UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF NORTH CAROLINA

ELBERN H. PERRINE,	)	
Plaintiff,	)	
v.	)	**Civil Action No.:**
ATRIUM MEDICAL CORPORATION, MAQUET CARDIOVASCULAR US SALES, LLC, and GETINGE AB,	)	**JURY TRIAL DEMANDED**
Defendants.	)	

COMPLAINT

Comes now, Plaintiff, Elbern H. Perrine ("Plaintiff"), by and through undersigned counsel, and brings this action against Defendants Atrium Medical Corporation, Maquet Cardiovascular US Sales, LLC, and Getinge AB (hereinafter "Defendants"), and allege as follows:

PARTIES

1. Plaintiff is, and was, at all relevant times, a citizen and resident of North Carolina and the United States.

2. Defendant, Atrium Medical Corporation ("Atrium") is incorporated under the laws of Delaware. At all pertinent times, Atrium's manufacturing and

support facilities were located in Hudson, New Hampshire. Atrium Medical Corporation identifies its registered agent for service of process as The Corporation Trust Company located at Corporation Trust Center, 1209 Orange Street, Wilmington, DE 19801. Atrium is a medical device company involved in the research, development, testing, manufacture, production, marketing, promotion and/or sale of medical devices including C-QUR Mesh (hereinafter "C-QUR" or "product" or "mesh").

3. Maquet Cardiovascular US Sales, LLC ("Maquet") is a limited liability company organized under the laws of New Jersey, with its principal place of business located at 45 Barbour Pond Drive, Wayne, New Jersey 07470. Maquet is registered with the North Carolina Secretary of State to transact business in North Carolina. Maquet's regional office is located at 160 Mine Lake Ct., Ste. 200, Raleigh, NC 27615. Following reasonable inquiry and diligent search, upon information and belief, each of the LLC members of Maquet CV are citizens of states other than North Carolina. Maquet identifies its registered agent for service of process as National Registered Agents, Inc. located at 160 Mine Lake Ct., Suite 200, Raleigh, NC 27615-6417. 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. At all times pertinent hereto, Atrium has operated within, and as a business unit of, Maquet.

4. Getinge AB ("Getinge") is a Swedish corporation, organized under the laws of Sweden with its principal place of business in Sweden. At all times pertinent hereto, Maquet was a wholly-owned subsidiary of Getinge AB.

5. Getinge is a holding company the purpose of which is to coordinate the administration, finances and activities of its subsidiary companies, including Maquet and its business unit/division Atrium, and to act as manager and to direct or coordinate the management of its subsidiary companies or of the business, property and estates of any subsidiary company, including Maquet and its business unit/division Atrium.

6. The financial accounts of Maquet and its business unit/division Atrium are consolidated within those of Getinge.

7. In 2011, after the implantation of the C-QUR Mesh in Plaintiff Elbern H. Perrine, Getinge acquired Atrium through a merger. When Getinge acquired Atrium through said merger, it acquired Atrium's assets and assumed Atrium's liabilities.

8. Since the merger, Atrium has operated as a division/business unit of Getinge subsidiary Maquet.

9. Getinge is the owner of 100% of the controlling shares of Atrium stock and assets, including the rights to Atrium's C-QUR patents. Maquet has direct control over Atrium's activities. Following the merger with Atrium, Getinge and Maquet have continued to manufacture and sell the same defective C-QUR product line as Atrium under the same brand so as to hold themselves out to the public as a continuation of Atrium and benefit from Atrium's brand and goodwill. The Maquet Getinge Group website (www.maquet.com) lists the C-QUR product as one of Maquet Getinge Group's "biosurgery" products. (http://www.maquet.com/us/products/C-QUR-mesh/?ccid=231).

10. Defendants Getinge and Maquet represent that Atrium is "part of 'Maquet Getinge Group.'" See http://www.atriummed.com (stating that "Atrium is now part of Maquet Getinge Group"); http://www.atriummed.com/News/atriumnews.asp?articleid=60&zoneid=1 (press release detailing the acquisition of Atrium by Maquet Getinge Group).

11. Getinge and Maquet are liable for any acts and/or omissions by or through Atrium. Following the merger, which occurred prior to the sale and implantation of the C-QUR mesh implanted in Plaintiff Elbern H. Perrine, Atrium was so organized and controlled and its business conducted in such manner as to make it merely an alter ego or business conduit of Getinge and Maquet. Because

Atrium's assets and capital are subject to the ownership and control of Maquet and Getinge, Atrium is undercapitalized and the failure to disregard Atrium's corporate form would result in the inequitable and unjust result that Plaintiff may be unable to satisfy any judgment ultimately obtained against Atrium. Atrium acts as agent for Getinge and Maquet. Maquet, Getinge and Atrium combine their property and labor in a joint undertaking for profit, with rights of mutual control.

12. Maquet and Getinge, directly and/or through the actions of their Atrium division and business unit, have at all pertinent times been responsible for the research, development, testing, manufacture, production, marketing, promotion, distribution and/or sale of C-QUR Mesh.

13. Defendants are individually, jointly and severally liable to Plaintiff for damages suffered by Plaintiff arising from the Defendants' design, manufacture, marketing, labeling, distribution, sale and placement of its defective mesh products at issue in the instant suit, effectuated directly and indirectly through their respective agents, servants, employees and/or owners, all acting within the course and scope of their representative agencies, services, employments and/or ownership.

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

JURISDICTION AND VENUE

15. This Court has subject-matter jurisdiction over this action pursuant to 28 U.S.C. § 1332(a) based on complete diversity of citizenship between Plaintiff and all Defendants. The amount in controversy exceeds $75,000.

16. This Court has personal jurisdiction over each of the Defendants pursuant to the North Carolina Long-Arm Statute, NC ST § 1-75.4 (2002). All of the Defendants transact business within the State of North Carolina, contracted to sell and supply their C-QUR mesh products in the State of North Carolina, and committed tortious acts and omissions in North Carolina. Defendants' tortious acts and omissions caused injury to Plaintiff in the State of North Carolina. Defendants employ sales representatives in the State of North Carolina to sell their C-QUR mesh products throughout the State, including the C-QUR Mesh implanted in Plaintiff. Defendants have purposefully engaged in the business of developing, manufacturing, publishing information, marketing, distributing, promoting and/or selling, either directly or indirectly, through third parties, as successor in interest,

or other related entities, medical devices including C-QUR mesh products in North Carolina, for which they derived significant and regular income. The Defendants intended and reasonably expected that that their defective mesh products, including C-QUR, would be sold and implanted in North Carolina and could cause injury in North Carolina.

17. Maquet is registered to transact business in North Carolina.

18. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(b)(2).

FACTS COMMON TO ALL COUNTS

19. On or about May 18, 2010, Plaintiff Elbern H. Perrine underwent repair of an umbilical hernia by Dr. William G. Cloud at CMC Blue Ridge Hospital in Morganton, North Carolina. A 8.9 x 8.9 cm C-Qur Mesh was implanted in Mr. Perrine during this repair.

20. Defendants, manufactured, sold, and/or distributed the C-QUR Mesh Products to Plaintiff Elbern H. Perrine, through his healthcare providers, to be used for treatment of hernia repair.

21. On or about July 7, 2012, Plaintiff Elbern H. Perrine was admitted at McDowell Hospital in Marion, North Carolina. He presented with a 2 day history of Abdominal Pain. After a CT of the abdomen it was discovered that the Mr. Perrine had partial bowel obstruction in the area of the previous hernia repair.

22. On or about August 20, 2012, Plaintiff Elbern H. Perrine underwent an EGD and Colonoscopy at Carolina's Healthcare. A hiatal Hernia was revealed.

23. On or about February 11, 2014, Plaintiff Elbern H. Perrine underwent surgery at CMC Blue Ridge Hospital in Morganton, North Carolina for adhesions. During the procedure it was discovered that there were multiple adhesions to the anterior abdominal wall. Lysis of the Adhesions was performed.

24. On or about April 11, 2014, Plaintiff Elbern H. Perrine was admitted at McDowell Hospital in Marion, North Carolina. It was discovered that Mr. Perrine had a small bowel obstruction. A CT scan revealed recurrent distal small bowel obstruction likely on the basis of ventral adhesions in the right lower quadrant.

25. Upon information and belief, Plaintiff, Elbern H. Perrine has now been advised by his surgeon that due to complications caused by the C-QUR Mesh, it needs to be removed, but the procedure is considered very dangerous. Mr. Perrine's current surgeon is reluctant to perform any additional surgeries due to the serious nature of the complications Mr. Perrine has suffered due to the implantation of the Defendants' C-QUR Mesh.

26. Mr. Perrine suffers daily chronic pain and he has been advised to seek treatment from a pain management clinic to treat pain associated with complications caused by the C-QUR Mesh.

27. Plaintiff, Elbern H. Perrine's treatment is ongoing. He continues to suffer from complications associated with the C-QUR Mesh that will result in additional ongoing future treatment including surgical procedures.

28. Getinge and Maquet were, at all times relevant hereto, responsible for the actions of Atrium and exercised control over Atrium's functions specific to the oversight and compliance with applicable safety standards relating to including C-QUR Mesh sold in the United States. In such capacity, they committed or allowed to be committed tortious and wrongful acts, including the violation of numerous safety standards relating to device manufacturing, quality assurance/control, and conformance with design and manufacturing specifications. Their misfeasance and malfeasance caused Plaintiffs to suffer injury and damages.

29. Defendants at all times material to this lawsuit were responsible for the research, design, development, testing, manufacture, production, marketing, promotion, distribution and sale of C-QUR Mesh, including providing the warnings and instructions concerning the product.

30. Among the intended purposes for which Defendants designed, manufactured and sold C-QUR Mesh was for use by surgeons for hernia repair surgeries, the same purpose for which the C-QUR Mesh was implanted in Plaintiff Elbern H. Perrine.

31. Defendants represented to Plaintiff and Plaintiff's physicians that C-QUR Mesh was a safe and effective product for hernia repair.

32. Defendants' C-QUR Mesh was defectively designed and/or manufactured, was not reasonably safe for its intended use in hernia repair, and the risks of the design outweighed any potential benefits associated with the design. As a result of the defective design and/or manufacture of the C-QUR Mesh, there was an unreasonable risk of severe adverse reactions to the mesh or mesh components including: chronic pain; recurrence of hernia; foreign body response; rejection; infection; inadequate or failure of incorporation/in growth; scarification; improper wound healing; excessive and chronic inflammation; allergic reaction; adhesions to internal organs; erosion; abscess; fistula formation; granulomatous response; seroma formation; nerve damage; tissue damage and/or death; and other complications, including, the inability to remove the C-QUR Mesh absent serious injury or death .

33. The C-QUR Mesh was manufactured from polypropylene, and has a unique Omega 3 gel coating derived from fish oil ("Omega 3 coating"), which is not used in any other hernia repair product sold in the United States. The Omega 3 coating was represented by the Defendants to prevent or minimize adhesion and inflammation and to facilitate incorporation of the mesh into the body, but it did not. Instead, the Omega 3 coating prevented adequate incorporation of the mesh into the body and caused an intense inflammatory and chronic foreign body response resulting in an adverse tissue reaction including damage to surrounding tissue in the form of sclerotic, granulomatous and/or fibrotic tissue and improper healing.

34. When affixed to the body's tissue, the impermeable Omega 3 coating of the C-QUR Mesh prevents fluid escape, which leads to seroma formation and which in turn, can cause infection or abscess formation and other complications.

35. The Omega 3 coating provides an ideal bacteria breeding ground in which the bacteria cannot be eliminated by the body's immune response, which allows infection to proliferate.

36. The Omega 3 coating of Defendants' C-Qur Mesh is cytotoxic, immunogenic, and not biocompatible, which causes or contributes to complications

such as delayed wound healing, inflammation, foreign body response, rejection, infection, and other complications.

37. Defendants knew or should have known of the cytotoxic and immunogenic properties of the Omega 3 coating of the C-Qur Mesh prior to introducing it into the stream of commerce.

38. When the Omega 3 coating is disrupted and/or degrades, the "naked" polypropylene mesh is exposed to the adjoining tissue and viscera, and can become adhered to organs, and cause incarceration of organs, and fistula formation.

39. Due to serious problems with sterilization and quality control in the Atrium manufacturing facilities, the Omega 3 coating was not uniformly applied to the C-QUR Mesh devices. The Omega 3 coating applied to the mesh caused or contributed to the propensity of the C-QUR Mesh to roll, curl and deform upon insertion into the body, intensifying the inflammatory and foreign body response to the mesh, and exacerbating the lack of adequate incorporation and improper healing response, and potential for adhesion. The Omega 3 coating was also unreasonably susceptible to deterioration and degradation, and even separation from the polypropylene mesh, both in the packaging and inside the body. The Omega 3 coating of the C-QUR Mesh also failed to conform to the manufacturer's specifications in terms of shelf-life, thickness, durability, and quality.

40. These manufacturing and design defects associated with the C-QUR Mesh were directly and proximately related to the injuries suffered by Plaintiff Elbern H. Perrine.

41. Neither Plaintiff Elbern H. Perrine, nor his implanting physician were adequately warned or informed by Defendants of the defective and dangerous nature of C-QUR Mesh. Moreover, neither Plaintiff Elbern H. Perrine nor his implanting physician were adequately warned or informed by Defendants of the risks associated with the C-QUR Mesh.

42. The C-QUR Mesh implanted in Plaintiff Elbern H. Perrine failed to reasonably perform as intended. The mesh caused serious injury. Plaintiff has had to undergo invasive surgery due to the chronic pain; foreign body response; rejection; infection; inadequate or failure of incorporation/in growth; scarification; improper wound healing; excessive and chronic inflammation; allergic reaction; adhesions to internal organs; nerve damage; and tissue damage caused by the Defendants' C-QUR mesh. Furthermore, upon information and belief Plaintiff has been advised that additional invasive, dangerous, serious and life threatening surgeries will more likely than not be necessary in order to repair the hernia that the C-QUR was initially implanted to treat.

43. Plaintiff, Elbern H. Perrine's severe adverse reaction, and the necessity for surgical revision of the C-QUR Mesh, directly and proximately resulted from the defective and dangerous condition of the product and Defendants' defective and inadequate warnings about the risks associated with the product. Plaintiff Elbern H. Perrine has suffered, and will continue to suffer, both physical injury and pain and mental anguish, severe complications that continue to require present and future medical treatment, permanent disability and he and has incurred and will continue to incur substantial medical bills and other expenses, resulting from the defective and dangerous condition of Defendants' C-QUR Mesh.

COUNT I

North Carolina Products Liability Act: Defective Manufacture

44. Plaintiff incorporates herein by reference the allegations in paragraphs 1 through 43 as if fully set forth herein.

45. Defendants expected and intended the C-QUR Mesh product to reach users such as Plaintiff Elbern H. Perrine in the condition in which the product was sold.

46. The implantation of C-QUR Mesh in Plaintiff's body was medically reasonable, and was a type of use that Defendants intended and foresaw when it designed, manufactured and sold the product.

47. At the time the C-QUR Mesh that was implanted in Plaintiff Elbern H. Perrine's body, the product was defectively manufactured.

48. Defendants' manufacturing and quality control/assurance facilities where the C-QUR Mesh is manufactured, processed, inspected and packaged failed to comply to minimum industry and governmental standards and regulatory requirements regarding quality assurance, manufacturing practices, and sterilization, and as a result, the C-QUR Mesh products manufactured and sold by Defendants, including the C-QUR Mesh implanted in Plaintiff Elbern H. Perrine, suffered manufacturing defects adversely affecting the safety and efficacy of the device.

49. Defendants' manufacturing and quality control/assurance non-compliance resulted in the non-conformance of the C-QUR Mesh implanted in Plaintiff Elbern H. Perrine with intended manufacturing and design specifications. The Omega-3 gel coating was incapable of being adequately sterilized and applied consistently in accordance with the Defendants' specifications.

50. Defendants' ETO sterilization process was changed without performing adequate testing or verification of sterility or other potential effects on the safety of 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.

51. The Omega 3 coating of the C-QUR Mesh also failed to conform to the Defendants' specifications in terms of shelf-life, thickness, durability, and quality.

52. Upon information and belief, Defendants utilized substandard and adulterated polypropylene and raw fish oil materials in their finished C-QUR Mesh devices which deviated from Defendants' material and supply specifications.

53. As a direct and proximate result of the defective manufacture of the C-QUR Mesh as outlined herein, Plaintiff suffered injuries and damages as summarized herein.

WHEREFORE, as a result of the acts and omissions and conduct of Defendants set forth herein, Plaintiff Elbern H. Perrine is entitled to recover for his personal injuries; past, present, and future medical and related expenses; past, present, and future lost wages; past, present and future loss of earning capacity; past, present and future mental and physical pain and suffering; permanent impairment; disfigurement; permanent injury; and all other damages allowed by North Carolina law and such further relief as the Court deems equitable and just.

COUNT II

North Carolina Products Liability Act: Defective Design or Formulation

54. Plaintiff incorporates herein by reference the allegations in paragraphs 1 through 43 as if fully set forth herein.

55. At the time C-QUR Mesh was implanted in Plaintiff Elbern H. Perrine, the product was defectively designed and/or formulated. As described above, there was an unreasonable risk that the product would not perform safely and effectively for the purposes for which it was intended, and Defendants failed to design against such dangers, and failed to provide adequate warnings and instructions concerning the risks associated with the defective design or formulation.

56. Defendants expected and intended the C-QUR Mesh product to reach users such as Plaintiff Elbern H. Perrine in the condition in which the product was sold.

57. The implantation of C-QUR Mesh in Plaintiff's body was medically reasonable, and was a type of use that Defendants intended and foresaw when it designed, manufactured and sold the product.

58. The risks of the C-QUR Mesh significantly outweigh any benefits that Defendants contend could be associated with the product. The Omega 3 coating, which is not used in any other hernia mesh product sold in the United States,

prevents tissue from incorporating into the mesh, leading to encapsulation, deformation, scarification and contraction, migration, erosion and rejection. The impermeable Omega 3 coating leads to seroma formation, and provides a breeding ground for infection, and protects bacteria from being eliminated by the body's natural immune response. This fish oil coating also causes immunogenic response, and was known to be cytotoxic.

59. The Omega 3 coating of the C-QUR Mesh, which was marketed, promoted and intended as a barrier against adhesion to the bowel, was only temporary; it was expected and intended to degrade over time inside the body. Thus, this coating prevented tissue in growth in the short term, and degraded in the long-term, eventually leaving the "naked" polypropylene mesh exposed to the internal viscera and tissues. Once exposed to the viscera, the mesh will inevitably adhere to the viscera, initiating a cascade of adverse consequences. Any purported beneficial purpose of the coating (to prevent adhesion to the bowel and internal viscera) was non-existent; the product provided no benefit while substantially increasing the risks to the patient.

60. The polypropylene mesh used in the C-QUR Mesh was in and of itself dangerous and defective, particularly when used in the manner intended by Defendants and particularly when coupled with use of the Omega 3 coating. The

particular polypropylene material used in the C-QUR Mesh was substandard, adulterated and non-medical grade, and was unreasonably subject to oxidative degradation within the body, further exacerbating the adverse reactions to the product once the Omega 3 coating degraded. When implanted adjacent to the bowel and other internal organs, as Defendants intended for C-QUR Mesh to be, polypropylene mesh is unreasonably susceptible to adhesion, bowel perforation or erosion, fistula formation and bowel strangulation or hernia incarceration, and other injuries.

61. The appropriate treatment for complications associated with C-QUR Mesh involves additional invasive surgery to remove the mesh from the body, thus eliminating any purported benefit that the mesh was intended to provide to the patient.

62. The C-QUR Mesh was designed and intended for intra-peritoneal implantation, which required the product to be placed in contact with internal organs, which unnecessarily increased the risks of adhesion, erosion, fistula formation, and other injuries.

63. At the time the C-QUR Mesh was implanted in Plaintiff Elbern H. Perrine, there were safer feasible alternative designs for hernia mesh products that would have prevented the injuries he suffered.

64. The C-QUR Mesh product cost significantly more than competitive products because of its unique Omega 3 coating, even though the Omega 3 coating provided no benefit to consumers, and increased the risks to patients implanted with C-QUR Mesh.

65. The C-QUR Mesh implanted in Plaintiff Elbern H. Perrine failed to reasonably perform as intended necessitating further treatment including additional surgery and additional future treatment including surger(ies), and thus provided no benefit to him.

66. As a direct and proximate result of the defective and unreasonably dangerous condition of Defendants' C-QUR Mesh, Plaintiff suffered injuries and damages as summarized herein.

WHEREFORE, as a result of the acts and omissions and conduct of Defendants set forth herein, Plaintiff Elbern H. Perrine is entitled to recover for his personal injuries; past, present, and future medical and related expenses; past, present, and future lost wages; past, present and future loss of earning capacity; past, present and future mental and physical pain and suffering; permanent impairment; disfigurement; permanent injury; and all other damages allowed by North Carolina law and such further relief as the Court deems equitable and just.

COUNT III

North Carolina Products Liability Act: Failure to Warn

67. Plaintiff incorporates herein by reference the allegations in paragraphs 1 through 43 as if fully set forth herein.

68. At the time C-QUR Mesh that was implanted in Plaintiff Elbern H. Perrine, the warnings and instructions provided by Defendants for the C-QUR Mesh were inadequate and defective. As described above, there was an unreasonable risk that the product would not perform safely and effectively for the purposes for which it was intended, and Defendants failed to design and/or manufacture against such dangers, and failed to provide adequate warnings and instructions concerning these risks.

69. Defendants expected and intended the C-QUR Mesh product to reach users such as Plaintiff Elbern H. Perrine in the condition in which the product was sold.

70. Plaintiff and his physicians were unaware of the defects and dangers of C-QUR Mesh, and were unaware of the frequency, severity and duration of the risks associated with the C-QUR Mesh.

71. The Defendants' Instructions for Use provided with the C-QUR Mesh expressly understates and misstates the risks known to be associated specifically with the C-QUR Mesh by representing that the complications associated with C-

QUR Mesh were the same as those "with the use of any surgical mesh." No other surgical mesh sold in the United States has the dangerous and defective Omega 3 coating, which itself causes or increases the risks of numerous complications, including prevention of incorporation, increased risk of seroma formation, immunologic response, increased risk for infection, and increased inflammatory reaction and foreign body response. Defendants provided no warning to physicians about the risks or increased risks specifically associated with the unique design of the C-QUR Mesh.

72. The Defendants' Instructions for Use for the C-QUR Mesh failed to adequately warn Plaintiff's physicians of numerous risks which Defendants knew or should have known were associated with the C-QUR Mesh, including the risks of the product's inhibition of tissue incorporation, pain, immunologic response, dehiscence, encapsulation, rejection, migration, scarification, contraction, adhesion to internal organs and viscera, erosion through adjacent tissue and viscera, bowel obstruction, or hernia incarceration or strangulation.

73. Defendants failed to adequately train or warn Plaintiff or his physicians about the necessity for invasive surgical intervention in the event of complications, or how to properly treat such complications when they occurred.

74. Defendants failed to adequately warn Plaintiff or his physicians that the surgical removal of the C-QUR Mesh in the event of complications would leave the hernia unrepaired, and would necessitate further medical treatment to attempt to repair the same hernia that the failed C-QUR Mesh was intended to treat.

75. Defendants represented to physicians, including Plaintiff's physician, that the Omega 3 coating would prevent or reduce adhesion, and expressly intended for the C-QUR Mesh to be implanted in contact with the bowel and internal organs and marketed and promoted the product for said purpose. Defendants failed to warn physicians that the Omega 3 coating prevented tissue in growth, which is the desired biologic response to an implantable mesh device. Defendants failed to warn physicians that the Omega 3 coating was only temporary and therefore at best would provide only a temporary adhesion barrier, and when the coating inevitably degraded, the exposed polypropylene would become adhered to the bowel or tissue.

76. With respect to the complications that were listed in the Defendants' warnings, Defendants provided no information or warning regarding the frequency, severity and duration of those complications, even though the complications

associated with C-QUR Mesh were more frequent, more severe and lasted longer than those with safer feasible alternative hernia repair treatments.

77. If Plaintiff Elbern H. Perrine and/or his physicians had been properly warned of the defects and dangers of C-QUR Mesh, and of the frequency, severity and duration of the risks associated with the C-QUR Mesh, Plaintiff Elbern H. Perrine would not have consented to allow the C-QUR Mesh to be implanted in his body, and Plaintiff Elbern H. Perrine's physicians would not have implanted the C-QUR Mesh in Plaintiff Elbern H. Perrine.

78. As a direct and proximate result of the inadequate and defective warnings and instructions, Plaintiff suffered injuries and damages as summarized herein.

WHEREFORE, as a result of the acts and omissions and conduct of Defendants set forth herein, Plaintiff Elbern H. Perrine is entitled to recover for his personal injuries; past, present, and future medical and related expenses; past, present, and future lost wages; past, present and future loss of earning capacity; past, present and future mental and physical pain and suffering; permanent impairment; disfigurement; permanent injury; and all other damages allowed by North Carolina law and such further relief as the Court deems equitable and just.

COUNT IV

Negligence

79. Plaintiff incorporates herein by reference the allegations in Paragraphs 1 through 43 as if fully set forth herein.

80. Defendants had a duty to use reasonable care in designing, testing, inspecting, manufacturing, packaging, labeling, marketing, distributing, and preparing written instructions and warnings for C-QUR Mesh, but failed to do so.

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

82. As a direct and proximate result of Defendants' negligence in designing, testing, inspecting, manufacturing, packaging, labeling, marketing, distributing, and preparing written instructions and warnings for C-QUR Mesh, Plaintiffs suffered injuries and damages as summarized herein.

WHEREFORE, as a result of the acts and omissions and conduct of Defendants set forth herein, Plaintiff Elbern H. Perrine is entitled to recover for his personal injuries; past, present, and future medical and related expenses; past,

present, and future lost wages; past, present and future loss of earning capacity; past, present and future mental and physical pain and suffering; permanent impairment; disfigurement; permanent injury; and all other damages allowed by North Carolina law and such further relief as the Court deems equitable and just.

COUNT V

Reckless and Wanton Conduct

83. Plaintiff incorporates herein by reference the allegations in paragraphs 1 through 43 as if fully set forth herein.

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

85. The acts and omissions of Defendants, whether taken singularly or in combination with others, constitute wantonness, recklessness, gross negligence or willful and/or intentional conduct that proximately caused injuries to Plaintiff as set out herein. 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, as a result of the acts and omissions and conduct of Defendants set forth herein, Plaintiff Elbern H. Perrine is entitled to recover for his personal injuries; past, present, and future medical and related expenses; past, present, and future lost wages; past, present and future loss of earning capacity; past, present and future mental and physical pain and suffering; permanent impairment; disfigurement; permanent injury; and all other damages allowed by North Carolina law. Plaintiff further seeks an award of punitive damages and such further relief as the Court deems equitable and just.

COUNT VI

Discovery Rule and Fraudulent Concealment

86. 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.

87. Despite diligent investigation by Plaintiff into the cause of his injuries, including consultations with his medical providers, the nature of his

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 Plaintiff's claims. Therefore, under appropriate application of the discovery rule, Plaintiff's suit was filed within the applicable statutory limitations period.

88. Defendants are estopped from relying on or asserting any statute of limitations or repose defense because Defendants fraudulently concealed from Plaintiff the nature of his injuries and the connection between the injuries and Defendants' tortious conduct. Moreover, Defendants are estopped from relying on any statutes of limitations or repose by virtue of their acts of fraudulent concealment, which include their intentional concealment from Plaintiff, the medical community, and the general public that the C-QUR Mesh was defective, while continually marketing the C-QUR Mesh as described herein.

89. Given the Defendants' affirmative actions of concealment by failing to disclose the known but non-public information about the C-QUR Mesh defects – information over which Defendants had exclusive control – and because Plaintiff and the general public could not reasonably have known that the C-QUR Mesh was defective, Defendants are estopped from relying on any statutes of limitations or repose that might otherwise be applicable to the claims asserted herein.

COUNT VII

Punitive Damages

90. Plaintiff incorporates herein by reference the allegations in paragraphs 1 through 43 as if fully set forth herein.

91. Defendants failed to adequately test and study the C-QUR Mesh to determine and ensure that the product was safe and effective prior to releasing the product for sale for permanent human implantation, and Defendants continued to manufacture and sell C-QUR Mesh after obtaining knowledge and information that the product was defective and unreasonably unsafe.

92. Defendants were aware of the probable consequences of implantation of the dangerous and defective C-QUR Mesh, including the risk of failure and serious injury, such as suffered by Plaintiff Elbern H. Perrine.

93. Defendants failed to avoid those consequences, and in doing so, Defendants acted intentionally, wantonly, maliciously and recklessly with regard to the safety of those persons who might foreseeably have been harmed by the C-QUR product, including Plaintiff, justifying the imposition of punitive damages.

94. 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 and complications which are permanent and lasting in nature.

95. At all times material hereto, Defendants attempted to misrepresent and did intentionally, knowingly, wantonly and/or with reckless disregard did misrepresent facts concerning the safety of their C-Qur Mesh product.

96. 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 his implanting physician with vital and necessary information with which to make a fully informed decision about whether to use C-Qur mesh in his care and treatment.

97. At all times material hereto, Defendants knew and wantonly, 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 methods, products, procedures, and/or treatment.

98. At all times material hereto, Defendants knew and wantonly, 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.

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

100. 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 intentional, wanton and/or with reckless disregard of the likely and foreseeable harm caused by C-Qur Mesh to members of the public including Plaintiff.

101. 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.

102. 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.

103. Even though Defendants have other technology and/or safer alternatives that do not present the same risks as the C-QUR Mesh, Defendants developed, designed and sold C-QUR Mesh, and continue to do so, because the C-QUR Mesh has a significantly higher profit margin than other hernia repair products.

104. 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, as a result of the acts and omissions and conduct of Defendants set forth herein, Plaintiff Elbern H. Perrine is entitled to recover for his personal injuries; past, present, and future medical and related expenses; past, present, and future lost wages; past, present and future loss of earning capacity; past, present and future mental and physical pain and suffering; permanent impairment; disfigurement; permanent injury; and all other damages allowed by

North Carolina law. Plaintiff further seeks an award of punitive damages 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 and according to proof;

ii. That any amount of compensatory damages awarded to Plaintiff be trebled under the provisions of N.C. Gen. Stat. 75-16.

iii. Punitive damages;

iv. Reasonable attorney's fees as provided by law;

v. The costs of these proceedings, including past and future cost of the suit and attorneys fees incurred herein pursuant to N.C. Gen. Stat. 75-16.1

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

vii. 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 ELBERN H. PERRINE
By his attorney,

/s/ Brian L. Kinsley
Brian L. Kinsley, Esq.
N.C. Bar Number 38683
CRUMLEY ROBERTS, LLP
2400 Freeman Mill Road
Greensboro, North Carolina 27406
Phone: (336) 333-9899
Facsimile: (336) 333-9894
bkinsley@crumleyroberts.com

APPEARANCE ANTICIPATED:

W. Todd Harvey, Esq.
BURKE HARVEY, LLC
3535 Grandview Parkway, Suite 100
Birmingham, Alabama 35243
Phone: (205) 930-9091
Facsimile: (205) 930-9054
tharvey@burkeharvey.com

David L. Selby, II, Esq.
BAILEY & GLASSER LLP
3000 Riverchase Galleria
Suite 905
Birmingham, Alabama 35244
Phone: (205) 682-7575
Facsimile: (205) 733-4896
dselby@baileyglasser.com

Adam M. Evans, Esq.
Hollis Law Firm, P.A.
5100 W. 95th St.
Prairie Village, Kansas 66207
Phone: (913) 385-5400
Facsimile: (913) 385-5402
adam@hollislawfirm.com