UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF
KENTUCKY AT BOWLING GREEN

KENT SIMMONS, 13899 Fountain Run Rd. Fountain Run, KY 42133 *Plaintiff,* v. ATRIUM MEDICAL CORPORATION, *by and through Kentucky Secretary of State: 9 Capitol Street, Concord, NH 03301* *Defendants.*	)	Civil Action No. 1:16-cv-191-GNS COMPLAINT AND JURY DEMAND

Plaintiff, Kent Simmons, for his Complaint against Defendant Atrium Medical Corporation, states as follows:

PARTIES

1. Plaintiff Kent Simmons is a resident of 13899 Fountain Run Rd., Fountain Run, Monroe County, KY 42133 and is now and has been at all relevant times a citizen of Kentucky and the United States.

2. Defendant Atrium Medical Corporation ("Atrium") is a Delaware corporation with its corporate headquarters and principal place of business formerly located in Hudson, New Hampshire and currently located at 4 Continental Drive in the Town of Merrimack, County of Hillsborough and State of New Hampshire. Defendant ATRIUM MEDICAL CORPORATION

("Defendant") is a corporation organized and existing under the laws of Delaware with its principal place of business in New Hampshire. Atrium Medical Corporation identifies its registered agent for service of process as CT Corporation System, located at 9 Capitol Street, Concord, NH 03301 which shall be served by and through the Kentucky Secretary of State pursuant to KRS 454.210.

3. At all relevant times, Defendant Atrium designed, developed, manufactured, licensed, marketed, distributed, sold and/or placed in the stream of commerce the Hernia Mesh Products, including certain Hernia Mesh Products at issue in this lawsuit.

4. At all times mentioned herein, Defendant Atrium acted, by and through their agents, representatives and employees who acted within the scope and course of their agency and employment with this Defendant.

5. At all relevant times, Defendant Atrium, was and still is a corporation authorized to do business in the Commonwealth of Kentucky.

6. At all times hereinafter mentioned, upon information and belief, the Defendant Atrium, was and still is a business entity conducting business in the Commonwealth of Kentucky.

7. At all times hereinafter mentioned, the Defendant Atrium was and is engaged in the business of designing, manufacturing, advertising, marketing, and selling Hernia Mesh Products including the Atrium C-Qur Mesh, and in pursuance of this business, transacts business within the Commonwealth of Kentucky and contracts to provide goods and services in the Commonwealth of Kentucky.

8. At all times hereinafter mentioned, upon information and belief, Defendant Atrium committed a tortious act within the territorial boundaries of the Commonwealth of Kentucky, which caused injury to Plaintiff.

9. At all times hereinafter mentioned, upon information and belief, Defendant Atrium expects or should reasonably expect its acts to have consequences in the Commonwealth of Kentucky, and in doing so derives substantial revenue from interstate or international commerce.

10. At all times mentioned herein Defendant acted by and through its agents, representatives, and employees who acted within the scope and course of their agency and employment.

VENUE AND JURISDICTION

11. This Court has jurisdiction pursuant to 28 U.S.C. §1332(a) and (c).

12. Venue is proper in this District pursuant to 28 U.S.0 § 1391(b), (c) and (d) because Defendant resides in this District, a substantial part of the events or omissions giving rise to the claim occurred in this District, and this Court has personal jurisdiction over Defendant.

FACTUAL ALLEGATIONS AND CAUSES OF ACTION

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

14. Specifically, Atrium sought and secured 510(k) clearance on the following medical devices indicated and/or sold for hernia repair; ProLite Mesh (K930669) on December 16, 1993, ProLite Ultra Mesh (K002093) on July 24, 2000, C-Qur Mesh (K050311) on March 31, 2006, Prolite Ultra S Mesh (K070192) on March 8, 2007, C-Qur Lite V-Patch (K080688) on April 16, 2008, C-Qur Edge V-Patch (K080691) on April 16, 2008, Prolite S Mesh (K082748) on January 14, 2009, C-Qur V-Patch (K090909) on June 4, 2009, C-Qur Ovt (K100076) on January 26, 2010, Centrilfx (K110110) on February 15, 2011, C-Qur Rpm (K121070) on April 26, 2012, Prolite, Prolite Ultra, Proloo

(K151437) on August 27, 2015, and C-Qur, C-Qur Fx, C-Qur Tachshield, C-Qur V-Patch, C-Qur CentriFX, and C-Qur Mosiac (K151386) on October 22, 2015.

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

16. 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 an 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.

17. Defendants' statements made to the FDA regarding these Medical Devices inadequately relied on predicate devices and not clinical testing or other design verification or testing. These statements induced the Plaintiff into relying upon the Defendants' judgment.

18. Upon information and belief, Defendants' numerous suppliers of various forms of polypropylene warn on their United States Material Safety Data Sheet ("MSDS") that it is prohibited to permanently implant polypropylene into the human body.

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

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

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

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

23. 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.

24. The O3FA is derived from fish. Fish are considered to be commonly allergenic. If various remnants of the fish, such as proteins, remain in the O3FA coating, allergic reactions can occur, ranging from increased sensitivity and rashes to death.

25. Proteins are not very soluble in oils; however, non-soluble proteins are still able to be present in the oil as particulate matter.

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

27. Upon information and belief, Defendants utilized adulterated O3FA.

28. Prior to the C-Qur mesh entering the stream of commerce, The United States Food and Drug Administration ("FDA") and other governmental regulatory agencies worldwide expressed their stark concerns to Defendants regarding severe, life-threatening allergic reactions to the O3FA coating when implanted in humans.

29. Upon receiving reports from surgeons and physicians of apparent allergic reactions to the C-Qur Mesh, Defendants not only failed to notify the FDA, but 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 lying to 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.

30. 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. The FDA was not notified of the deviation.

31. 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.

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

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

34. 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.

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

36. 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.

37. 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.

38. 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.

39. 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.

40. 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.

41. 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.

42. 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. The FDA was not notified of the deviation.

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

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

45. 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.

46. 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.

47. 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 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 experience significant, life-changing injuries, prolonged hospital stays, and even death.

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

49. 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.

50. 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.

51. 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 of the change on patient safety. The FDA was not notified of the deviation.

52. Upon information and belief, at 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 of the change on patient safety. The FDA was not notified of the deviation.

53. 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.

54. 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.

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

56. 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.

57. Defendants failed to properly investigate and disclose adverse event reports to the FDA and other regulatory agencies worldwide.

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

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

60. 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, regulatory agencies, or consumers of the recall or high levels of adverse events.

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

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

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

64. 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. This resulted in fewer adverse event reports to the FDA and more C-Qur Mesh implants nationwide.

65. Defendants marketed the C-Qur Mesh to the medical community and to patients as safe, effective, 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' did not undergo pre-market approval for the C-Qur Mesh and are therefore prohibited by the FDA from asserting superiority claims. 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.

66. 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.

67. 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.

68. 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, regulatory agencies, 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 FDA, the medical community, patients, and the public at large.

69. Defendants have known and continue to know that their disclosures to the FDA were and are incomplete and misleading; and that the Defendants' C-Qur Meshes were and are causing numerous patients severe injuries and complications. The Defendants suppressed this information, and failed to accurately and completely disseminate or share this and other critical information with the FDA, health care providers, or the patients. As a result, the Defendants actively and intentionally misled and continue to mislead the public, including the medical community, health care providers and patients, into believing that the defendants' C-Qur Meshes were and are safe and effective, leading to the prescription for and implantation of the C-Qur Mesh into the Plaintiff.

70. 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.

71. 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.

72. 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.

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

74. 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.

75. 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.

76. Defendant 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, private offices, and include the provision of valuable benefits to health care providers. Also utilized were documents, patient brochures, and websites.

77. On December 4th, 2015, Plaintiff Kent Simmons, underwent revision surgery to remove and repair surgical hernia site which had been previously surgically repaired with Atrium C-QUR mesh on October 15, 2015.

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

79. On or about December 1, 2015, Plaintiff presented to the Emergency Room at Monroe County Medical Center regarding the severe abdominal pain he was having. Plaintiff was transferred to TJ Samson Hospital in Glasgow on December 3, 2016, for further treatment.

80. On December 4, 2015, Plaintiff was taken into surgery with Dr. William Klapheke for removal of an exposed mesh and debridement of devitalized tissue of the abdominal wall all of which constitutes a substantial factor in causing Plaintiff's complaints voiced herein.

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

82. Other than any degradation caused by faulty design 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 Defendant, and in the condition directed by and expected by Defendant.

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

84. In reliance on Defendant's representations, Plaintiff's doctor was induced to, and did use the C-QUR Mesh Products, thereby resulting in severe and permanent personal injuries and damages complained of herein.

FIRST CAUSE OF ACTION: NEGLIGENCE

85. Plaintiff incorporates by reference the forgoing paragraphs as if fully set forth herein.

86. At all relevant times, Defendant had a duty to use reasonable care in designing, manufacturing, marketing, labeling, packaging, and/or selling the mesh products.

87. On the occasion in question the Defendant breached its duty and was negligent in designing, manufacturing, marketing, labeling, packaging, and/or selling the unreasonably dangerous mesh products.

88. As a direct, proximate and foreseeable result of the mesh products' aforementioned defects, Plaintiff Kent Simmons 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.

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

SECOND CAUSE OF ACTION: STRICT LIABILITY — DESIGN DEFECT

90. Plaintiff incorporates by reference the factual portion of this complaint as if fully set forth herein and additionally or in the alternative, if same be necessary, allege as follows:

91. At the time, each implanting surgeon implanted the mesh product in Plaintiff Kent Simmons, Defendant was engaged in the business of selling said product.

92. The mesh product was defectively designed when sold.

93. The mesh product was unreasonably dangerous, taking into consideration the utility of said product and the risks involved in their use.

94. The mesh product reached Plaintiff Kent Simmons' implanting surgeon and him without substantial change in the condition in which it was sold.

95. The defective and unreasonably dangerous condition of the mesh product was the proximate cause of the damages and injuries to Plaintiff Kent Simmons.

96. As a direct and proximate result of the mesh product's aforementioned defects, Plaintiff Kent Simmons 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.

97. Defendant is strictly liable to Plaintiff Kent Simmons.

THIRD CAUSE OF ACTION:
STRICT LIABILITY — MANUFACTURING DEFECT

98. Plaintiff incorporates by reference the factual portion of this complaint as if fully set forth herein and additionally or in the alternative, if same be necessary, allege as follows:

99. At the time, Plaintiff Kent Simmons' doctor implanted the mesh product in his body, Defendant was engaged in the business of selling said product.

100. The mesh product was defectively designed and manufactured when sold.

101. The mesh product was unreasonably dangerous, taking into consideration the utility of said product and the risks involved in its use.

102. The mesh product reached implanting surgeon and Plaintiff Kent Simmons without substantial change in the condition in which it was sold.

103. The defective and unreasonably dangerous condition of the mesh product was a proximate cause of the damages and injuries to Plaintiff Kent Simmons.

104. As a direct and proximate result of the mesh products' aforementioned defects, Plaintiff Kent Simmons 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, lost wages and impairment of his power to labor and earn money and obligations for medical services and expenses, and other damages.

105. Defendant is strictly liable to Plaintiff Kent Simmons.

FOURTH CAUSE OF ACTION:
STRICT LIABILITY — FAILURE TO WARN

106. Plaintiff incorporates by reference the factual portion of this complaint as if fully set forth herein and additionally or in the alternative, if same be necessary, alleges as follows:

107. The mesh product implanted in Plaintiff Kent Simmons was not reasonably safe for intended use and was defective as a matter of law due to its lack of appropriate and necessary warnings.

108. As a direct and proximate result of the mesh product's aforementioned defects, Plaintiff Kent Simmons 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.

109. Defendant is strictly liable to Plaintiff Kent Simmons.

FIFTH CAUSE OF ACTION:
BREACH OF EXPRESS WARRANTY

110. Plaintiff incorporates by reference the factual portion of this petition as if fully set forth herein and additionally or in the alternative, if same be necessary, alleges as follows:

111. Defendant made assurances to the general public, hospitals, and health care professionals that the mesh products were safe and reasonably fit for their intended purpose.

112. Plaintiff Kent Simmons and/or his healthcare providers chose the mesh product based upon Defendant's warranties and representations regarding the safety and fitness of the mesh product.

113. Plaintiff Kent Simmons, individually and/or by and through his physicians, reasonably relied upon Defendant's express warranties and guarantees that the mesh product was safe, merchantable, and reasonably fit for its intended purpose.

114. Defendant breached these express warranties because the mesh product implanted in Plaintiff Kent Simmons was unreasonably dangerous and defective and not as Defendant had represented.

115. Defendant's breaches of express warranties resulted in the implantation of an unreasonably dangerous and defective product in Plaintiff Kent Simmons' body, placing his health and safety in jeopardy.

116. As a direct and proximate result of Defendant's breaches of the aforementioned express warranties, Plaintiff Kent Simmons 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.

SIXTH CAUSE OF ACTION:
BREACH OF IMPLIED WARRANTY

117. Plaintiff incorporates by reference the factual portion of this petition as if fully set forth herein and additionally or in the alternative, if same be necessary, allege as follows:

118. Defendant impliedly warranted that the mesh products were merchantable and were fit for the ordinary purpose for which they were intended.

119. When the mesh product was implanted in Plaintiff Kent Simmons to treat his medical condition(s), the product was being used for the ordinary purpose for which intended.

120. Plaintiff Kent Simmons, individually and/or by and through his physicians, relied upon Defendant's implied warranty of merchantability in consenting to have the mesh product implanted in him.

121. Defendant breached this implied warranty of merchantability because the mesh product implanted in Plaintiff Kent Simmons Kent Simmons was neither merchantable nor suited for its intended use as warranted.

122. Defendant's breaches of their implied warranties resulted in the implantation of an unreasonably dangerous and defective product in Plaintiffs Kent Simmons 's body, placing his health and safety in jeopardy.

123. As a direct and proximate result of Defendant's breaches of the aforementioned implied warranties, Plaintiff Nicole Young 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.

EXEMPLARY DAMAGES

124. Plaintiffs incorporate by reference the factual portion of this complaint as if fully set forth herein and additionally or in the alternative, if same be necessary, allege as follows:

125. Defendant's conduct in designing, manufacturing, marketing, labeling, packaging and selling the unreasonably safe and defective mesh products amounted to gross negligence, outrageous, unconscionable willful, wanton, and/or reckless conduct and/or criminal indifference to civil obligations affecting the rights of others, including Plaintiff Kent Simmons manifesting the

Defendant's malice toward and oppression of this Plaintiff, Kent Simmons such as to justify and demand an award of punitive damages against this Defendant pursuant to the provisions of KRS 411.184, as enacted.

126. The acts, conduct, and omissions of Defendant, as alleged throughout this complaint were grossly negligent, reckless and/or willful, oppressive and malicious and were done with a conscious disregard for the rights of Plaintiff, Kent Simmons, and other users of Defendant's product and for the primary purpose of increasing Defendant's profits from the sale, distribution, and use of Defendant's products. Defendant's outrageous and unconscionable conduct warrants an award of enhanced compensatory damages against each Defendant in an amount appropriate to provide full and complete compensation as well as an award of punitive damages.

127. Plaintiff Kent Simmons is entitled to an award of compensatory damages and punitive damages.

VICARIOUS LIABILITY

128. Whenever in this complaint it is alleged that Defendant 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 Defendant or was done in the normal and routine course and scope of employment of Defendants' officers, agents, servants, employees, and representatives.

WHEREFORE, Plaintiff prays for judgment against Defendant as follows:

1. For past and future general damages in an amount in excess of the minimum jurisdictional limits of this Court;
2. For general damages for personal injury, including permanent impairment, physical injury, physical and mental pain and suffering, distress, and loss of enjoyment of life;
3. For past and future medical and incidental expenses, according to proof;

4. For past and future loss of earnings and/or earning capacity, according to proof;

5. For prejudgment interest on all damages as is allowed by law;

6. For past and future costs of suit incurred herein;

7. For enhanced compensatory or punitive damages in an amount to be determined at trial; and

8. For such other and further relief as the Court deems just and proper.

JURY DEMAND

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

Respectfully submitted,

KENT SIMMONS
By his attorneys,

/s/ Gary S. Logsdon

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JS 44 (Rev. 07/16)

CIVIL COVER SHEET 1:16-cv-191-GNS

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

I. (a) PLAINTIFFS

KENT SIMMONS

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

(c) Attorneys *(Firm Name, Address, and Telephone Number)*

GARY S. LOGSDON
PO BOX 382, BROWNSVILLE, KY 42210, 2705972134

DEFENDANTS

ATRIUM MEDICAL CORPORATION

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

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

Attorneys *(If Known)*

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

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

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

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

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

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

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

TORTS

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

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

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

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

PRISONER PETITIONS

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

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

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

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

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

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

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 840 Trademark

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

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

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

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

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

VI. CAUSE OF ACTION

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

Brief description of cause:
PRODUCTS LIABILITY AND PERSONAL INJURY

VII. REQUESTED IN COMPLAINT:

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

DEMAND $

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

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE DOCKET NUMBER

DATE
11/30/2016

SIGNATURE OF ATTORNEY OF RECORD
/s/ Gary S. Logsdon

FOR OFFICE USE ONLY

RECEIPT # AMOUNT APPLYING IFP JUDGE MAG. JUDGE

INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

I.(a) Plaintiffs-Defendants. Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.

(b) County of Residence. For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)

(c) Attorneys. Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".

II. Jurisdiction. The basis of jurisdiction is set forth under Rule 8(a), F.R.Cv.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.
United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.
United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.
Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.
Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below; **NOTE: federal question actions take precedence over diversity cases.**)

III. Residence (citizenship) of Principal Parties. This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.

IV. Nature of Suit. Place an "X" in the appropriate box. If the nature of suit cannot be determined, be sure the cause of action, in Section VI below, is sufficient to enable the deputy clerk or the statistical clerk(s) in the Administrative Office to determine the nature of suit. If the cause fits more than one nature of suit, select the most definitive.

V. Origin. Place an "X" in one of the seven boxes.
Original Proceedings. (1) Cases which originate in the United States district courts.
Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441. When the petition for removal is granted, check this box.
Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.
Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.
Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.
Multidistrict Litigation – Transfer. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407.
Multidistrict Litigation – Direct File. (8) Check this box when a multidistrict case is filed in the same district as the Master MDL docket.
PLEASE NOTE THAT THERE IS NOT AN ORIGIN CODE 7. Origin Code 7 was used for historical records and is no longer relevant due to changes in statue.

VI. Cause of Action. Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity.** Example: U.S. Civil Statute: 47 USC 553 Brief Description: Unauthorized reception of cable service

VII. Requested in Complaint. Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.
Demand. In this space enter the actual dollar amount being demanded or indicate other demand, such as a preliminary injunction.
Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.

VIII. Related Cases. This section of the JS 44 is used to reference related pending cases, if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.

Date and Attorney Signature. Date and sign the civil cover sheet.

AO 440 (Rev. 12/09) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

KENT SIMMONS

Plaintiff

v.

ATRIUM MEDICAL CORPORATION

Defendant

Civil Action No. 1:16-cv-191-GNS

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* ATRIUM MEDICAL CORPORATION
C/O
CT CORPORATION SYSTEM
9 CAPITOL STREET
CONCORD, NH 03301

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: GARY S. LOGSDON & ASSOCIATES
PO BOX 382
BROWNSVILLE, KY 42210
270-597-2134

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

Signature of Clerk or Deputy Clerk