate testing in the presence of Defendant's knowledge of lack of safety.

70. As a result of having the Product implanted in her, the Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages.

71. Defendant participated in the marketing, distribution and sale of the Product. It represented the Product as safe for its intended purpose, fully and properly tested for safety and potential risks, and free from the kinds of risks and hazards that the Product actually posed to the public.

72. After the Product was placed on the market, Defendant began receiving actual notices of failures and Product defects. Defendant actively and intentionally concealed this notice of the defective and dangerous condition associated with the Product from the Plaintiff, the Plaintiff's physicians, and the general public. The Product inserted in the Plaintiff experienced a failure due to its defective design which caused injuries to the Plaintiff.

73. After the defective and dangerous Product was already placed on the market, the Defendant was placed on notice as to its danger to the public. Whether intentionally or negligently, Defendant failed to properly conduct and monitor the safety of its product.

74. Upon information and belief, Defendant was aware of the defect in manufacture and design of the non-recalled Product and chose not to issue a recall on the Product in the face of the high degree of complication and failure rates.

75. The Product implanted in Ms. Aguirre was designed, manufactured, sold and distributed by Defendant to be used by surgeons for hernia repair surgeries and was further represented by Defendant to be an appropriate, cost-effective and suitable product for such purpose.

76. Neither Ms. Aguirre nor Plaintiff's physicians were aware of the defective and dangerous condition of the Product.

77. In the time that followed the surgery, Ms. Aguirre's condition worsened. Ms. Aguirre suffered under extreme pain and discomfort. Despite an aggressive pain control regimen, neither the pain nor discomfort were abated. Ms. Aguirre was left to begin months of recovery, on-going pain maintenance, with substantial medical complications requiring expensive, painful and emotionally harmful medical intervention and care.

78. Ms. Aguirre has incurred substantial medical bills and has lost earning capacity and lost quality of life as a result of the Product, and continues to suffer physical pain and mental anguish.

79. Upon information and belief, Defendants were aware of the high degree of complication and failure rate associated with the Product when it was implanted in the Plaintiff.

80. Ms. Aguirre has incurred substantial medical bills and has lost earning capacity and lost quality of life as a result of the Product, and continues to suffer physical pain and mental anguish.

81. Defendants designed, manufactured, assembled, distributed, conveyed and/or sold the Product for hernia repair surgery.

82. At all times mentioned, the Product was substantially in the same condition

as when it left the possession of Defendant.

83. The Product implanted into defendant was being used in a manner reasonably anticipated at the time it was implanted in her by her surgeon.

84. Defendants knew the component parts of the Product as implemented through design and/or manufacture could cause injury to the end user.

85. Any other acts or failures to act by Defendant regarding the studying, testing, designing, developing, manufacturing, inspecting, producing, advertising, marketing, promoting, distributing, and/or sale of the Product for hernia repair surgery will be learned during discovery.

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

87. The Products present and constitute an unreasonable risk of danger and injury in the following respects:

1. the Product is likely to malfunction after being implanted;
2. the Product was not properly manufactured;
3. the Product was defectively designed;
4. the Product did not perform as safely as an ordinary consumer/patient would expect;
5. the Product was inadequate or insufficient to maintain its integrity during

normal use after implantation in the consumer/patient; and such further and additional defects as discovery and the evidence reveal.

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

89. Defendants' Product is defective because it possesses the potential for deformation, breakage or malfunction and, as a result, are subject to risk of resulting injury.

90. Defendants did not timely apprise the public and physicians of the defect in their Product, despite Defendants' knowledge that the Product had failed due to the described defects. Plaintiff has suffered injuries and will require continual medical monitoring and care. Accordingly, Plaintiff will incur future medical costs related to the Product.

91. Defendants' concealment of a known defect from Plaintiff tolls the applicable statute of limitation.

92. Defendants' conduct, as described in the preceding paragraphs, amounts to conduct purposely committed, which Defendants must have realized was dangerous, heedless and reckless, without regard to the consequences or the rights and safety of Plaintiff.

93. Defendants sold their Product to the healthcare providers of the Plaintiff and other healthcare providers in the state of implantation and throughout the United States without doing adequate testing to ensure that the Product was reasonably safe for implantation in the abdominal area.

94. Defendants sold the Product to Plaintiff, health care providers and other health care providers in the state of implantation and throughout the United States in spite of their knowledge that the Product can shrink, deform, move, disintegrate and/or degrade inside the body.

95. This caused the other problems heretofore set forth in this complaint, thereby causing severe and debilitating injuries suffered by the Plaintiff and numerous other people.

96. Defendants ignored reports from patients and health care providers throughout the United States and elsewhere of the Product's failures to perform as intended, which lead to the severe and debilitating injuries suffered by the Plaintiff and numerous other patients. Rather than doing adequate testing to determine the cause of these injuries, or to rule out the Product's designs or the processes by which the Product is manufactured as the cause of these injuries, Defendants chose instead to continue to market and sell the Product as safe and effective.

97. Defendants knew the Product was unreasonably dangerous in light of its risks of failure, pain and suffering, loss of life's enjoyment, remedial surgeries and treatments in an effort to cure the conditions proximately related to the use of the Product, as well as other severe and personal injuries which were permanent and lasting in nature.

98. Defendants withheld material information from the medical community and the public in general, including the Plaintiff, regarding the safety and efficacy of the Product.

99. Defendants knew and recklessly disregarded the fact that the Product caused debilitating and potentially life altering complications with greater frequency than feasible alternative methods and/or products used to treat abdominal hernia.

100. Defendants misstated and misrepresented data and continue to misrepresent data so as to minimize the perceived risk of injuries caused by the Product.

101. Defendant knew of the Product's defective and unreasonably dangerous nature, but continued to mislead physicians and patients and to manufacture, market, distribute, and sell the Product so as to maximize sales and profits at the expense of the health and safety of the public, including the Plaintiff. Defendants continue to conceal and/or fail to disclose to the public, including the Plaintiff, the serious complications associated with the use of the Product.

102. Defendants' conduct as described herein shows willful misconduct, malice, fraud, wantonness, oppression, or that entire want of care which raises the presumption of conscious indifference to consequences, thereby justifying an award of punitive damages.

CAUSES OF ACTION COUNT I: NEGLIGENCE

103. All previous paragraphs of this Complaint are hereby incorporated by reference as if fully set forth herein.

104. Defendants had a duty to individuals, including the Plaintiff named in the Complaint, to use reasonable care in designing, manufacturing, marketing, labeling, packaging and selling the Product.

105. Defendants were negligent in failing to use reasonable care, and breached its duty to the Plaintiff, as described herein, in designing, manufacturing, marketing, labeling, packaging and selling the Product. But for the Defendants' breaches the Plaintiff would not have sustained such injury. Defendant breached its aforementioned duty by, among other things:

1. a) Failing to design the Product so as to avoid an unreasonable risk of harm to patients in whom the Product was implanted, including the Plaintiff. The design did not provide for sufficient stability which caused the Product to deform and move in the Plaintiff, which caused trauma to the Plaintiff;
2. b) Failing to manufacture the Product so as to avoid an unreasonable risk of harm to women in whom the Product was implanted, including the Plaintiff;
3. c) Failing to use reasonable care in the testing of the Product so as to avoid an unreasonable risk of harm to patients in whom the Product was implanted, including the Plaintiff;
4. d) Failing to use reasonable care in inspecting the Product so as to avoid an unreasonable risk of harm to patients in whom the Product was implanted, including the Plaintiff;
5. e) Failing to use reasonable care in the training and instruction to physicians for the safe use of the Product;

6. f) Failing to use reasonable care in studying the Product to evaluate its safety and to determine the nature, magnitude, and frequency of serious, life threatening complications that were known or knowable; and
7. g) Otherwise negligently or carelessly designing, manufacturing, marketing, labeling, packaging and/or selling the Product.

106. The reasons that Defendant's negligence caused the Product to be unreasonably dangerous and defective include, but are not limited to:

1. a) The use of the material in the Product which caused adverse reactions and injuries;

2. b) The design of the Product to be inserted into and through an area of the body with high levels of bacteria that adhere to the mesh causing immune reactions and subsequent tissue breakdown and adverse reactions and injuries;
3. c) Biomechanical issues with the design of the Product, including, but not limited to, the propensity of the Product to deform, move and disintegrate inside the body, that in turn cause injuries to the surrounding;
4. d) The propensity of the Product to deform when subject to prolonged tension inside the body;
5. e) The propensity of the Product to move after implantation in the abdomen, causing pain and other adverse reactions;
6. f) The adverse tissue reactions caused by the Product, which are causally related to infection, as the materials used to construct the Product are foreign;
7. g) The creation of a non-anatomic condition in the abdomen leading to chronic pain and functional disabilities when the mesh is implanting according to the manufacturers' instructions.

107. Defendants also negligently failed to warn or instruct the Plaintiff and/or her health care providers of subjects including, but not limited to, the following, all of which were experienced by the Plaintiff due to the Product:

1. a) The Product's propensities to deform inside the body;
2. b) The Product's propensities for creep; ;
3. c) bowel obstruction;
4. d) The risk of chronic infections resulting from the Product;

5. e) The risk of recurrent, intractable abdominal pain and other pain resulting from the Product;
6. f) The need for corrective or revision surgery to adjust or remove the Product;
7. g) The severity of complications that could arise as a result of implantation of the Product;
8. h) The hazards associated with the Product;
9. i) The Product's defects described herein;
10. j) Treatment of abdominal hernia with the Product is no more effective than feasible available alternatives;
14. k) Treatment of abdominal hernia with the Product exposes patients to greater risk than feasible available alternatives;
15. l) Treatment of abdominal hernia with the Product makes future surgical repair more difficult than feasible available alternatives;
16. m) Use of the Product puts the patient at greater risk of requiring additional surgery than feasible available alternatives;
17. n) Removal of the Products due to complications may involve multiple surgeries and may significantly impair the patient’s quality of life; and

108. As a direct and proximate result of Defendants' negligence, the Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, lost income, and other damages.

109. Defendants at all times mentioned had a duty to properly manufacture, test, inspect, package, label, distribute, market, examine, maintain, supply, provide proper warnings and prepare for use the Product.

110. Defendant at all times mentioned knew or in the exercise of reasonable care should have known, that the Product was of such a nature that it was not properly manufactured, tested, inspected, packaged, labeled, distributed, marketed, examined, sold supplied, prepared and/or provided with the proper warnings, and were unreasonably likely to injure the Product's users.

111. Defendants so negligently and carelessly designed, manufactured, tested, failed to test, inspected, failed to inspect, packaged, labeled, distributed, recommended, displayed, sold, examined, failed to examine and supplied the Product, that they were dangerous and unsafe for the use and purpose for which it was intended.

112. Defendants were aware of the probable consequences of the Product.

113. Defendants knew or should have known the Product would cause serious injury; they failed to disclose the known or knowable risks associated with the Product.

114. Defendants willfully and deliberately failed to avoid those consequences, and in doing so, Defendant acted in conscious disregard of the safety of Plaintiff.

115. Defendants owed a duty to Plaintiff to adequately warn her and her treating physicians, of the risks of breakage, separation, tearing and splitting, deformation and moving associated with the Product and the resulting harm and risk it would cause patients.

116. Defendants breached their duty by failing to comply with state and federal regulations concerning the study, testing, design, development, manufacture,

inspection, production, advertisement, marketing, promotion, distribution, and/or sale of the Product.

117. As a direct and proximate result of the duties breached, the Product used in Plaintiff's hernia repair surgery failed, resulting in Plaintiff suffering pain, harm and trauma such as those described in her own words in this complaint.

118. As a direct and proximate result of Defendants' negligence, Plaintiff has suffered injuries and damages.

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

COUNT II: STRICT LIABILITY – DESIGN DEFECT

120. All previous paragraphs of this Complaint are hereby incorporated by reference as if fully set forth herein.

121. The Product implanted in the Plaintiff was not reasonably safe for its intended use and was defective as described herein with respect to its design. But for the Product's design defects, the Plaintiff would not have sustained such injuries. The Product failed to perform as safely as an ordinary consumer would have expected when used in an intended or reasonably foreseeable manner. This disintegration and misshappening resulted in trauma to the Plaintiff.

As previously stated, the Product's design defects include, but are not limited to:

1. a) The material in the Product and the immune reaction that results from such material, causing adverse reactions and injuries;
2. b) The design of the Product to be inserted into and through an area of the body with high levels of bacteria that adhere to the mesh causing immune reactions and subsequent tissue breakdown and adverse reactions and injuries;
3. c) Biomechanical issues with the design of the Product, including, but not limited to, the propensity of the Product to disintegrate and move and deform inside the body, that in turn cause surrounding tissue to be inflamed, become fibrotic, decompose, and contract, resulting in injury;
4. d) The propensity of the Product for disintegration and deformation when subject to prolonged tension inside the body;
5. e) The inelasticity of the Product, causing them to be improperly mated to the delicate and sensitive areas of the abdomen where they are implanted, and causing pain upon normal daily activities that involve movement in the abdomen;
6. f) The propensity of the Product for deformation, degradation or fragmentation over time;
7. g) The propensity of the Product to create bowel obstuction;
8. h) The adverse tissue reactions caused by the Product which are causally related to infection, as the material used to construct the Product is foreign;
9. i) The creation of a non-anatomic condition in the abdomen leading to chronic pain and functional disabilities when the mesh is implanting according to the manufacturers' instructions.

122. As a direct and proximate result of the Product's aforementioned defects as described herein, the Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo future medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, lost income, and other damages.

123. Defendants are strictly liable to the Plaintiff for designing, manufacturing, marketing, labeling, packaging and selling a defective products. The Product was inherently defective because it was not sturdy enough to prevent deformation and malformation. This resulted in the Product deforming and moving while in the Plaintiff's body. This in turn caused trauma to the Plaintiff's abdominal region which resulted in internal bleeding, infection, bowel obsturction, death of abdominal tissue and other serious injuries. The Defendants sold the Product to the Plaintiff in this defective and unreasonably dangerous condition. The Defendants are engaged in the business of selling this Product and the Product reached the Plaintiff without substantial change in the condition in which it was sold.

COUNT III: STRICT LIABILITY – MANUFACTURING DEFECT

124. All previous paragraphs of this Complaint are hereby incorporated by reference as if fully set forth herein.

125. The Product implanted in the Plaintiff was not reasonably safe for its intended use and was defective as described herein as a matter of law with respect to its manufacture, in that it deviated materially from Defendants' design and manufacturing specifications in such a manner as to pose unreasonable risks of serious bodily harm to the Plaintiff.

126. As a direct and proximate result of the Product's aforementioned defects as described herein, the Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and/or corrective surgery and hospitalization, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages.

127. Defendants are strictly liable to the female Plaintiff for designing, manufacturing, marketing, labeling, packaging and selling defective products.

COUNT IV: STRICT LIABILITY – FAILURE TO WARN

128. All previous paragraphs of this Complaint are hereby incorporated by reference as if fully set forth herein.

129. The Product implanted in the Plaintiff was not reasonably safe for its intended uses and was defective as described herein as a matter of law due to its lack of appropriate and necessary warnings. The Defendants did not adequately warn the Plaintiff of the dangers of the Product. This danger was reasonably foreseeable to the Defendants because of their knowledge of such defective products and would have been discoverable through reasonable inspection and analysis. This failure to warn caused the Plaintiff not to be aware of the defects which caused her injury. Specifically, Defendants did not provide sufficient or adequate warnings regarding, among other subjects:

1. a) The Product's propensities to move and deform inside the body;
2. b) The Product's propensities for creep;
3. c) The Product's inelasticity preventing proper mating with the abdominal region;
4. d) The rate and manner of mesh erosion or extrusion;

e) The risk of chronic inflammation resulting from the Product;

f) The risk of chronic infections resulting from the Product;

g) The risk of scarring as a result of the Product;

h) The risk of recurrent, intractable pain and other pain resulting from the Product;

i) The need for corrective or revision surgery to adjust or remove the Product;

j) The severity of complications that could arise as a result of implantation of the Product;

k) The hazards associated with the Product;

l) The Product's defects described herein;

m) Treatment of abdominal hernia with the Product is no more effective than feasible available alternatives;

n) Treatment of abdominal hernia with the Product exposes patients to greater risk than feasible available alternatives;

o) Treatment of abdominal hernia with the Product makes future surgical repair more difficult than feasible available alternatives;

p) Use of the Product puts the patient at greater risk of requiring additional surgery than feasible available alternatives;

q) Removal of the Product due to complications may involve multiple surgeries and may significantly impair the patient’s quality of life;

r) Complete removal of the Product may not be possible and may not result in complete resolution of the complications, including pain; and

19. s) The nature, magnitude and frequency of complications that could arise as a result of implantation of the Product.

130. As a direct and proximate result of the Product's aforementioned defects as described herein, the Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages.

131. Defendants are strictly liable to the female Plaintiff for designing, manufacturing, marketing, labeling, packaging and selling a defective product.

132. At the time of the design, manufacture and sale of the Product, and more specifically at the time Plaintiff received the Product it was defective and unreasonably dangerous when put to its intended and reasonably anticipated use.

133. Further the Product was not accompanied by proper warnings regarding significant adverse consequences associated with the Product.

134. Defendants failed to provide any warnings, labels or instructions of its dangerous propensities that were known or reasonably scientifically knowable at the time of distribution.

135. The reasonably foreseeable use of the Product involved significant dangers not readily obvious to the ordinary user of the Product. Defendant failed to warn of the known or knowable injuries associated with malfunction of the Product, including but not limited to the disintegration of the Product and infection which would require subsequent surgical procedures and could result in severe injuries.

136. The dangerous and defective conditions in the Product existed at the time it was delivered by the manufacturer to the distributor. At the time the Defendants had her hernia repair surgery the Product was in the same condition as when manufactured, distributed and sold.

137. Plaintiff did not know at the time of use of the Product, nor at any time prior thereto, of the existence of the defects in the Product.

138. Plaintiff suffered the aforementioned injuries and damages as a direct result of Defendants' failure to warn. The Plaintiff's use of the Product in a manner reasonably foreseeable to the Defendant involved a substantial danger that would not be readily recognized by the ordinary user of the Product. The Defendants knew, or should have known, of the danger given the generally recognized and prevailing scientific knowledge available at the time of the manufacture and distribution. The Defendants failed to provide an adequate warning against the danger created by the reasonably foreseeable use of the Product. The Defendants failed to adequately warn against the specific risk of harm created by the danger. The Defendants failed to provide adequate instruction to avoid the danger. The injuries sustained by the Plaintiff would not have occurred if adequate warning and instruction had been provided. The injury resulted from a use of the product that was reasonably foreseeable to the Defendants.

139. The conduct of Defendanst in continuing to market, promote, sell and distribute the Product after obtaining knowledge that the Product was failing and not performing as represented and intended, showed a complete indifference to or conscious disregard for the safety of others justifying an award in such sum which will serve to deter Defendant and others from similar conduct. But for the Defendants' failure to warn, the

Plaintiff would not have sustained such injuries.

COUNT V: BREACH OF EXPRESS WARRANTY

140. All previous paragraphs of this Complaint are hereby incorporated by reference as if fully set forth herein.

141. Defendants made assurances as described herein to the general public, hospitals and health care professionals that the Product was safe and reasonably fit for its intended purposes.

142. The Plaintiff and/or her healthcare provider chose the Product based upon Defendant's warranties and representations as described herein regarding the safety and fitness of the Product.

143. The Plaintiff, individually and/or by and through her physician, reasonably relied upon Defendants express warranties and guarantees that the Product was safe, merchantable, and reasonably fit for their intended purposes.

144. Defendants breached these express warranties because the Product implanted in the female Plaintiff was unreasonably dangerous and defective as described herein and not as Defendant had represented.

145. Defendants' breach of their express warranties resulted in the implantation of an unreasonably dangerous and defective product in the body of the Plaintiff, placing said Plaintiff's health and safety in jeopardy and causing the injuries mentioned herein.

146. As a direct and proximate result of Defendants' breach of the aforementioned express warranties, the Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, as described herein, has undergone medical treatment and will likely undergo further medical treatment and procedures, has suffered

financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages.

147. In the manufacturing, design, distribution, advertising, marketing, labeling and promotion of the Product, Defendants expressly warranted them to be safe and effective for consumers like Plaintiff.

148. At the time of making these express warranties, Defendants had knowledge of the purpose for which the product was to be used and warranted same in all respects to be safe and proper for such purpose.

149. The Product did not conform to these express warranties and representations because they are not safe and pose severe and serious risks of injury.

150. The implantation and use of the Product in Plaintiffs case was proper and pursuant to the intended and foreseeable use.

Plaintiff, by use of reasonable care, would not and could not have discovered the breach and realized its danger.

COUNT VI: BREACH OF IMPLIED WARRANTY

151. All previous paragraphs of this Complaint are hereby incorporated by reference as if fully set forth herein.

152. Defendants impliedly warranted that the Product was merchantable and was fit for the ordinary purposes for which it was intended.

153. When the Product was implanted in the Plaintiff to treat her abdominal hernia, the Product was being used for the ordinary purposes for which it was intended.

154. The Plaintiff, individually and/or by and through her physician, relied upon Defendant's implied warranties of merchantability in consenting to have the Product implanted in her.

155. Defendant breached these implied warranties of merchantability because the Product implanted in the female Plaintiff was neither merchantable nor suited for its intended uses as warranted. It was not suited for its intended purpose because it moved, disintegrated and misshappened inside the Plaintiff's body, causing injuries.

156. Defendant's breach of their implied warranties resulted in the implantation of an unreasonably dangerous and defective product in the body of the Plaintiff, placing said Plaintiff's health and safety in jeopardy.

157. As a direct and proximate result of Defendant's breach of the aforementioned implied warranties, the Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages.

158. Defendants sold the Product which was implanted in the Plaintiff.

159. Defendants impliedly warranted to the Plaintiff, her physicians and health care providers, that the Product was of merchantable quality and safe for the use for which they were intended. The Product sold to the Plaintiff would be rejected by someone with knowledge in the trade or failure to meet the contract description. The Product was not fit for the ordinary purpose for which it was sold, namely to safely repair hernias.

160. Defendants knew or should have known that the Product at the time of sale

was intended to be used for the purpose of surgically implanting them into the body for hernia repair.

161. The Plaintiff, her physicians and health care providers reasonably relied on Defendant's judgment, indications and statements that the Product was fit for such use.

162. When the Product was distributed into the stream of commerce and sold by Defendants, it was unsafe for their intended use, and not of merchantable quality, as warranted by Defendants in that they had very dangerous propensities due to problems and defects, when used as intended and implanted into a patient's body where they could cause serious injury of harm or death to the end user. Plaintiff suffered such injuries and damages as a result of Defendants' conduct and actions related to the tolling or extension of any applicable statute of limitations, including equitable tolling, delayed discovery, discovery rule, and fraudulent concealment.

WHEREFORE, the Plaintiff demands judgment against Defendants and requests compensatory damages, together with interest, cost of suit, attorneys' fees, and all such other relief as the Court deems just and proper as well as:

- 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, emotional distress, mental anguish, physical disfigurement and impairment; health and medical care costs, together with pre- and post-judgment interest and costs as provided by law;
- Restitution and disgorgement of profits;
- Reasonable attorneys' fees;
- The costs of these proceedings;

- All ascertainable economic damages;
- Punitive damages; and
- Such other and further relief as this Court deems just and proper.

PLAINTIFF DEMANDS A TRIAL BY JURY

Respectfully submitted,

THE LAW OFFICE OF
JASON S. MONTCLARE

"Electronically Filed"

/s/ Jason Montclare
JASON S. MONTCLARE

P.O. Box 2463
Alamogordo, N.M. 88311
575-921-2056
Counsel for Plaintiff

CERTIFICATE OF SERVICE

WE HEREBY CERTIFY that on this 15th day of February, 2018, we filed the foregoing electronically through the CM/ECF system, which caused all parties or counsel to be served by electronic means, as more fully reflected in the Notice of Electronic Filing.

THE LAW OFFICE OF JASON S. MONTCLARE, ESQ.

By: */s/ Jason Montclare*
Jason S. Montclare

JS 44 (Rev. 06/17)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS

Jesusita Aguirre

(b) County of Residence of First Listed Plaintiff _____
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Jason S. Montclare, Esq. P.O. Box 2463
Alamogordo, NM 88311(575) 921-2058

DEFENDANTS

Atrium Medical Corp., Getting Group, Getting USA, Inc., Maquet Cardiovascular, LLC.

County of Residence of First Listed Defendant Hillsborough, NH
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ☐ 1 U.S. Government Plaintiff
- ☐ 3 Federal Question *(U.S. Government Not a Party)*
- ☐ 2 U.S. Government Defendant
- ☒ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☒ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☒ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☒ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

Click here for: Nature of Suit Code Descriptions.

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☒ 195 Contract Product Liability
- ☐ 196 Franchise

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Personal Injury - Medical Malpractice

PERSONAL INJURY
- ☒ 365 Personal Injury - Product Liability
- ☐ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

CIVIL RIGHTS
- ☐ 440 Other Civil Rights
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 445 Amer. w/Disabilities - Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 448 Education

PRISONER PETITIONS

Habeas Corpus:
- ☐ 463 Alien Detainee
- ☐ 510 Motions to Vacate Sentence
- ☐ 530 General
- ☐ 535 Death Penalty

Other:
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition
- ☐ 560 Civil Detainee - Conditions of Confinement

FORFEITURE/PENALTY
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Management Relations
- ☐ 740 Railway Labor Act
- ☐ 751 Family and Medical Leave Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Employee Retirement Income Security Act

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 465 Other Immigration Actions

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 835 Patent - Abbreviated New Drug Application
- ☐ 840 Trademark

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ☐ 375 False Claims Act
- ☐ 376 Qui Tam (31 USC 3729(a))
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit
- ☐ 490 Cable/Sat TV
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 895 Freedom of Information Act
- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes

V. ORIGIN *(Place an "X" in One Box Only)*

☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from Another District *(specify)* ☐ 6 Multidistrict Litigation - Transfer ☐ 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing *(Do not cite jurisdictional statutes unless diversity)*:
28 USC Sec. 1332(a)

Brief description of cause:
Complaint for Damages For Personal Injury from Negligence, Strict Liability and Breach of Warranties

VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A **CLASS ACTION** UNDER RULE 23, F.R.Cv.P.

DEMAND $ $15,000,000

CHECK YES only if demanded in complaint:
JURY DEMAND: ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE _____ DOCKET NUMBER _____

DATE
February 15, 2018

SIGNATURE OF ATTORNEY OF RECORD Jason Montclare

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____