UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF PENNSYLVANIA

LEONARD BARTOSIEWICZ, and MARLENE BARTOSIEWICZ, H/W	)	**Civil Action No.:**
Plaintiffs,	)	**JURY TRIAL DEMANDED**
v.	)	
ATRIUM MEDICAL CORPORATION, MAQUET CARDIOVASCULAR US SALES, LLC, and GETINGE AB,	)	
Defendants.	)	

COMPLAINT

Come now Plaintiffs, Leonard Bartosiewicz and Marlene Bartosiewicz (collectively, "Plaintiffs"; Leonard Bartosiewicz may be referred to individually as "Plaintiff"), by and through their 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. Plaintiffs are, and were, at all relevant times, citizens and residents of the Middle District of Pennsylvania 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. Atrium operates within, and as a business unit of, Maquet. Following diligent search and reasonable inquiry, upon information and belief, each of Maquet's LLC members are citizens of states other than Pennsylvania.

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, 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 have and continue to transact business within the State of Pennsylvania, contract 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 June 1, 2011, Plaintiff Leonard Bartosiewicz was admitted to Geisinger Wyoming Valley Medical Center for surgical repair of an incisional hernia. Plaintiff was implanted with a C-Qur mesh manufactured and distributed by Defendants.

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

21. On or about June 14, 2016, Plaintiff reported to Geisinger Wyoming Valley Medical Center with severe abdominal pain. Plaintiff's physicians discovered a severe mesh infection and erosion of the C-Qur mesh into the bowel. Plaintiff's physicians performed an emergency exploratory laparotomy to remove the C-Qur mesh and resect a substantial portion of Plaintiff's bowel.

22. Following the removal of the C-Qur mesh, Plaintiff underwent an extensive wound care course including aggressive antibiotic therapy

23. Plaintiff is debilitated and permanently disfigured as a result of the above-described injuries which were caused by the defects of the C-Qur mesh.

24. The C-Qur Mesh was implanted in Plaintiff to repair his hernia, the use for which the C-Qur Mesh was designed, marketed and sold.

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

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

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

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

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

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

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

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

33. 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.

34. 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 Leonard Bartosiewicz.

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

36. 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.

37. 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.

38. 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.

39. 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.

40. 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.

41. 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.

42. 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.

43. 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.

44. These manufacturing and design defects associated with the C-QUR Mesh were directly and proximately related to the injuries suffered by Plaintiff Leonard Bartosiewicz.

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

46. The C-QUR Mesh implanted in Plaintiff Leonard Bartosiewicz 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.

47. Plaintiff Leonard Bartosiewicz'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 Leonard Bartosiewicz 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.

Punitive Damages Allegations

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

49. 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 that suffered by Plaintiff Leonard Bartosiewicz. 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 Leonard Bartosiewicz 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 Pennsylvania law; and Plaintiff Marlene Bartosiewicz is entitled to recover for her loss of consortium and services and all other damages allowed by Pennsylvania law; and Plaintiffs should be awarded punitive damages.

COUNT I
Strict Product Liability: Defective Manufacture

50. Plaintiffs incorporate herein by reference the allegations in all prior paragraphs as if fully set forth herein.

51. Defendants expected and intended the C-QUR Mesh product to reach users such as Plaintiff Leonard Bartosiewicz in the condition in which the product was sold.

52. 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.

53. At the time the C-QUR Mesh that was implanted in Plaintiff Leonard Bartosiewicz's body, the product was defectively manufactured.

54. 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 Leonard Bartosiewicz, suffered manufacturing defects adversely affecting the safety and efficacy of the device.

55. Defendants' manufacturing and quality control/assurance non-compliance resulted in the non-conformance of the C-QUR Mesh implanted in Plaintiff Leonard Bartosiewicz 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.

56. 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.

57. 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.

58. 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.

59. 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 damages substantially in excess of this Honorable Court's jurisdictional threshold, together with costs, interest, pre- and post-judgment interest, delay damages and punitive damages pursuant to the Federal Rules of Civil Procedure, and any further relief which this Honorable Court deems just and appropriate under the circumstances.

COUNT II
Strict Product Liability: Defective Design

60. Plaintiffs incorporate herein by reference the allegations in all prior paragraphs as if fully set forth herein.

61. At the time the C-QUR Mesh that was implanted in Plaintiff Leonard Bartosiewicz'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.

62. Defendants expected and intended the C-QUR Mesh product to reach users such as Plaintiff Leonard Bartosiewicz in the condition in which the product was sold.

63. 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.

64. 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.

65. 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.

66. 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.

67. 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.

68. 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.

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

70. The C-QUR Mesh product costs 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.

71. The C-QUR Mesh implanted in Plaintiff Leonard Bartosiewicz 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.

72. 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 damages substantially in excess of this Honorable Court's jurisdictional threshold, together with costs, interest, pre- and post-judgment interest, delay damages and punitive damages pursuant to the Federal Rules of Civil Procedure, and any further relief which this Honorable Court deems just and appropriate under the circumstances.

COUNT III
Strict Product Liability: Failure to Warn

73. Plaintiffs incorporate herein by reference the allegations in all prior paragraphs as if fully set forth herein.

74. At the time the C-QUR Mesh that was implanted in Plaintiff Leonard Bartosiewicz's body, 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.

75. Defendants expected and intended the C-QUR Mesh product to reach users such as Plaintiff Leonard Bartosiewicz in the condition in which the product was sold.

76. 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.

77. 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.

78. 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.

79. 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.

80. 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.

81. 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.

82. 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.

83. If Plaintiff Leonard Bartosiewicz 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 Leonard Bartosiewicz would not have consented to allow the C-QUR Mesh to be implanted in his body, and Plaintiff Leonard

Bartosiewicz's physicians would not have implanted the C-QUR Mesh in Plaintiff Leonard Bartosiewicz.

84. 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 damages substantially in excess of this Honorable Court's jurisdictional threshold, together with costs, interest, pre- and post-judgment interest, delay damages and punitive damages pursuant to the Federal Rules of Civil Procedure, and any further relief which this Honorable Court deems just and appropriate under the circumstances.

COUNT IV
Negligence

85. Plaintiffs incorporate herein by reference the allegations in all prior Paragraphs as if fully set forth herein.

86. 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.

87. 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.

88. 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, Plaintiffs demand damages substantially in excess of this Honorable Court's jurisdictional threshold, together with costs, interest, pre- and post-judgment interest, delay damages and punitive damages pursuant to the Federal Rules of Civil Procedure, and any further relief which this Honorable Court deems just and appropriate under the circumstances.

COUNT V
Loss of Consortium

89. Plaintiffs incorporate herein by reference the allegations in all prior paragraphs as if fully set forth herein.

90. As a direct and proximate result of the above-described injuries sustained by Plaintiff Leonard Bartosiewicz, his wife, Plaintiff Marlene Bartosiewicz, has suffered a loss of her husband's consortium, companionship, society, affection, services and support.

WHEREFORE, Plaintiffs demand damages substantially in excess of this Honorable Court's jurisdictional threshold, together with costs, interest, pre- and post-judgment interest, delay damages and punitive damages pursuant to the Federal Rules of Civil Procedure, and any further relief which this Honorable Court deems just and appropriate under the circumstances.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly and severally and request compensatory damages, punitive damages, together with interest, cost of suit, attorneys' fees, and all such other relief as the Court deems just a proper as well as:

i. Compensatory damages to Plaintiffs for past, present, and future damages, including, but not limited to, pain and suffering for severe and permanent personal injuries sustained by Plaintiffs, permanent impairment, mental pain and suffering, loss of enjoyment of life, past and future health and medical care costs, together with interest and costs as provided by law;

ii. Enhanced compensatory damages in an amount to be determined trial;

iii. Reasonable attorneys' fees;

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

v. All ascertainable economic damages, including past and future loss of earnings and/or earning capacity;

vi. Punitive damages;

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

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

JURY TRIAL DEMANDED

Plaintiffs hereby demand a trial by jury on all issues so triable.

Respectfully submitted,

THE BEASLEY FIRM, LLC

/s/ Dion G. Rassias
DION G. RASSIAS
Attorney for Plaintiff
1125 Walnut Street
Philadelphia, PA 19107

(215) 592-1000
(215) 592-1523 (fax)
dgr@beasleyfirm.com

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