UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF PENNSYLVANIA

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

COMPLAINT

Come now Plaintiff, Willie Calloway, by and through undersigned counsel, and bring 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 Ohio and the United States.

2. 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, NH. 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, NJ 07470. Maquet is registered with the Pennsylvania Secretary of

State to transact business in Pennsylvania. At all times pertinent hereto, Atrium has operated within, and as a business unit of, Maquet. Following reasonable inquiry and diligent search, upon information and belief, each of Maquet's LLC members are citizens of states other than Ohio.

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, Getinge acquired Atrium through a merger. When Getinge acquired Atrium through a 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 Willie Calloway, 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 Pennsylvania Long-Arm Statute, 42 Pa. C.S.A. § 5322. Defendants transact business within the State of Pennsylvania, contracted to sell and supply their C-QUR mesh products in the State of Pennsylvania, and committed tortious acts and omissions in Pennsylvania. Defendants' tortious acts and omissions caused injury to Plaintiff in the State of Pennsylvania. Defendants employ sales representatives in the State of Pennsylvania 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 Pennsylvania, 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 Pennsylvania and could cause injury in Pennsylvania.

17. Maquet is registered to transact business in Pennsylvania.

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 November 12, 2010, Plaintiff Willie Calloway underwent repair of an umbilical hernia by Dr. Biju Thomas at Uniontown Hospital in Uniontown, Pennsylvania. A 8 x 8 cm C-Qur Mesh was implanted in Ms. Calloway during this repair.

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

21. On or about February 13, 2015, Plaintiff Willie Calloway presented to Uniontown Hospital for repair of recurrent incarcerated hernia and severe adhesive disease. For several years she had noted a painful lump in the area of her prior hernia repair with C-Qur Mesh. There were large amounts of adhesions between the omentum to the anterior abdominal wall as well as severe adhesions between the terminal ileum and the C-Qur Mesh with several previous permanent tacks observed within the wall of the small bowel. Several serosal tears were noted after the small bowel was removed from the mesh. Due to the compromise of integrity of her bowel, a small bowel resection was performed and two feet of bowel were removed. A piece of Proceed mesh was used to repair the new hernia defect. Pathology from the excision of mesh and

bowel revealed synthetic mesh with embedded fibro-fatty tissue and chronic inflammation and small bowel portions with multiple areas of serosal adhesions and embedded mesh.

22. 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 Plaintiff to suffer injury and damages.

23. Defendants 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.

24. Among the intended purposes for which Defendants designed, manufactured and sold C-QUR Mesh was use by surgeons for hernia repair surgeries, the purpose for which the C-QUR Mesh was implanted in Plaintiff Willie Calloway.

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

26. 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/ingrowth; 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.

27. 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.

28. 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.

29. 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.

30. 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.

31. 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.

32. 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.

33. 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.

34. These manufacturing and design defects associated with the C-QUR Mesh were directly and proximately related to the injuries suffered by Plaintiff Willie Calloway.

35. Neither Plaintiff Willie Calloway nor her implanting physician were adequately warned or informed by Defendants of the defective and dangerous nature of C-QUR Mesh. Moreover, neither Plaintiff Willie Calloway nor her implanting physician were adequately warned or informed by Defendants of the risks associated with the C-QUR Mesh.

36. The C-QUR Mesh implanted in Plaintiff Willie Calloway failed to reasonably perform as intended. The mesh caused serious injury and had to be surgically removed via invasive surgery, and necessitated additional invasive surgery to repair the hernia that the C-QUR was initially implanted to treat.

37. Plaintiff Willie Calloway's severe adverse reaction, and the necessity for surgical removal 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 Willie Calloway has suffered, and will continue to suffer, both physical injury and pain and mental anguish, permanent and severe scarring and disfigurement, lost wages and earning capacity, and has incurred substantial medical bills and other expenses, resulting from the defective and dangerous condition of the product and from Defendants' defective and inadequate warnings about the risks associated with the product.

COUNT I
Strict Product Liability: Defective Manufacture

38. Plaintiff incorporates herein by reference the allegations in all prior paragraphs as if fully set forth herein.

39. Defendants expected and intended the C-QUR Mesh product to reach users such as Plaintiff Willie Calloway in the condition in which the product was sold.

40. 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.

41. At the time the C-QUR Mesh that was implanted in Plaintiff Willie Calloway's body, the product was defectively manufactured.

42. 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 Willie Calloway, suffered manufacturing defects adversely affecting the safety and efficacy of the device.

43. Defendants' manufacturing and quality control/assurance non-compliance resulted in the non-conformance of the C-QUR Mesh implanted in Plaintiff Willie Calloway 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.

44. 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.

45. 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.

46. 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.

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

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

COUNT II
Strict Product Liability: Defective Design

48. Plaintiff incorporates herein by reference the allegations in all prior paragraphs as if fully set forth herein.

49. At the time the C-QUR Mesh that was implanted in Plaintiff Willie Calloway's body, the product was defectively designed. 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 these risks.

50. Defendants expected and intended the C-QUR Mesh product to reach users such as Plaintiff Willie Calloway in the condition in which the product was sold.

51. 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.

52. 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 caused immunogenic response, and was known to be cytotoxic.

53. 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 ingrowth 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.

54. The polypropylene mesh within the defective Omega 3 coating of the C-QUR Mesh was in itself dangerous and defective, particularly when used in the manner intended by Defendants in the C-QUR Mesh. 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, polypropylene mesh is unreasonably

susceptible to adhesion, bowel perforation or erosion, fistula formation and bowel strangulation or hernia incarceration, and other injuries.

55. 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.

56. The C-QUR Mesh was designed and intended for intraperitoneal 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.

57. At the time the C-QUR Mesh was implanted in Plaintiff Willie Calloway, there were safer feasible alternative designs for hernia mesh products that would have prevented the injuries she suffered.

58. 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 these devices.

59. The C-QUR Mesh implanted in Plaintiff Willie Calloway failed to reasonably perform as intended, and had to be surgically removed necessitating further invasive surgery to repair the very issue that the product was intended to repair, and thus provided no benefit to him.

60. As a direct and proximate result of the defective and unreasonably dangerous condition of the product, Plaintiff suffered injuries and damages as summarized herein.

WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages,

punitive damages, together with interest, cost of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT III
Strict Product Liability: Failure to Warn

61. Plaintiff incorporates herein by reference the allegations in all prior paragraphs as if fully set forth herein.

62. At the time the C-QUR Mesh that was implanted in Plaintiff Willie Calloway's body, the warnings and instructions provided by Defendant 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.

63. Defendants expected and intended the C-QUR Mesh product to reach users such as Plaintiff Willie Calloway in the condition in which the product was sold.

64. Plaintiff and her 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.

65. 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.

66. 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.

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

68. Defendants failed to adequately warn Plaintiff or her 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.

69. 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 ingrowth, 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.

70. 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.

71. If Plaintiff Willie Calloway and/or her 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 Willie Calloway would not have consented to allow the C-QUR Mesh to be implanted in her body, and Plaintiff Willie Calloway's physicians would not have implanted the C-QUR Mesh in Plaintiff Willie Calloway.

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

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

COUNT IV
Negligence

73. Plaintiff incorporates herein by reference the allegations in all prior Paragraphs as if fully set forth herein.

74. 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.

75. 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.

76. 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, Plaintiff suffered injuries and damages as summarized herein.

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

Punitive Damages Allegations

77. Plaintiff incorporates herein by reference the allegations in all prior paragraphs as if fully set forth herein.

78. 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. Even though Defendants have other hernia repair mesh devices 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. 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 Willie Calloway. Defendants willfully and recklessly failed to avoid those consequences, and in doing so, Defendants acted intentionally, maliciously and recklessly with regard the safety of those persons who might foreseeably have been harmed by the C-QUR product, including Plaintiff, justifying the imposition of punitive damages.

WHEREFORE, as a result of the acts and omissions and conduct of Defendants set forth herein, Plaintiff Willie Calloway is entitled to recover for her 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 Pennsylvania law; and Plaintiff should be awarded punitive damages.

Plaintiff demands trial by jury, judgment against Defendants, jointly and severally, for compensatory damages and punitive damages, as well as costs, attorney fees, interest, or any other relief, monetary or equitable, to which they are entitled.

Respectfully submitted,

HOLMAN SCHIAVONE, LLC

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Pro Hac Vice Application Forthcoming

ATTORNEYS FOR PLAINTIFF

JS 44 (Rev. 12/12)

CIVIL COVER SHEET

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

I. (a) PLAINTIFFS

Willie Calloway,

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

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Anne Schiavone, HOLMAN SCHIAVONE, LLC, 4600 Madison Ave., Ste. 810, Kansas City, MO 64112

DEFENDANTS

Atrium Medical Corporation, et al.

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.

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
- ❒ 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

VI. CAUSE OF ACTION

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

Brief description of cause:
Diversity of citizenship

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
01/12/2017

SIGNATURE OF ATTORNEY OF RECORD
s/Anne Schiavone

FOR OFFICE USE ONLY

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

JS 44AREVISED June, **2009**
IN THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF PENNSYLVANIA
THIS CASE DESIGNATION SHEET MUST BE COMPLETED

PART A

This case belongs on the (○ Erie ○ Johnstown ◉ Pittsburgh) calendar.

1. **ERIE CALENDAR -** If cause of action arose in the counties of Crawford, Elk, Erie, Forest, McKean. Venang or Warren, OR any plaintiff or defendant resides in one of said counties.

2. **JOHNSTOWN CALENDAR -** If cause of action arose in the counties of Bedford, Blair, Cambria, Clearfield or Somerset OR any plaintiff or defendant resides in one of said counties.

3. Complete if on **ERIE CALENDAR**: I certify that the cause of action arose in_____ County and that the _____resides in_____County.

4. Complete if on **JOHNSTOWN CALENDAR**: I certify that the cause of action arose in _____County and that the_____resides in _____County.

PART B (You are to check ONE of the following)

1. ○ This case is related to Number_____ . Short Caption_____.
2. ◉ This case is not related to a pending or terminated case.

DEFINlTIONS OF RELATED CASES:

CIVIL: Civil cases are deemed related when a case filed relates to property included in another suit or involves the same issues of fact or it grows out of the same transactions as another suit or involves the validity or infringement of a patent involved in another suit EMINENT DOMAIN: Cases in contiguous closely located groups and in common ownership groups which will lend themselves to consolidation for trial shall be deemed related. HABEAS CORPUS & CIVIL RIGHTS: All habeas corpus petitions filed by the same individual shall be deemed related. All pro se Civil Rights actions by the same individual shall be deemed related.

PARTC

I. CIVIL CATEGORY (Select the applicable category).

1. ○ Antitrust and Securities Act Cases
2. ○ Labor-Management Relations
3. ○ Habeas corpus
4. ○ Civil Rights
5. ○ Patent, Copyright, and Trademark
6. ○ Eminent Domain
7. ○ All other federal question cases
8. ◉ All personal and property damage tort cases, including maritime, FELA, Jones Act, Motor vehicle, products liability, assault, defamation, malicious prosecution, and false arrest
9. ○ Insurance indemnity, contract and other diversity cases.
10. ○ Government Collection Cases (shall include HEW Student Loans (Education), V A 0verpayment, Overpayment of Social Security, Enlistment Overpayment (Army, Navy, etc.), HUD Loans, GAO Loans (Misc. Types), Mortgage Foreclosures, SBA Loans, Civil Penalties and Coal Mine Penalty and Reclamation Fees.)

I certify that to the best of my knowledge the entries on this Case Designation Sheet are true and correct

Date: 1/17/2017 s/Anne Schiavone

ATTORNEY AT LAW

NOTE: ALL SECTIONS OF BOTH FORMS MUST BE COMPLETED BEFORE CASE CAN BE PROCESSED.

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 six 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. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407. When this box is checked, do not check (5) above.

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.