UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF GEORGIA

THERESA CALLAWAY,	)	**Civil Action No.:**
	)	
Plaintiff,	)	
	)	
v.	)	**COMPLAINT AND JURY**
	)	**DEMAND**
	)	
ATRIUM MEDICAL	)	
CORPORATION,	)	
MAQUET CARDIOVASCULAR,	)	
LLC	)	
d/b/a MAQUET MEDICAL	)	
SYSTEMS	)	
USA; and GETINGE USA, INC.,	)	
	)	
Defendants.		

Plaintiff, by and through her undersigned counsel, bring this Complaint for damages against Defendants and in support thereof state 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. As a result, Plaintiff THERESA CALLAWAY suffered permanent injuries and significant pain and suffering, emotional distress, lost wages and earning capacity, and diminished

quality of life. The Plaintiff respectfully seeks all damages to which she may be legally entitled.

I. STATEMENT OF PARTIES

2.

Plaintiff Theresa Callaway ("Plaintiff") is, and was, at all relevant times, a citizen and resident of Georgia and the United States.

3.

Defendant Atrium Medical Corporation ("Atrium") is a corporation organized under the laws of Delaware, with its corporate headquarters and principal place of business located in Merrimack, New Hampshire. Atrium Medical Corporation identifies its registered agent for service of process as CT Corporation System, located at 9 Capitol Street in Concord, New Hampshire. Atrium is a pharmaceutical and medical device company involved in the research, development, testing, manufacture, production, distribution, marketing, promotion and/or sale of medical devices used for hernia repair, including C-Qur mesh.

4.

Defendant Maquet Cardiovascular, LLC ("Maquet CV") is a corporation organized under the laws of Delaware, with its principal place of business at 45 Barbour Pond Drive, Wayne, New Jersey 07470. Maquet CV also conducts

business under the name Maquet Medical Systems USA, although such entity name is not registered in the States of Delaware or New Jersey. Maquet CV is a pharmaceutical and medical device company involved in the research, development, testing, manufacture, production, distribution, marketing, promotion and/or sale of medical devices used for hernia repair, including C-Qur mesh.

5.

Defendant Getinge USA, INC. ("Getinge USA") is a corporation organized under the laws of Delaware, with its principle place of business 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 C-Qur mesh. Getinge USA is a subsidiary of Getinge.

6.

At all relevant times, each of the Defendants designed, developed, manufactured, licensed, marketed, distributed, sold and/or placed Hernia Mesh Products in the stream of commerce, including the C-Qur mesh that is at issue in this lawsuit.

7.

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

8.

At all relevant times, each of the Defendants was and still is a corporation authorized to do business in the State of Georgia.

9.

At all times hereinafter mentioned, upon information and belief, each of the Defendants, was and still is a business entity actually doing business in the State of Georgia.

10.

Defendants share many of the same officers, directors and operations; and maintain ownership in the assets and/or liabilities relating to the design, manufacture, marketing, distribution and sale of the medical device line at issue in this litigation and shall be referenced collectively hereinafter as "Defendants."

11.

At all times hereinafter mentioned, each of the Defendants were, and are currently, engaged in the business of designing, manufacturing, advertising,

marketing, and selling Hernia Mesh Products including the C-Qur Mesh Family (referred to herein, at times as "C-Qur Mesh" or "Hernia Mesh Product"), and in pursuance of this business, transacts business within the State of Georgia and contracts to provide goods and services in the State of Georgia.

12.

At all times hereinafter mentioned, upon information and belief, Defendants committed tortious acts inside and outside the State of Georgia, which caused injury to Plaintiff inside the State of Georgia.

13.

At all times hereinafter mentioned, upon information and belief, Defendants expect or should reasonably expect its acts to have consequences in the State of Georgia, and derives substantial revenue from interstate or international commerce.

II. VENUE AND JURISDICTION

14.

Damages sought in this matter are in excess of $75,000.00. Subject matter jurisdiction is proper pursuant to 28 U.S.C. §1332(a)-(c).

15.

This Court has subject matter jurisdiction over the parties pursuant to 28 U.S.C. §1332(a) because the parties are citizens of different states and the amount in controversy exceeds $75,000.00, exclusive of interest and cost.

16.

Venue is proper in this Court pursuant to 28 U.S.C. §1332(a)-(c) by virtue of the facts that (a) a substantial part of the events or omissions giving rise to the claims occurred in this District and (b) Defendants' products are sold to and consumed by individuals in the State of Georgia, thereby subjecting Defendants to personal jurisdiction in this action and making them all "residents" of this judicial District.

17.

Defendants have and continue to conduct substantial business in the State of Georgia and in this District, distribute Hernia Mesh Products in this District, receive substantial compensation and profits from sales of Hernia Mesh Products in this District, and made material omissions and misrepresentations and breaches of warranties in this District, so as to subject them to *in personam* jurisdiction in this District.

18.

Defendants conducted business in the State of Georgia through sales representatives conducting business in the State of Georgia and because Defendants were engaged in testing, developing, manufacturing, labeling, marketing, distributing, promoting and/or selling, either directly or indirectly, and/or through third parties or related entities, Hernia Mesh Products in Georgia.

19.

Consistent with the Due Process Clause of the Fifth and Fourteenth Amendments, this Court has *in personam* jurisdiction over Defendants, because Defendants are present in the State of Georgia, such that requiring an appearance does not offend traditional notices of fair and substantial justice.

III. DEFENDANTS' HERNIA MESH PRODUCTS

20.

In or about 1993, Defendants began to market and sell surgical mesh for the treatment of multiple medical conditions, primarily hernia repair.

21.

Defendants' Hernia Mesh Products were designed, patented, manufactured, labeled, marketed, sold, and distributed by the Defendants at all relevant times herein.

22.

Defendants' products contain polypropylene mesh. Despite claims that this material is inert, a substantial body of scientific evidence shows that this mesh material is biologically incompatible with human tissue and promotes and immune response in a large subset of the population receiving Defendants' products. This immune response promotes degradation of the polypropylene mesh, as well as the surrounding tissue, and can contribute to the formation of severe adverse reactions to the mesh.

23.

Defendants' polypropylene based Hernia Mesh Products are designed, intended, and utilized for permanent implantation into the human body.

24.

Defendants failed to warn or notify doctors, regulatory agencies, and consumers of the known severe and life-threatening risks associated with polypropylene.

25.

Upon information and belief, Defendants use adulterated polypropylene in their Hernia Mesh Products.

26.

Defendants' failed to warn or notify doctors, regulatory agencies, and consumers of the Defendants' use of adulterated polypropylene in their Hernia Mesh Products.

27.

Defendants' C-Qur Mesh utilizes a blend of Omega 3 Fatty Acid Fish Oil ("O3FA") to form a barrier coating on its C-Qur Mesh.

28.

The O3FA is derived from fish. Fish derivatives are considered to be commonly allergenic and immunogenic. If various remnants of the fish – such as proteins, genetic material, or adjuvant compounds – remain in the O3FA coating, an immune response can occur, causing complications including but not limited to pain, graft rejection, graft migration, organ damage, complex seroma, fistula, sinus tract formation, delayed wound closure, infection, sepsis, and death.

29.

Proteins are not very soluble in oils; however, non-soluble proteins may remain in the oil as particulate matter.

30.

Upon information and belief, Defendants failed to adequately test, inspect, and/or verify that each supplied batch of O3FA was free from proteins, genetic material, and adjuvant compounds.

31.

Upon information and belief, Defendants utilized adulterated O3FA in the production of the C-Qur Mesh.

32.

Upon receiving reports from surgeons and physicians of apparent allergic reactions to the C-Qur Mesh, Defendants misled physicians about the ability and tendency of O3FA to cause allergic reactions in patients implanted with a C-Qur Mesh and attempted to convince the physicians of alternate causes. Defendants' intentionally, or at very least, recklessly disregarded human life by misleading physicians about the possible causes of the allergic reaction, resulting in significantly more severe injuries in those already implanted with the C-Qur Mesh, and more patients nationwide being implanted with the C-Qur Mesh.

33.

Upon information and belief, Defendants' changed the way in which they handled and/or applied the O3FA coating to the C-Qur Mesh. This change in the

manufacturing process was a deviation from the initial design and was carried out without first conducting tests to determine the effect of the change on patient safety.

34.

Upon information and belief, Defendants utilized non-conforming goods in the production of the C-Qur Mesh, including accepting goods without the required documentation to verify the source, quality, authenticity, or chain of custody of the goods.

35.

Upon information and belief, the O3FA component of Defendants' C-Qur Mesh is cytotoxic, immunogenic, and not biocompatible, resulting in complications such as delayed wound healing, inflammation, foreign body response, rejection, infection, and death.

36.

Upon information and belief, Defendants had actual knowledge of the cytotoxic and immunogenic properties of the O3FA component of the C-Qur Mesh prior to introducing it into the stream of commerce.

37.

Defendants failed to adequately test the effects of the known cytotoxicity of the C-Qur Mesh in animals and humans, both before and after the product entered the stream of commerce.

38.

Defendants failed to warn or notify doctor, regulatory agencies, and consumers of the cytotoxicity of the C-Qur Mesh.

39.

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

40.

Moisture and high humidity levels are contraindicated for the C-Qur Mesh, as it will result in the O3FA coating peeling off the polypropylene and/or sticking to the packaging.

41.

Defendants' use of ETO on the C-Qur Mesh results in either:

A. High infection rates due to inadequate moisture during the ETO cycle; or

B. O3FA coating peeling off the polypropylene due to moisture.

42.

Defendants failed to warn or instruct distributors and facilities of critical environmental guidelines, such as relative humidity or temperature during transportation and/or storage of the C-Qur Mesh. The environmental guidelines for the C-Qur Mesh are unique to the C-Qur Mesh and are not necessary for other similar or competing hernia mesh products. Excess temperature and/or humidity result in the C-Qur Mesh degrading and transforming into an even more dangerous product.

43.

Defendants failed to conduct adequate testing to determine the proper environmental guidelines for storage and transportation of the C-Qur Mesh prior to introducing it into the stream of commerce.

44.

ETO is ineffective at sterilizing the C-Qur Mesh due the O3FA coating, multiple layers of the mesh, and mated surfaces of the C-Qur Mesh.

45.

Defendants changed the process of their ETO sterilization cycle without performing adequate testing or verification of sterility, or other effects the changes might have had on the product. This change in the manufacturing process was a deviation from the initial design and was carried out without first conducting tests to determine the effect of the change on patient safety.

46.

Upon information and belief, Defendants utilized a package that allowed humidity levels to fluctuate to unacceptably high levels within the package.

47.

Upon information and belief, Defendants utilized a packaging material that promoted the O3FA coating to adhere to the packaging of the C-Qur Mesh.

48.

Upon information and belief, Defendants manufactured the C-Qur Mesh in a way that promoted that O3FA coating to adhere to the packaging of the C-Qur Mesh.

49.

Defendants failed to properly warn physicians, regulatory agencies, and consumers of the risk associated with the O3FA coating adhering to the package. Defendants assured physicians and regulatory agencies that the C-Qur Mesh was still fit for human implantation, even if some or all of the O3FA coating had been pulled away.

50.

Once the O3FA coating has started or shown propensity to detach from the polypropylene, it is much more likely that the O3FA coating will detach from the polypropylene once implanted. If the O3FA coating detaches once implanted, it can float in the body or ball up, causing an even more intense foreign body reaction, resulting in rejection and other complications related to the C-Qur Mesh.

Detachment of the O3FA coating also greatly increases the risk of the C-Qur Mesh adhering to the patients' underlying organs, resulting in significantly more difficult and complex surgeries to remove the mesh. Due to the C-Qur Mesh adhering to the underlying organs, patients can experience significant, life-changing injuries, prolonged hospital stays, and even death.

51.

Defendants were and are currently aware of the life-threatening complications associated with the O3FA coating peeling off inside of patients.

52.

Defendants encouraged physicians to implant C-Qur Mesh in which the O3FA coating had peeled away from the polypropylene and was stuck to the packaging.

53.

Defendants' encouragement of physicians to implant C-Qur Mesh in which the O3FA coating had adhered to the packaging and was no longer present on the polypropylene was an intentional, or at very least, a reckless disregard of human life, and health.

54.

Defendants changed the way in which the C-Qur Mesh is packaged. This change in the manufacturing process was a deviation from the initial design and was carried out without first conducting tests to determine the effect on patient safety.

55.

Upon information and belief, at all relevant times, Defendants modified the processing temperature and processing speed of one or more steps in the manufacturing process. This change in the manufacturing process was a deviation from the initial design and was carried out without first conducting tests to determine the effect on patient safety.

56.

Upon information and belief, Defendants adjusted the threshold for reporting and recalling the C-Qur Mesh due to nonconformities and adverse event reports when the threshold was met, resulting in a large number of injurious events that were deemed by the Defendants to be "acceptable" and went unreported as a result and unrecalled.

57.

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

58.

Upon information and belief, Defendants paid researchers, doctors, clinicians, study designers, authors, and/or scientists to study the effectiveness of the C-Qur Mesh, but did not disclose these relationships in the study itself.

59.

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

60.

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

61.

Defendants failed to employ an adequate number of staff to receive, process, investigate, document, and report adverse events.

62.

Defendants "stealth recalled" multiple types of C-Qur Mesh that were experiencing high levels of adverse events, by simply halting production of multiple types of C-Qur Mesh without notifying physicians, or consumers of the recall or high levels of adverse events.

63.

Defendants failed to implement adequate procedures and policies to detect the presence of foreign materials in or on the C-Qur Mesh.

64.

Defendants failed to implement adequate procedures and policies to prevent C-Qur Mesh with known foreign materials from entering the stream of commerce.

65.

Defendants failed to design a method or process that ensures conformity in the amount of O3FA applied to each type of C-Qur Mesh.

66.

Defendants failed to warn or instruct physicians on the proper and/or contraindicated methods of securing and/or implanting the C-Qur Mesh. Defendants blamed physicians' methods of implantation and securing the C-Qur

Mesh when complications known by the Defendants to be caused by a defect in the C-Qur Mesh were reported by physicians.

67.

Defendants marketed the C-Qur Mesh to the medical community and to patients as safe, effective and reliable medical devices for the treatment of hernia repair, and as safer and more effective as compared to the traditional products and procedures for treatment, and other competing mesh products. Defendants have made claims that the C-Qur Mesh is superior in a variety of ways, but have never conducted a single clinical study on the C-Qur Mesh implanted in humans. Defendants' deception through false advertising resulted in more physicians utilizing the C-Qur Mesh.

68.

Defendants signed a national contract with Premier Inc. ("Premier"), a group purchasing organization, on August 10, 2010. Premier supplies medical devices in bulk to member hospitals at a reduced cost. Defendants' contract with Premier greatly increased the nationwide demand for the C-Qur Mesh. Defendants changed numerous aspects of the manufacturing process of the C-Qur Mesh, before and after the contract with Premier, in order to increase production and decrease cost.

69.

Defendants marketed and sold the C-QUR Mesh Products to the medical community at large and patients through carefully planned, multifaceted marketing campaigns and strategies. These campaigns and strategies include, but are not limited to, aggressive marketing to health care providers at medical conferences, hospitals, and private offices, and include the provision of valuable benefits to health care providers. Also utilized were documents, patient brochures, and websites.

70.

For years the Defendants have been notified and warned about the widespread catastrophic complications associated with the C-Qur Mesh by leading hernia repair specialists, surgeons, hospitals, patients, internal consultants, and employees. However, not a single C-Qur Mesh has been recalled from the market. Defendants have misrepresented the efficacy and safety of the C-Qur Mesh, through various means and media, actively and intentionally misleading the medical community, patients, and the public at large.

71.

Defendants failed to perform or rely on proper and adequate testing and research in order to determine and evaluate the risks and benefits of the Defendants' C-Qur Mesh.

72.

Defendants failed to design and establish a safe, effective procedure for removal of the Defendants' C-Qur Mesh; therefore, in the event of a failure, injury, or complications it is impossible to easily and safely remove the Defendants' C-Qur Mesh.

73.

Feasible and suitable alternative procedures and instruments, as well as suitable alternative designs for implantation and treatment of hernias and soft tissue repair have existed at all times relevant as compared to the Defendants' C-Qur Mesh.

74.

The Defendants' C-Qur Mesh were at all times utilized and implanted in a manner foreseeable to the Defendants.

75.

The Defendants have at all times provided incomplete, insufficient, and misleading training and information to physicians, in order to increase the number of physicians utilizing the Defendants' C-Qur Mesh, and thus increase the sales of the C-Qur Mesh, and also leading to the dissemination of inadequate and misleading information to patients, including Plaintiff.

76.

The C-Qur Mesh implanted into the Plaintiff was in the same or substantially similar condition as when it left the possession of the Defendants, and in the condition directed by and expected by the Defendants.

IV. FACTUAL BACKGROUND

77.

On February 27, 2008, Plaintiff was seen at Spalding Regional Medical Center for laparoscopic repair of a ventral hernia. A 20 x 15 piece of C-Qur Edge mesh was used to repair this defect.

78.

Defendant, manufactured, sold, and/or distributed the C-QUR Mesh Product to Plaintiff, through her doctors, to be used for treatment of hernia repair.

79.

On March 24, 2008, Plaintiff presented to the Emergency Room at Piedmont Henry Hospital with abdominal pain, nausea, and vomiting.

80.

On April 14, 2008, Plaintiff was seen at Piedmont Henry Hospital with continued abdominal pain that had lasted over a week.

81.

On April 15, 2008, Plaintiff was again seen at Piedmont Henry Hospital where a 10 x 15 C-Qur Edge mesh was implanted for recurrent ventral hernia. On November 15, 2008, Plaintiff was seen at Piedmont Henry Hospital for acute abdominal pain at the mesh repair area. It was noted the mesh area was diffusely tender and there was the possibility of small groin cellulitis.

82.

On December 20, 2013 through February 9, 2014, Plaintiff was admitted to Piedmont Henry Hospital for severe and chronic abdominal pain. During her hospital stay she underwent an exploratory laparotomy, subtotal colectomy, small bowel resection, and recurrent incisional hernia repair. During the operation the surgeon noted the C-Qur Edge hernia mesh seemed to be "bunched up in layers" before dividing through it to open up the abdomen.

83.

On March 7, 2014, Plaintiff presented to Piedmont Henry Hospital with nausea and vomiting for two weeks. She was unable to keep anything down and felt very weak.

84.

On March 13, 2014, Plaintiff presented to Piedmont Henry Hospital for stomach cramping without vomiting. She was admitted and given intravenous fluids for hydration.

85.

On March 14, 2014, Plaintiff underwent a esophogastroduodenoscopy. There was no evidence of obstruction, but there was significant reflux esophagitis which was thought to be secondary to vomiting. No mechanical cause for the vomiting was noted.

86.

On April 6, 2014, Plaintiff was seen again for persistent chronic nausea and vomiting, abdominal pain, headache, and hip pain. She was found to be in severe septic shock, acute renal failure, and hypotension likely secondary to dehydration and high ostomy output.

87.

On June 24, 2014, Plaintiff was seen at Piedmont Henry Hospital for severe abdominal pain with an open abdominal wound.

88.

On August 4-8, 2015, Plaintiff was admitted to Piedmont Henry Hospital feeling weak, lethargic, with an active MRSA infection of her open abdominal wound. The wound edge was draining purulent and bloody malodorous fluid.

89.

On August 10, 2015, Plaintiff was seen by Dr. Fitzsimmons for exposed mesh in her open wound. He felt she was too ill, and would remain too ill to undergo surgery to remove the mesh entirely. However, due to the pain she felt from the mesh poking into her open wound when she bends over, Dr. Fitzsimmons decided to trim away exposed pieces of mesh without using anesthesia. He noted the mesh was "folded up" in that area and it took an extended amount of time to remove a large amount of mesh, which measured 8 x 2 cm when laid out flat.

90.

The C-Qur Mesh Products were at all times utilized and implanted in a manner foreseeable to Defendant, as Defendant generated the instructions for use and created procedures for implanting the mesh.

91.

Other than any degradation caused by faulty design, manufacturing, or faulty packaging, the C-QUR Mesh implanted into the Plaintiff was in the same or substantially similar condition as when it left the possession of Defendants, and in the condition directed by and expected by Defendant.

92.

Plaintiff and her physicians foreseeably used and implanted the C-QUR Mesh Products, and did not misuse, or alter the Products in an unforeseeable manner.

93.

Defendants advertised, promoted, marketed, sold, and distributed the C-QUR Mesh Products as a safe medical device when Defendant knew or should have known the C-QUR Mesh Products were not safe for their intended purposes and that the mesh products could cause serious complications.

94.

Defendants had sole access to material facts concerning the defective nature of the products and their propensity to cause serious and dangerous side effects and complications.

95.

In reliance on Defendants' representations, Plaintiff's doctor was induced to, and did use the C-Qur Mesh to treat Plaintiff.

96.

As a result of having the C-Qur Mesh implanted in her, Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, permanent and substantial physical deformity, has undergone and will undergo corrective surgery or surgeries, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and present and future lost wages.

97.

Defendants' C-Qur Meshes have been and continue to be marketed to the medical community and to patients as safe, effective, reliable, medical devices; implanted by safe and effective, minimally invasive or open surgical techniques for the treatment of medical conditions, primarily hernia repair and soft tissue repair, and as a safer and more effective as compared to the traditional products and procedures for treatment, and other competing hernia mesh products.

98.

The Defendants have marketed and sold the Defendants' C-Qur Meshes to the medical community at large and patients through carefully planned, multifaceted marketing campaigns and strategies. These campaigns and strategies include, but are not limited to, direct to consumer advertising, aggressive marketing to health care providers at medical conferences, hospitals, private offices, and/or group purchasing organizations, and include a provision of valuable consideration and benefits to the aforementioned.

99.

The injuries, conditions, and complications suffered due to Defendants' C-Qur Meshes include but are not limited to foreign body reaction, rashes, infection, adhesions, organ perforation, inflammation, fistula, mesh erosion, scar tissue, blood loss, dyspareunia, neuropathic and other acute and chronic nerve damage and pain, abdominal pain, nausea, vomiting, kidney failure, and in many cases the patients have been forced to undergo intensive medical treatment, including but not limited to operations to locate and remove the C-Qur Mesh, operations to attempt to repair abdominal organs, tissue, and nerve damage, the use of narcotics for pain control and other medications, and repeat operations to remove various tissues that are contaminated with the C-Qur Mesh.

100.

Plaintiff in the exercise of due diligence, could not have reasonably discovered the cause of her injuries including but not limited to the defective design and/or manufacturing the C-Qur Mesh implanted inside of her until a date within the applicable statute of limitations.

COUNT I

NEGLIGENCE

101.

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

102.

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

103.

Defendants breached their duty of care to the Plaintiff, as aforesaid, in the manufacture, design, labeling, warnings, instructions, sale, marketing, distribution, and recruitment and training of physicians to implant the C-Qur Mesh.

104.

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

105.

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

106.

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

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

COUNT II

STRICT LIABILITY – DESIGN DEFECT

107.

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

108.

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

109.

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

110.

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

111.

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

112.

The C-Qur Mesh failed to perform as safely as an ordinary consumer and/or her physician would expect when used as intended or when used in a manner reasonably foreseeable by the manufacturer, and the risks and dangers of the C-Qur mesh outweigh its benefits. The design defects in the C-Qur mesh were not known, knowable and/or reasonably visible to Plaintiff and/or her physician or discoverable upon any reasonable examination. The C-Qur mesh was used and implanted in the manner in which it was intended to be used and implanted by Defendants pursuant to the instructions for use and the product specifications

provided by Defendants.

113.

The defective and unreasonably dangerous condition of the C-Qur Mesh was the proximate cause of the damages and injuries complained of by Plaintiff.

114.

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

115.

Defendants are strictly liable to Plaintiff.

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

COUNT III

STRICT LIABILITY – MANUFACTURING DEFECT

116.

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

117.

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

118.

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

119.

The C-Qur Mesh was expected to reach and did reach Plaintiff's implanting surgeon and Plaintiff without substantial change in the condition in which it was

manufactured, suppled, distributed sold and/or otherwise placed in the stream of commerce.

120.

The manufacturing defect in the C-Qur mesh implanted in Plaintiff was not known, knowable or readibly visible to Plaintiff's physician or to Plaintiff nor was it discoverable upon any reasonable examination by Plaintiff's physician or Plaintiff. The C-Qur Mesh was used and implanted in the very manner in which it was intended to be used and implanted by Defendant in accordance with the instructions for use and specifications provided by Defendants.

121.

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

122.

The defective and unreasonably dangerous condition of the C-Qur Mesh product was a proximate cause of damages and injuries suffered by Plaintiff.

123.

As a direct and proximate result of the C-Qur Mesh's aforementioned manufacturing defect, Plaintiff was caused and in the future will be caused to

suffer severe personal injuries, pain and suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligations for medical services and expenses, and other damages.

124.

Defendants are strictly liable to Plaintiff.

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

COUNT IV

STRICT LIABILITY – FAILURE TO WARN

125.

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

126.

Defendants manufacture, design, market, sell and/or otherwise place into the stream of commerce their C-Qur mesh.

127.

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

128.

The Defendants failed to properly and adequately warn and instruct Plaintiff and her treating physician as to the risks and benefits of the Defendants' C-Qur Mesh. To the contrary, Defendants withheld information from Plaintiff and her treating physician regarding the true risks as relates to implantation of their C-Qur mesh.

129.

The Defendants failed to properly and adequately warn and instruct Plaintiff and her treating physician that inadequate research and testing of the C-Qur Mesh was done prior to C-Qur mesh being placed on the market and in the stream of commerce and that Defendants' lacked a safe, effective procedure for removal of

the C-Qur Mesh once complications from same arise.

130.

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

131.

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

132.

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

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

COUNT V

BREACH OF EXPRESS WARRANTY

133.

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

134.

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

135.

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

136.

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

Defendants.

137.

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

138.

Defendants breached express representations and warranties made to Plaintiff and her physicians and healthcare providers with respect to the C-Qur Mesh implanted in Plaintiff including the following particulars:

A. Defendants represented to Plaintiff and her physicians and healthcare providers through labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions among other ways that the

Defendants' C-Qur Mesh was safe; meanwhile Defendants fraudulently withheld and concealed information about the substantial risks of serious injury associated with using C-Qur Mesh;

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

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

139.

At the time of making such express warranties, Defendants knew or should have known that Defendants' C-Qur Mesh does not conform to the express warranties and Defendants' acts were motivated by financial gain while the adverse consequences of Defendants' conduct was outrageous, fraudulent, oppressive, done

with malice or gross negligence and evidenced reckless indifference to Plaintiff's rights, health and safety so as to warrant the imposition of punitive damages.

140.

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

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

COUNT VI

BREACH OF IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS OF PURPOSE

141.

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

in the alternative, if same be necessary, alleges as follows:

142.

At all relevant times, Defendants manufactured, distributed, advertised, promoted, and sold the Defendants' C-Qur Mesh.

143.

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

144.

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

145.

Defendants breached implied warranties with respect to the C-Qur Mesh including the following particulars:

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

B. Defendants represented to Plaintiff and her physicians and healthcare providers that the Defendants' C-Qur Mesh was safe, as safe as and/or safer than other alternative procedures and devices; meanwhile Defendants fraudulently concealed information, which demonstrated that the C-Qur Mesh was not safe, as safe as or safer than alternatives and other products available on the market; and

C. Defendants represented to Plaintiff and her physicians and healthcare providers that the Defendants' C-Qur Mesh were more

efficacious than other alternative procedures and/or devices; meanwhile Defendants fraudulently concealed information, regarding the true efficacy of C-Qur Mesh.

146.

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

147.

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

148.

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

149.

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

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

COUNT VII

VIOLATION OF CONSUMER PROTECTION LAWS

150.

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

151.

Plaintiff by and through her treating physician was implanted with

Defendants' C-Qur Mesh for the sole, primary and personal use and purpose of treating her physical medical condition and thereby suffered ascertainable losses as a result of Defendants' actions in violation of the consumer protection laws.

152.

Had Defendants not engaged in the deceptive conduct described herein, Plaintiff would not have purchased and/or otherwise been implanted with C-Qur Mesh, and would not have suffered permanent physical injury as described herein and incurred medical costs and expenses.

153.

Defendants engaged in wrongful conduct while at the same time obtaining, under false pretenses, moneys from Plaintiff for C-Qur Mesh that would not have been paid had Defendants not engaged in unfair and deceptive conduct.

154.

Defendants engaged in unfair methods of competition and/or deceptive acts or practices that were prescribed by law, including the following:

A. Representing that goods or services have characteristics, ingredients, uses, benefits or qualities that they do not have.

B. Advertising goods or services with the intent not to sell them as advertised; and,

C. Engaging in fraudulent or deceptive conduct that creates a likelihood of confusion or misunderstanding.

155.

Plaintiff was injured by the cumulative and indivisible nature of Defendants' conduct. The cumulative effect of Defendants' conduct directed at patients, physicians and consumers was to create demand for and sell the Defendants' C-Qur Mesh. Each aspect of Defendants' conduct combined to artificially create sales of Defendants' C-Qur Mesh.

156.

Defendants have a statutory duty to refrain from unfair or deceptive acts or trade practices in the design, labeling,

157.

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

158.

Defendants' actions, as complained of herein, constitute unfair competition or unfair, unconscionable, deceptive or fraudulent acts, or trade practices in

violation of federal and state consumer protection statues, as listed below.

159.

Defendants have engaged in unfair competition or unfair or deceptive acts or trade practices or have made false representations in violation of:

- 15 U.S.C. §§ 2301-2312 (1982)
- Georgia Fair Business Practices Act (O.C.G.A. Sections 10-1-390 *et seq.*)

160.

Under the statutes listed above that protect consumers from unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising, Defendants are the suppliers, manufacturers, advertisers, and sellers, who are subject to liability under such legislation for unfair, deceptive, fraudulent and unconscionable consumer sales practices.

161.

Defendants violated the statutes that were enacted in Georgia to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising, by knowingly and falsely representing that the Defendants' C-Qur Mesh was fit to be used for the purpose for which it was intended while in fact it was defective and dangerous, and by other acts alleged

herein. These representations were made in marketing and promotional materials.

162.

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

163.

Defendants had actual knowledge of the defective and dangerous condition of Defendants' C-Qur Mesh and failed to take any action to cure such defective and dangerous conditions to the detriment of Plaintiff and other consumers.

164.

The medical community including Plaintiff's physician and other health care providers relied upon Defendants' misrepresentations and omissions in determining whether to use Defendants' C-Qur mesh.

165.

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

166.

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

167.

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

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly and severally, and requests restitution and disgorgement of profits, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems just and proper.

COUNT VIII

GROSS NEGLIGENCE AND INTENTIONAL CONDUCT

168.

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

169.

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

170.

The acts and omissions of Defendants, whether taken singularly or in combination with others, constitute gross negligence or willful and/or intentional conduct that proximately caused injuries to Plaintiff. In that regard, Plaintiff seeks exemplary and punitive damages in an amount that would punish Defendants for their conduct and which would deter other similar medical device manufacturers or entities from engaging in such misconduct in the future.

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

COUNT IX

UNJUST ENRICHMENT

171.

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

172.

Defendants are and at all times were the manufacturers, sellers, and/or suppliers of C-Qur Mesh.

173.

Plaintiff was implanted with Defendants' C-Qur Mesh for the purpose of treatment for hernia repair and/or a soft tissue injury and Defendants were paid for Plaintiffs' use of said product.

174.

Defendants have accepted payment by Plaintiff and/or by others on Plaintiff's behalf for the purchase of the C-Qur Mesh with which Plaintiff was implanted.

175.

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

176.

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

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

VICARIOUS LIABILITY

177.

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

DISCOVERY RULE AND FRAUDULENT CONCEALMENT

178.

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

179.

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

180.

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

181.

Defendant is estopped from asserting a statute of limitations defense because Defendant fraudulently concealed from Plaintiff the nature of her injuries and the connection between the injuries and Defendants' tortious conduct.

PUNITIVE DAMAGES ALLEGATIONS

182.

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

183.

At all times relevant hereto, Defendants knew or should have known that C-Qur Mesh was inherently more dangerous with respect to the risks of foreign body response, allergic reactions, rejection, infection, failure, erosion, pain and suffering, organ perforation, dense adhesions, 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 are permanent and lasting in nature.

184.

At all times material hereto, Defendants attempted to misrepresent and did

intentionally and knowingly misrepresent facts concerning the safety of their C-Qur Mesh product.

185.

Defendants' misrepresentation included knowingly withholding material information from the medical community and the public, including Plaintiff, concerning the safety and efficacy of the C-Qur Mesh which deprived Plaintiff and her implanting physician with vitally necessary information with which to make a fully informed decision about whether to use C-Qur mesh in her care and treatment.

186.

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

187.

At all times material hereto, Defendants knew and recklessly and/or intentionally disregarded the fact that C-Qur Mesh can cause debilitating and potentially life threatening side effects with greater frequency than safer alternative products and/or methods of treatment and recklessly failed to advise the medical

community and the general public including Plaintiff of the same.

188.

At all times material hereto, Defendants intentionally misstated and misrepresented data and continue to misrepresent data so as to minimize the risk of injuries and the rate of complication caused by and associated with C-Qur Mesh.

189.

Notwithstanding the foregoing and the growing body of knowledge and information regarding the true defective nature of C-Qur Mesh with its increased risk of side effects and serious complications, Defendants continue to aggressively market C-Qur Mesh to the medical community and to consumers without disclosing the true risk of such complications and side effects.

190.

At the time Plaintiff was implanted with C-Qur Mesh and since that time, Defendants knew that C-Qur Mesh was defective and unreasonably dangerous but continued to manufacture, produce, assemble, market, distribute, and sell C-Qur Mesh so as to maximize sales and profits at the expense of the health and safety of the Public, including Plaintiff, in a conscious, reckless and/or intentional disregard of the likely and foreseeable harm caused by C-Qur Mesh to members of the public including Plaintiff.

191.

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

192.

Defendants conduct, acts and omissions as described herein are of such character and nature so as to entitle Plaintiff to an award of punitive damages in accordance with applicable statutory and common law.

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

PRAYER FOR RELIEF

Plaintiff demands judgment against Defendants, and each of them, 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, past and future health and medical care costs and economic damages including past and future lost earnings and/or earning capacity together with interest and costs as provided by law;

ii. Punitive damages

iii. Reasonable attorneys' fees as provided by law;

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

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

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

JURY TRIAL DEMANDED

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

Respectfully submitted,

PLAINTIFF THERESA CALLAWAY
By her attorney,

/s/ W. Todd Harvey
W. Todd Harvey (Georgia Bar No.: 335553)
BURKE HARVEY, LLC

2 Ravinia Drive, Suite 1330
Atlanta, Georgia 30243

3535 Grandview Parkway, Suite 100
Birmingham, AL 35243
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Fax: 205-930-9054
tharvey@burkeharvey.com

ATTORNEY FOR PLAINTIFF

JS44 (Rev. 6/16 NDGA)

CIVIL COVER SHEET

The JS44 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 is required for the use of the Clerk of Court for the purpose of initiating the civil docket record. (SEE INSTRUCTIONS ATTACHED)

I. (a) PLAINTIFF(S)

Theresa Callaway

(b) COUNTY OF RESIDENCE OF FIRST LISTED PLAINTIFF Clayton County, GA
(EXCEPT IN U.S. PLAINTIFF CASES)

DEFENDANT(S)

Atrium Medical Corporation, Maquet Cardiovascular, LLC d/b/a Maquet Medical Systems USA; and Getinge USA Inc.,

COUNTY OF RESIDENCE OF FIRST LISTED DEFENDANT Hillsborough County, NH
(IN U.S. PLAINTIFF CASES ONLY)

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

(c) ATTORNEYS (FIRM NAME, ADDRESS, TELEPHONE NUMBER, AND E-MAIL ADDRESS)

W. Todd Harvey
Burke Harvey, LLC
2 Ravinia Drive, Suite 1330 Atlanta, GA 30243
3535 Grandview Parkway, Suite 100 Birmingham, AL 35243 T: 205-930-9091 EM: tharvey@burkeharvey.com

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)

PLF	DEF		PLF	DEF	
☑ 1	☐ 1	CITIZEN OF THIS STATE	☐ 4	☐ 4	INCORPORATED OR PRINCIPAL PLACE OF BUSINESS IN THIS STATE
☐ 2	☐ 2	CITIZEN OF ANOTHER STATE	☐ 5	☑ 5	INCORPORATED AND PRINCIPAL PLACE OF BUSINESS IN ANOTHER STATE
☐ 3	☐ 3	CITIZEN OR SUBJECT OF A FOREIGN COUNTRY	☐ 6	☐ 6	FOREIGN NATION

IV. 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 District)
- ☐ 6 MULTIDISTRICT LITIGATION - TRANSFER
- ☐ 7 APPEAL TO DISTRICT JUDGE FROM MAGISTRATE JUDGE JUDGMENT
- ☐ 8 MULTIDISTRICT LITIGATION - DIRECT FILE

V. CAUSE OF ACTION (CITE THE U.S. CIVIL STATUTE UNDER WHICH YOU ARE FILING AND WRITE A BRIEF STATEMENT OF CAUSE - DO NOT CITE JURISDICTIONAL STATUTES UNLESS DIVERSITY)

28§1332 PL - Medical device tort action arising out of the failure of the Defendants Hernia Mesh Product.

(IF COMPLEX, CHECK REASON BELOW)

- ☐ 1. Unusually large number of parties.
- ☐ 2. Unusually large number of claims or defenses.
- ☐ 3. Factual issues are exceptionally complex
- ☐ 4. Greater than normal volume of evidence.
- ☐ 5. Extended discovery period is needed.
- ☐ 6. Problems locating or preserving evidence
- ☐ 7. Pending parallel investigations or actions by government.
- ☐ 8. Multiple use of experts.
- ☐ 9. Need for discovery outside United States boundaries.
- ☐ 10. Existence of highly technical issues and proof.

CONTINUED ON REVERSE

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT $_____ APPLYING IFP _____ MAG. JUDGE (IFP) _____

JUDGE _____ MAG. JUDGE _____ NATURE OF SUIT _____ CAUSE OF ACTION _____
(Referral)

VI. NATURE OF SUIT (PLACE AN "X" IN ONE BOX ONLY)

CONTRACT - "0" MONTHS DISCOVERY TRACK
- ☐ 150 RECOVERY OF OVERPAYMENT & ENFORCEMENT OF JUDGMENT
- ☐ 152 RECOVERY OF DEFAULTED STUDENT LOANS (Excl. Veterans)
- ☐ 153 RECOVERY OF OVERPAYMENT OF VETERAN'S BENEFITS

CONTRACT - "4" MONTHS DISCOVERY TRACK
- ☐ 110 INSURANCE
- ☐ 120 MARINE
- ☐ 130 MILLER ACT
- ☐ 140 NEGOTIABLE INSTRUMENT
- ☐ 151 MEDICARE ACT
- ☐ 160 STOCKHOLDERS' SUITS
- ☐ 190 OTHER CONTRACT
- ☐ 195 CONTRACT PRODUCT LIABILITY
- ☐ 196 FRANCHISE

REAL PROPERTY - "4" MONTHS DISCOVERY TRACK
- ☐ 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 - "4" MONTHS DISCOVERY TRACK
- ☐ 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
- ☑ 365 PERSONAL INJURY - PRODUCT LIABILITY
- ☐ 367 PERSONAL INJURY - HEALTH CARE/ PHARMACEUTICAL PRODUCT LIABILITY
- ☐ 368 ASBESTOS PERSONAL INJURY PRODUCT LIABILITY

TORTS - PERSONAL PROPERTY - "4" MONTHS DISCOVERY TRACK
- ☐ 370 OTHER FRAUD
- ☐ 371 TRUTH IN LENDING
- ☐ 380 OTHER PERSONAL PROPERTY DAMAGE
- ☐ 385 PROPERTY DAMAGE PRODUCT LIABILITY

BANKRUPTCY - "0" MONTHS DISCOVERY TRACK
- ☐ 422 APPEAL 28 USC 158
- ☐ 423 WITHDRAWAL 28 USC 157

CIVIL RIGHTS - "4" MONTHS DISCOVERY TRACK
- ☐ 440 OTHER CIVIL RIGHTS
- ☐ 441 VOTING
- ☐ 442 EMPLOYMENT
- ☐ 443 HOUSING/ ACCOMMODATIONS
- ☐ 444 WELFARE
- ☐ 445 AMERICANS with DISABILITIES - Employment
- ☐ 446 AMERICANS with DISABILITIES - Other
- ☐ 448 EDUCATION

IMMIGRATION - "0" MONTHS DISCOVERY TRACK
- ☐ 462 NATURALIZATION APPLICATION
- ☐ 465 OTHER IMMIGRATION ACTIONS

PRISONER PETITIONS - "0" MONTHS DISCOVERY TRACK
- ☐ 463 HABEAS CORPUS- Alien Detainee
- ☐ 510 MOTIONS TO VACATE SENTENCE
- ☐ 530 HABEAS CORPUS
- ☐ 535 HABEAS CORPUS DEATH PENALTY
- ☐ 540 MANDAMUS & OTHER
- ☐ 550 CIVIL RIGHTS - Filed Pro se
- ☐ 555 PRISON CONDITION(S) - Filed Pro se
- ☐ 560 CIVIL DETAINEE: CONDITIONS OF CONFINEMENT

PRISONER PETITIONS - "4" MONTHS DISCOVERY TRACK
- ☐ 550 CIVIL RIGHTS - Filed by Counsel
- ☐ 555 PRISON CONDITION(S) - Filed by Counsel

FORFEITURE/PENALTY - "4" MONTHS DISCOVERY TRACK
- ☐ 625 DRUG RELATED SEIZURE OF PROPERTY 21 USC 881
- ☐ 690 OTHER

LABOR - "4" MONTHS DISCOVERY TRACK
- ☐ 710 FAIR LABOR STANDARDS ACT
- ☐ 720 LABOR/MGMT. RELATIONS
- ☐ 740 RAILWAY LABOR ACT
- ☐ 751 FAMILY and MEDICAL LEAVE ACT
- ☐ 790 OTHER LABOR LITIGATION
- ☐ 791 EMPL. RET. INC. SECURITY ACT

PROPERTY RIGHTS - "4" MONTHS DISCOVERY TRACK
- ☐ 820 COPYRIGHTS
- ☐ 840 TRADEMARK

PROPERTY RIGHTS - "8" MONTHS DISCOVERY TRACK
- ☐ 830 PATENT

SOCIAL SECURITY - "0" MONTHS DISCOVERY TRACK
- ☐ 861 HIA (1395ff)
- ☐ 862 BLACK LUNG (923)
- ☐ 863 DIWC (405(g))
- ☐ 863 DIWW (405(g))
- ☐ 864 SSID TITLE XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS - "4" MONTHS DISCOVERY TRACK
- ☐ 870 TAXES (U.S. Plaintiff or Defendant)
- ☐ 871 IRS - THIRD PARTY 26 USC 7609

OTHER STATUTES - "4" MONTHS DISCOVERY TRACK
- ☐ 375 FALSE CLAIMS ACT
- ☐ 376 Qui Tam 31 USC 3729(a)
- ☐ 400 STATE REAPPORTIONMENT
- ☐ 430 BANKS AND BANKING
- ☐ 450 COMMERCE/ICC RATES/ETC.
- ☐ 460 DEPORTATION
- ☐ 470 RACKETEER INFLUENCED AND CORRUPT ORGANIZATIONS
- ☐ 480 CONSUMER CREDIT
- ☐ 490 CABLE/SATELLITE TV
- ☐ 890 OTHER STATUTORY ACTIONS
- ☐ 891 AGRICULTURAL ACTS
- ☐ 893 ENVIRONMENTAL MATTERS
- ☐ 895 FREEDOM OF INFORMATION ACT
- ☐ 899 ADMINISTRATIVE PROCEDURES ACT / REVIEW OR APPEAL OF AGENCY DECISION
- ☐ 950 CONSTITUTIONALITY OF STATE STATUTES

OTHER STATUTES - "8" MONTHS DISCOVERY TRACK
- ☐ 410 ANTITRUST
- ☐ 850 SECURITIES / COMMODITIES / EXCHANGE

OTHER STATUTES - "0" MONTHS DISCOVERY TRACK
- ☐ 896 ARBITRATION (Confirm / Vacate / Order / Modify)

*** PLEASE NOTE DISCOVERY TRACK FOR EACH CASE TYPE. SEE LOCAL RULE 26.3**

VII. REQUESTED IN COMPLAINT:

☐ CHECK IF CLASS ACTION UNDER F.R.Civ.P. 23 DEMAND $_____

JURY DEMAND ☑ YES ☐ NO (CHECK YES ONLY IF DEMANDED IN COMPLAINT)

VIII. RELATED/REFILED CASE(S) IF ANY

JUDGE_____ DOCKET NO._____

CIVIL CASES ARE DEEMED RELATED IF THE PENDING CASE INVOLVES: (CHECK APPROPRIATE BOX)
- ☐ 1. PROPERTY INCLUDED IN AN EARLIER NUMBERED PENDING SUIT.
- ☐ 2. SAME ISSUE OF FACT OR ARISES OUT OF THE SAME EVENT OR TRANSACTION INCLUDED IN AN EARLIER NUMBERED PENDING SUIT.
- ☐ 3. VALIDITY OR INFRINGEMENT OF THE SAME PATENT, COPYRIGHT OR TRADEMARK INCLUDED IN AN EARLIER NUMBERED PENDING SUIT.
- ☐ 4. APPEALS ARISING OUT OF THE SAME BANKRUPTCY CASE AND ANY CASE RELATED THERETO WHICH HAVE BEEN DECIDED BY THE SAME BANKRUPTCY JUDGE.
- ☐ 5. REPETITIVE CASES FILED BY PRO SE LITIGANTS.
- ☐ 6. COMPANION OR RELATED CASE TO CASE(S) BEING SIMULTANEOUSLY FILED (INCLUDE ABBREVIATED STYLE OF OTHER CASE(S)):

- ☐ 7. EITHER SAME OR ALL OF THE PARTIES AND ISSUES IN THIS CASE WERE PREVIOUSLY INVOLVED IN CASE NO. _____, WHICH WAS DISMISSED. This case ☐ IS ☐ IS NOT (check one box) SUBSTANTIALLY THE SAME CASE.

SIGNATURE OF ATTORNEY OF RECORD

10/31/16
DATE