IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND
NORTHERN DIVISION

CHARLES RACINE 259 Emelia Drive Bear, DE 19701 Plaintiff, v. **ETHICON, INC.** Serve on: Johnson & Johnson Resident Agent One Johnson & Johnson Plaza New Brunswick, NJ 8933 and **JOHNSON & JOHNSON** Serve on: Johnson & Johnson Resident Agent One Johnson & Johnson Plaza New Brunswick, NJ 8933 Defendants.	Civil Action No.:

COMPLAINT AND DEMAND FOR JURY TRIAL

Charles Racine, Plaintiff, by and through his attorneys, Michael Paul Smith, Eugene A. Arbaugh, Jr. and Smith, Gildea and Schmidt, LLC sues Ethicon, Inc. and Johnson & Johnson and for cause states:

PARTIES

1. Plaintiff Charles Racine ("Mr. Racine") is a resident of New Castle County, Delaware.

2. Defendant Johnson & Johnson ("J&J") is a corporation incorporated in New Jersey with its principal place of business in New Brunswick, New Jersey.

3. Defendant Ethicon, Inc. ("Ethicon") is a corporation incorporated in New Jersey with its

principle place of business in Somerville, New Jersey and is a wholly owned subsidiary of Johnson & Johnson.

4. According to J&J's website, it is the world's largest and most diverse medical device and diagnostics company. J&J organizes its subsidiary businesses into individual Business Units to coordinate the development, manufacture, testing, marketing promotion, training, distribution and sale of its products, including but not limited to its hernia repair mesh products. Within J &J there are three sectors: medical devices and diagnostics, pharmaceutical, and consumer. Within the medical devices and diagnostic sector are "Business Units" including the "Ethicon Franchise." The Ethicon Franchise was charged by J&J with the design, development, promotion, marketing, testing, training, distribution and sale of the hernia repair mesh products at issue in this case. The Company Group Chairman and Worldwide Franchise Chairman for the Ethicon Franchise, Gary Pruden, is employed by J&J. The companies which comprise the Ethicon Franchise are thus controlled by J&J and include, but are not limited to, Defendant Ethicon, Inc.

5. Ethicon is a medical device company involved in the research, development, testing, manufacture, production, marketing, promotion and/ or sale of medical devices including Physiomesh.

6. J&J, directly and/or through the actions of Ethicon, has at all pertinent times been responsible for the research, development, testing, manufacture, production, marketing, promotion, distribution and/or sale of Physiomesh (which hereinafter may be referred to as the "product").

7. Defendants are individually, jointly and severally liable to Plaintiff for damages suffered by Mr. Racine arising from the Defendants' design, manufacture, marketing, labeling,

distribution, sale and placement of its defective mesh products at issue in the instant action, 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.

8. Defendants are vicariously liable for the acts and/or omissions of its 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

9. Physiomesh, which is the subject of this suit, was surgically inserted into Mr. Racine at Union Hospital of Cecil County at 106 Bow Street, in Elkton, Cecil County, Maryland.

10. A substantial part of the events giving rise to this claim, including surgical insertion of the product and the subsequent medical treatment provided as a result of the defective product, occurred within the State of Maryland.

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

12. This Court has personal jurisdiction over each of the Defendants pursuant to the Maryland Code, Courts and Judicial Proceedings, § 6-103(b). Defendants transact business within the State of Maryland, and Defendants caused tortious acts and omissions in Maryland. Defendants' tortious acts and omissions caused injury to Mr. Racine in the State of Maryland. 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 Physiomesh in Maryland, for which they derived significant and regular income. The Defendants reasonably expected that that their defective mesh products, including Physiomesh, would be sold and implanted in Maryland.

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

FACTS COMMON TO ALL COUNTS

14. The previous paragraphs are included as if specifically stated herein.

15. Defendants designed, manufactured, marketed, packaged, labeled and sold medical devices, including a medical device known as Physiomesh for the repair of hernias.

16. On or about March 4, 2014, Mr. Racine is admitted to Union Hospital of Cecil County and has Physiomesh, a flexible composite hernia mesh with catalog number PHY 2025V, implanted laparoscopically to repair a ventral hernia.

17. On or about March 10, 2014, Mr. Racine returns to Union Hospital of Cecil County complaining of abdominal pain, vomiting and diarrhea.

18. On or about February 17, 2016, Mr. Racine undergoes a diagnostic laparoscopy, which appears to show significant adhesions throughout the middle of his abdomen associated with the mesh. The operative surgeon also noted loops of small bowel attached to the adhesions in the upper and mid abdomen and also the mesh.

19. Defendants manufactured, sold, and/or distributed the Physiomesh device to Mr. Racine, through his doctors, to be used for treatment of hernia repair. Defendants were responsible for the research, design, development, testing, manufacture, production, marketing, promotion, distribution, and sale of Physiomesh, including providing the warnings and instructions concerning the product.

20. Among the intended purposes for which Defendants designed, manufactured and sold Physiomesh was use by surgeons for hernia repair surgeries, the purpose for which the Physiomesh was implanted in Mr. Racine.

21. Defendants represented to Mr. Racine and Mr. Racine's physicians that Physiomesh was a safe and effective product for hernia repair.

22. Defendants' Physiomesh 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 Physiomesh, there was an unreasonable risk of severe adverse reactions to the mesh or mesh components including but not limited to: chronic pain; recurrence of hernia; foreign body response; rejection; infection; inadequate or failure of incorporation/ingrowth; migration; scarification; deformation of mesh; improper wound healing; excessive and chronic inflammation; adhesions to internal organs; erosion; abscess; fistula formation; granulomatous response; seroma formation; nerve damage; bowel obstruction; tissue damage and/or death; and other complications.

23. The Physiomesh has numerous defects that create a high risk of unreasonable and dangerous injuries and side effects with severe permanent adverse health consequences. These defects include, but are not limited to the following:

    a. The material used in the Physiomesh is not inert and therefore reacts to human tissues and /or other naturally occurring human bodily contents adversely affecting patient health;

    b. The mesh material harbors infections that adversely affect human tissues and patient health;

c. The Physiomesh and its mesh components migrate from the location of their implantation, adversely affecting tissues and patient health;

d. The Physiomesh and its mesh components abrades tissues adversely affecting patient health;

e. The Physiomesh and its mesh components regularly fail to perform the purpose of their implantation such that the patient requires removal of the Physiomesh and repeated treatment and surgery;

f. Due to the various defects, the Physiomesh and its mesh components regularly cause significant injury to patients such that the Physiomesh must be removed, resulting in additional surgery;

g. The Physiomesh and its mesh components become embedded in human tissue over time such that when removal is required due its various defects, the removal causes damage to organs and tissues, adversely affecting patient health;

h. The Physiomesh is defective in shape, composition, weight, physical properties, chemical properties and mechanical properties and inappropriately designed and engineered for use in hernia repair.

24. Because of its numerous defects, the Physiomesh creates an unreasonable risk of injury and other adverse health consequences for patients, including, but not limited to, severe and chronic pain, infection, hernia recurrence, adhesions, mesh migration, mesh contraction and repeated surgeries. These manufacturing and design defects associated with the Physiomesh were directly and proximately related to the injuries suffered by Mr. Racine.

25. Defendants represented to Mr. Racine and Mr. Racine's physicians that Physiomesh was

a safe and effective product for hernia repair.

26. Defendants' Physiomesh 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 Physiomesh, 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; migration; scarification; deformation of mesh; improper wound healing; excessive and chronic inflammation; adhesions to internal organs; bowel obstruction; erosion; abscess; fistula formation; granulomatous response; seroma formation; nerve damage; tissue damage and/or death; and other complications.

27. Physiomesh has a unique design incorporating five (5) distinct layers: two layers of polyglecaprone-25 ("Monocryl") film covering two underlying layers of polydioxanone film ("PDS"), which in tum coat a polypropylene mesh. This design is not used in any other hernia repair product sold in the United States. The multi-layer coating was represented and promoted 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 multi-layer coating prevented adequate incorporation of the mesh into the body and caused or contributed to an intense inflammatory and chronic foreign body response resulting in an adverse tissue reaction including migration and 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 multi-layer coating of the

Physiomesh prevents fluid escape, which leads to seroma formation, and which in tum can cause infection, abscess formation and other complications.

29. The multi-layer coating provides a breeding ground for bacteria in which the bacteria cannot be eliminated by the body's immune response, which allows infection to proliferate.

30. The multi-layer coating of Defendants' Physiomesh 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 multi-layer coating of the Physiomesh prior to introducing it into the stream of commerce.

32. When the multi-layer coating of the Physiomesh 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 damage to organs, and potentiate fistula formation.

33. These manufacturing and design defects associated with the Physiomesh were directly and proximately related to the injuries suffered by Mr. Racine.

34. Neither Mr. Racine nor his implanting physician were adequately warned or informed by Defendants of the defective and dangerous nature of Physiomesh. Moreover, neither Mr. Racine nor his implanting physician were adequately warned or informed by Defendants of the risks associated with the Physiomesh or the frequency, severity, or duration of such risks.

35. The Physiomesh implanted in Mr. Racine failed to reasonably perform as intended. The

mesh caused serious injury and necessitated additional otherwise unnecessary invasive surgeries to diagnose the hernia that the Physiomesh was initially implanted to treat, in addition to repair some damage caused by the defective product itself. Mr. Racine will also need future surgical procedures performed to fully repair the damage caused by the defective product.

36. Mr. Racine's severe adverse reaction, and the necessity for further surgical removal of the Physiomesh, 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, and the frequency, severity and duration of such risks. Mr. Racine 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.

37. The Physiomesh implanted in Mr. Racine failed to reasonably perform as intended. The mesh caused serious injury and will require additional invasive surgery to properly fully remedy.

38. In May of 2016, Defendants issued an "Urgent: Field Safety Notice" relating to its Physiomesh Flexible Composite Mesh, the same product implanted in Mr. Racine, and sent such notifications to hospitals and medical providers in various countries worldwide. In this safety notice, Defendants advise these providers of "a voluntary product recall," citing two international device registries which reported data reflecting recurrence/reoperation rates after laparoscopic placement as being higher than that

observed from a data set relating to patient outcomes after being implanted with other mesh. However, in the United States, Defendants failed to issues a nationwide recall, opting instead to simply remove the product from shelves and cease further sales within the United States.

39. All such injuries and damages were directly and proximately caused by the negligence of Defendants without any negligence on the part of Mr. Racine.

COUNT 1: STRICT PRODUCT LIABILITY: DEFECTIVE DESIGN

40. The previous paragraphs are included as if specifically stated herein.

41. The risks of the Physiomesh significantly outweigh any benefits that Defendants contend could be associated with the product. The multi-layer 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 multi-layer 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.

42. The multi-layer coating of the Physiomesh, which was marketed, promoted and intended as a barrier against adhesion to the internal organs, 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. The degradation of this multi-layer coating caused or exacerbated an intense inflammatory and foreign body reaction. Once exposed to the viscera, the polypropylene mesh will inevitably adhere to

the viscera, initiating a cascade of adverse consequences. Any purported beneficial purpose of the multi-layer coating (to prevent adhesion to the internal viscera and organs) was non-existent; the product provided no benefit while substantially increasing the risks to the patient.

43. The polypropylene mesh within the defective multi-layer coating of the Physiomesh was in itself dangerous and defective, particularly when used in the manner intended by Defendants in the Physiomesh. When implanted adjacent to the intestines and other internal organs, as Defendants intended for Physiomesh, polypropylene mesh is unreasonably susceptible to adhesion, bowel perforation or erosion, fistula formation and bowel strangulation or hernia incarceration, and other injuries.

44. The appropriate treatment for complications associated with Physiomesh 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.

45. Physiomesh was designed and intended for intraperitoneal implantation, which involved the product being implanted in contact with the intestines and/or other internal organs, which unnecessarily increased the risks of adhesion, erosion, fistula formation, and other injuries.

46. At the time the Physiomesh was implanted in Mr. Racine, there were safer feasible alternative designs for hernia mesh products that would have prevented the injuries he suffered.

47. The Physiomesh product cost significantly more than competitive products because of its unique multi-layer coating, even though the multi-layer coating provided no benefit to consumers, and increased the risks to patients implanted with these devices.

48. The Physiomesh implanted in Mr. Racine failed to reasonably perform as intended, and will require further invasive surgery to repair the very issue that the product was intended to address, and thus provided no benefit to him.

49. At the time the Physiomesh was implanted in Mr. Racine'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. The defects in the Physiomesh existed from its inception, therefore the defects were present when it left the possession and control of Defendants.

51. Defendants expected and intended the Physiomesh product to reach users such as Mr. Racine in the condition in which the product was sold.

52. The implantation of Physiomesh in Mr. Racine'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. The foreseeable risks of harm posed by the design of the Physiomesh could have been reduced and/or avoided by the adoption of a reasonable alternative design by Defendants, and the failure of Defendants to adopt a safer alternative design rendered the Physiomesh unreasonably unsafe.

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

COUNT 2: STRICT PRODUCT LIABILITY: DEFECTIVE MANUFACTURE

55. The previous paragraphs are included as if specifically stated herein.

56. One or more of the defects in the Physiomesh is the result of improper or incorrect manufacturing processes that result in the Physiomesh as manufactured deviating from its intended design.

57. The defects caused by manufacturing defect rendered the Physiomesh unreasonably dangerous to consumers and Mr. Racine.

58. The defects in the Physiomesh implanted in Mr. Racine existed from its manufacture, therefore the defects were present when it left the possession and control of Defendants.

59. As a direct and proximate result of Defendants' defective manufacture, Mr. Racine suffered injuries and damages as detailed in this Complaint.

COUNT 3: STRICT PRODUCT LIABILITY: MARKETING DEFECT

60. The previous paragraphs are included as if specifically stated herein.

61. The Physiomesh was defective by reason of failure of Defendants to provide adequate warnings or instructions.

62. Defendants failed to provide such warning or instruction that a manufacturer exercising reasonable care would have provided to physicians who implanted the Physiomesh or to those patients who had been implanted with the Physiomesh, concerning the following risks, of which Defendants had actual or constructive knowledge at the time the Physiomesh left the Defendants' control:

a. the high failure rate of the Physiomesh;

b. the high rate of infections and abscesses caused by the Physiomesh;

c. the high rate of abdominal erosions and extrusions caused by the Physiomesh;

d. the high rate of chronic pain caused by the Physiomesh;

e. the high rate of migration of the Physiomesh;

f. the high rate of bowel obstruction caused by the Physiomesh;

g. the high rate of diminished bowel motility caused by the Physiomesh;

h. the high rate of corrective surgeries caused by the defective Physiomesh;

i. the high rate of patient injuries caused by the Physiomesh's migration, decomposition, infections, abscesses, erosion, extrusion, adhesion to bodily organs, and interference with normal bodily functions.

63. After receiving notice of numerous bodily injuries resulting from the Physiomesh, Defendants failed to timely provide such post-marketing or post-sale warnings or instructions that a manufacturer exercising reasonable care should have provided to physicians who implanted the Physiomesh, or the persons who had been implanted with the Physiomesh, that the Physiomesh was causing an unreasonably high rate of injury to patients and unreasonably high rate of corrective surgeries required to treat Physiomesh related complications.

64. Furthermore Defendants failed to provide post-marketing or post-sale warnings or instructions concerning the necessity to remove the Physiomesh from the patient's body in the event of Physiomesh failure, migration, decomposition, adhesions to organs, infections, abscesses, erosion, or extrusion.

65. As a direct and proximate result of Defendants' marketing defect, Mr. Racine suffered injuries and damages as detailed in this Complaint.

COUNT 4: STRICT PRODUCT LIABILITY: FAILURE TO WARN

66. The previous paragraphs are included as if specifically stated herein.

67. At the time the Physiomesh was implanted in Mr. Racine's body, the warnings and instructions provided by Defendants for the Physiomesh 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.

68. Defendants expected and intended the Physiomesh product to reach users such as Mr. Racine in the condition in which the product was sold.

69. Mr. Racine and his physicians were unaware of the defects and dangers of Physiomesh, and were unaware of the frequency, severity and duration of the defects and risks associated with the Physiomesh.

70. The Defendants' Instructions for Use provided with the Physiomesh expressly understates and misstates the risks known to be associated specifically with the Physiomesh by stating that, "Potential adverse reactions are those typically associated with surgically implantable materials." No other surgical mesh sold in the United States – and no other "surgically implantable material" – suffers the same serious design flaws as Physiomesh. No other device or material contains the dangerous and defective multi-layer 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 Physiomesh.

71. The Defendants' Instructions for Use for the Physiomesh failed to adequately warn Mr. Racine's physicians of numerous risks which Defendants knew or should have known were associated with the Physiomesh, including the risks of the product's inhibition of

tissue incorporation, pain, immunologic response, dehiscence, encapsulation, rejection, migration, scarification, shrinkage/contraction, adhesion to internal organs and viscera, erosion through adjacent tissue and viscera, bowel obstruction, failure of repair/hernia recurrence, or hernia incarceration or strangulation.

72. Defendants failed to adequately train or warn Mr. Racine 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.

73. Defendants failed to adequately warn Mr. Racine or his physicians that the necessary surgical removal of the Physiomesh 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 Physiomesh was intended to treat.

74. Defendants represented to physicians, including Mr. Racine's physician, that the multi-layer coating would prevent or reduce adhesion, and expressly intended for the Physiomesh to be implanted in contact with the intestines and internal organs and marketed and promoted the product for said purpose. Defendants failed to warn physicians that the multi-layer coating prevented tissue ingrowth, which is the desired biologic response to an implantable mesh device. Defendants failed to warn physicians that the multi-layer 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 organs or tissue.

75. 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

Physiomesh were more frequent, more severe and lasted longer than those with safer feasible alternative hernia repair treatments.

76. If Mr. Racine and/or his physicians had been properly warned of the defects and dangers of Physiomesh, and of the frequency, severity and duration of the risks associated with the Physiomesh, Mr. Racine would not have consented to allow the Physiomesh to be implanted in his body, and Mr. Racine's physicians would not have implanted the Physiomesh in Mr. Racine.

77. As a direct and proximate result of Defendants' failure to warn, Mr. Racine suffered injuries and damages as detailed in this Complaint.

COUNT 5: BREACH OF EXPRESS WARRANTY

78. The previous paragraphs are included as if specifically stated herein.

79. Defendants expressly represented to Mr. Racine and his medical providers that the Physiomesh was safe and fit for its intended purposes, that it was of merchantable quality, that it did not produce any dangerous side effects, and that it was adequately tested.

80. The Physiomesh does not conform to Defendants' express representations because it is not safe, has numerous and serious side effects, and causes severe and permanent injuries, including but not limited to the risk of bowel adhesions, diminished bowel motility, bowel obstructions, chronic abdominal pain, and a high rate of corrective surgeries required to treat Physiomesh related complications.

81. At all relevant times, the Physiomesh did not perform as safely as an ordinary consumer would expect, when used as intended or in a reasonably foreseeable manner.

82. Mr. Racine and other consumers relied upon Defendants' express warranties.

83. As a direct and proximate result of Defendants' breach of express warranty, Mr. Racine suffered injuries and damages as detailed in this Complaint.

COUNT 6: BREACH OF IMPLIED WARRANTY

84. The previous paragraphs are included as if specifically stated herein.

85. Defendants designed, manufactured, tested, trained, marketed, promoted, packaged, labeled, and/or sold the Physiomesh.

86. At all relevant times, Defendants knew of the use for which the Physiomesh was intended and impliedly warranted the Physiomesh to be of merchantable quality and safe and fit for such use.

87. Defendants were aware that consumers, including Mr. Racine would use the Physiomesh for the treatment and repair of inguinal and incisional hernias.

88. Mr. Racine and other consumers reasonably relied upon the judgment and sensibility of Defendants to sell the Physiomesh only if was indeed of merchantable quality and safe and fit for its intended use.

89. Defendants breached their implied warranty to consumers, including Mr. Racine; the Physiomesh was not of merchantable quality or safe and fit for its intended use.

90. Consumers, including Mr. Racine, reasonably relied upon Defendants' implied warranty for the Physiomesh.

91. The Physiomesh reached consumers without substantial change in the condition in which it was designed, manufactured, tested, trained, marketed, promoted, packaged, labeled, and/or sold by Defendants.

92. As a direct and proximate result of Defendants' breach of implied warranty, Mr. Racine suffered injuries and damages as detailed in this Complaint.

COUNT 7: NEGLIGENCE

93. The previous paragraphs are included as if specifically stated herein.

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

95. Defendants knew, or in the exercise of reasonable care should have known, that Physiomesh was defectively and unreasonably designed and/or manufactured, and was unreasonably dangerous and likely to injure patients in whom Physiomesh was implanted. Defendants knew or should have known that Mr. Racine was unaware of the dangers and defects inherent in the Physiomesh.

96. 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 Physiomesh, Mr. Racine suffered injuries and damages as summarized herein.

COUNT 8: NEGLIGENT MISREPRESENTATION

97. The previous paragraphs are included as if specifically stated herein.

98. Defendants designed, manufactured, marketed, inspected, labeled, promoted, distributed and sold the Physiomesh that was implanted in Mr. Racine in March of 2014.

99. Prior to, on, and after the dates during which Mr. Racine was implanted with the Physiomesh, Defendants negligently and carelessly represented to Mr. Racine, Mr. Racine's treating physicians, and the general public that Physiomesh was safe, fit, and effective for use.

100. These representations were untrue.

101. Defendants owed a duty in all of its undertakings, including the dissemination of information concerning its Physiomesh, to exercise reasonable care to ensure that it did not in those undertakings create unreasonable risks of personal injury to others, such as Mr. Racine.

102. Defendants disseminated to health care professionals and consumers through published labels, labeling, marketing materials, and otherwise information concerning the properties and effects of Physiomesh, with the intention that health care professionals and consumers would rely upon that information in their decisions concerning whether to prescribe and use the Physiomesh.

103. Defendants, as medical device designers, manufacturers, sellers, promoters and/or distributors, knew or should reasonably have known that health care professionals and consumers, in weighing the potential benefits and potential risks of prescribing or using the Physiomesh, would rely upon information disseminated and marketed by Defendants to them regarding the Physiomesh.

104. Defendants failed to exercise reasonable care to ensure that the information they disseminated to health care professionals and consumers concerning the properties and effects of Physiomesh, was accurate, complete, and not misleading and, as a result, disseminated information to health care professionals and consumers that was negligently and materially inaccurate, misleading, false, and unreasonably dangerous to consumers such as Mr. Racine and Mr. Racine's physicians.

105. Defendants, as designers, manufacturers, sellers, promoters, and/or distributors, also knew or reasonably should have known that patients, such as Mr. Racine, receiving Physiomesh, as recommended by health care professionals in reliance upon information

disseminated by Defendants as the manufacturer/distributor of Physiomesh would be placed in peril of developing the serious, life-threatening, and life-long injuries including, but not limited to, pain, immunologic response, dehiscence, encapsulation, rejection, migration, scarification, shrinkage/contraction, adhesion to internal organs and viscera, erosion through adjacent tissue and viscera, bowel obstruction, failure of repair/hernia recurrence, or hernia incarceration or strangulation, if the information disseminated and relied upon was materially inaccurate, misleading, or otherwise false.

106. Defendants had a duty to promptly correct material misstatements it knew others were relying upon in making healthcare decisions.

107. Defendants failed in each of these duties by misrepresenting to Mr. Racine, Mr. Racine's physicians, and the entire medical community the safety and efficacy of Physiomesh, and failing to correct known misstatements and misrepresentations.

108. As a direct and proximate result of Defendants' negligent misrepresentations, Mr. Racine suffered injuries and damages as detailed in this Complaint.

COUNT 9: NEGLIGENCE *PER SE*

(Violations of 21 U.S.C. §§321, 331, 352 and 21 C.F.R. §§1.21, 801, 803, 807, 820) 246.

109. The previous paragraphs are included as if specifically stated herein.

110. At all times herein mentioned, Defendants were subject to a variety of federal, state, and local laws, rules, regulations and ordinances, including the Federal Food, Drug and Cosmetic Act ("FFDCA") and its applicable regulations, concerning the manufacture, design, testing, production, processing, assembling, inspection, research, promotion, advertising, distribution, marketing, promotion, labeling, packaging, preparation for use,

consulting, sale, warning, and post-sale warning and other communications of the risks and dangers of Physiomesh.

111. By reason of its conduct as alleged herein, Defendants violated provisions of statutes and regulations, including but not limited to:

a. FFDCA, 21 U.S.C. §§331 and 352, by misbranding the Physiomesh;

b. FFDCA, 21 U.S.C. § 321, by making statements and/or representations via word, design, device, or any combination thereof failing to reveal material facts with respect to the consequences that may result from the use of Physiomesh, to which the labeling and advertising relates;

c. 21 C.F.R. § 1.21, by misleading its consumers and patients by concealing material facts in light of representations made regarding safety and efficacy of its Physiomesh;

d. 21 C.F.R. § 801, by mislabeling Physiomesh, as to safety and effectiveness of its products and by failing to update its label to reflect post-marketing evidence that the Physiomesh was associated with an increased risk of injuries due to adhesion, bowel perforation or erosion, fistula formation and bowel strangulation or hernia incarceration, and other injuries;

e. 21 C.F.R. §§801.109 and 801.4 by learning that Physiomesh was adulterated and misbranded and failing to correct and recall the devices;

f. 21 C.F.R. § 803, by not maintaining accurate medical device reports regarding adverse events of adhesion, bowel perforation or erosion, fistula formation and bowel strangulation or hernia incarceration, and other injuries and/or misreporting these adverse events maintained via the medical device reporting system;

g. 21 C.F.R. § 807, by failing to notify the FDA and/or the consuming public when its Physiomesh was no longer substantially equivalent with regard to safety and efficacy with regard to post-marketing adverse events and safety signals;

h. 21 C.F.R. § 820, by failing to maintain adequate quality systems regulation including, but not limited to, instituting effective corrective and preventative actions;

i. 21 CFR 201.128, by promoting each of their subject devices, including Physiomesh, off-label and for conditions, purposes and uses beyond their labeled and intended uses; and

j. 210 CFR 801.4, by their knowledge of off-label uses of their devices, including Physiomesh, for unintended and unlabeled conditions, purposes and uses, and failing as required to provide adequate labeling which accords with such unlabeled and unintended uses.

112. These statutes, rules and regulations, along with those listed in Count 12, are designed to protect the health, safety, and well-being of consumers like Mr. Racine.

113. Defendants' violation of these statutes, rules and regulations, as well as those detailed in Count 12, constitutes negligence *per se*.

114. As a direct and proximate result of Defendants' negligence *per se*, Mr. Racine suffered injuries and damages as detailed in this Complaint.

COUNT 10: FRAUDULENT MISREPRESENTATION

115. The previous paragraphs are included as if specifically stated herein.

116. At all times relevant to this cause, and as detailed above, Defendants intentionally provided Mr. Racine, Mr. Racine's physicians, the medical community, and the public at

large with false or inaccurate information. Defendants also omitted and misrepresented material information concerning Physiomesh, including but not limited to the following topics:

a. The safety of Physiomesh;

b. The efficacy of the Physiomesh;

c. The rate of failure of the Physiomesh;

d. The pre-market testing of Physiomesh;

e. The approved uses of the Physiomesh; and

f. The ability to retrieve the device at any time over a person's life.

117. The information Defendants distributed to the public, the medical community, and Mr. Racine was in the form of reports, press releases, advertising campaigns, labeling materials, print advertisements, commercial media containing material representations, and instructions for use, as well as through their officers, directors, agents, and representatives.

118. These materials contained false and misleading material representations, which included: that Physiomesh, was safe and fit when used for its intended purpose or in a reasonably foreseeable manner; that it did not pose dangerous health risks in excess of those associated with the use of other similar hernia mesh; that any and all side effects were accurately reflected in the warnings; and that it was adequately tested to withstand normal placement within the human body.

119. Defendants made the foregoing misrepresentations knowing that they were false or without reasonable basis. These materials included instructions for use and a warning document that was included in the package of the Physiomesh implanted in Mr. Racine.

120. Defendants' intent and purpose in making these misrepresentations was to deceive and defraud the public and the medical community, including Mr. Racine's health care providers; to gain the confidence of the public and the medical community, including Mr. Racine's health care providers; to falsely assure the public and the medical community of the quality of Physiomesh, and their fitness for use; and to induce the public and the medical community, including Mr. Racine's healthcare providers, to request, recommend, prescribe, implant, purchase, and continue to use Physiomesh, all in reliance on Defendants' misrepresentations.

121. The foregoing representations and omissions by Defendants were false.

122. Physiomesh, is not safe, fit, and effective for human use in its intended and reasonably foreseeable manner.

123. Further, the use of Physiomesh, is hazardous to the users' health, and this mesh has a serious propensity to cause users to suffer serious injuries, including without limitation the injuries Mr. Racine suffered.

124. Finally, Physiomesh, have a statistically significant higher rate of failure and injury than does other comparable hernia mesh.

125. In reliance upon the false and negligent misrepresentations and omissions made by Defendants, Mr. Racine and Mr. Racine's health care providers were induced to, and did, use the Physiomesh, thereby causing Mr. Racine to sustain severe and permanent personal injuries.

126. Defendants knew and had reason to know that Mr. Racine, Mr. Racine's health care providers, and the general medical community did not have the ability to determine the true facts intentionally and/or negligently concealed and misrepresented by Defendants,

and would not have prescribed and implanted the Physiomesh if the true facts regarding that filter had not been concealed and misrepresented by Defendants.

127. Defendants had sole access to material facts concerning the defective nature of the products and their propensities to cause serious and dangerous side effects in the form of dangerous injuries and damages to persons who were implanted with Physiomesh.

128. At the time Defendants failed to disclose and intentionally misrepresented the foregoing facts, and at the time Mr. Racine used the Physiomesh, Mr. Racine and Mr. Racine's health care providers were unaware of Defendants' misrepresentations and omissions.

129. As a direct and proximate result of Defendants' fraudulent misrepresentations, Mr. Racine suffered injuries and damages as detailed in this Complaint.

COUNT 11: FRAUDULENT CONCEALMENT

130. The previous paragraphs are included as if specifically stated herein.

131. In marketing and selling Physiomesh, Defendants concealed material facts from Mr. Racine and Mr. Racine's healthcare providers.

132. These concealed material facts include, but are not limited to:

a. Physiomesh was unsafe and not fit when used for its intended purpose or in a reasonably foreseeable manner;

b. Physiomesh posed dangerous health risks in excess of those associated with the use of other similar hernia meshes;

c. That there were additional side effects related to implantation and use of Physiomesh, that were not accurately and completely reflected in the warnings associated with those filters; and

d. That Physiomesh was not adequately tested to withstand normal placement within the human body.

133. Mr. Racine and Mr. Racine's healthcare providers were not aware of these and other facts concealed by Defendants.

134. In concealing these and other facts, Defendants intended to deceive Mr. Racine and Mr. Racine's healthcare providers.

135. Mr. Racine and Mr. Racine's healthcare providers were ignorant of and could not reasonably discover the facts Defendants fraudulently concealed, and reasonably and justifiably relied on Defendants' representations concerning the supposed safety and efficacy of the Physiomesh.

136. As a direct and proximate result of Defendants' fraudulent concealment of material facts, Mr. Racine suffered injuries and damages as detailed in this Complaint.

COUNT 12: VIOLATIONS OF MARYLAND CONSUMER PROTECTION ACT ("MCPA")

(Maryland Code: Commercial Law – Title 13)

137. The previous paragraphs are included as if specifically stated herein.

138. Defendants had a statutory duty to refrain from unfair or deceptive acts or practices in the sale and promotion of Physiomesh.

139. Defendants knowingly, deliberately, willfully and/or wantonly engaged in unfair, unconscionable, deceptive, fraudulent, and misleading acts or practices in violation of the MCPA.

140. Through its false, untrue, and misleading promotion of Physiomesh, Defendants induced Mr. Racine to purchase and/or pay for the purchase of the Physiomesh.

141. Defendants misrepresented the alleged benefits and characteristics of Physiomesh; suppressed, omitted, concealed, and failed to disclose material information concerning known adverse effects of Physiomesh; misrepresented the quality and efficacy of Physiomesh, as compared to much lower-cost alternatives; misrepresented and advertised that Physiomesh, was of a particular standard, quality, or grade that it was not; misrepresented Physiomesh, in such a manner that later, on disclosure of the true facts, there was a likelihood that Mr. Racine and Mr. Racine's physicians would have opted for an alternative mesh or method of repairing the hernia.

142. Defendants' conduct created a likelihood of, and in fact caused, confusion and misunderstanding.

143. Defendants' conduct misled, deceived, and damaged Mr. Racine, and Defendants' fraudulent, misleading, and deceptive conduct was perpetrated with an intent that Mr. Racine rely on said conduct by purchasing and/or paying for the Physiomesh.

144. Moreover, Defendants knowingly took advantage of Mr. Racine, who was unable to protect his own interests due to ignorance of the harmful adverse effects of Physiomesh.

145. Defendants' conduct was willful, outrageous, immoral, unethical, oppressive, unscrupulous, unconscionable, and substantially injurious to Mr. Racine, and offends the public conscience.

146. Mr. Racine purchased the Physiomesh primarily for personal, family, or household purposes.

147. As a result of Defendants violative conduct, Mr. Racine purchased and/or paid for the Physiomesh, which purchase was not made for resale.

148. Defendants engaged in unfair competition or deceptive acts or practices in violation of the MCPA.

149. As a direct and proximate result of Defendants violations of these statutes, Mr. Racine suffered injuries and damages as detailed in this Complaint, and seeks all available damages under the MCPA.

COUNT 13: PUNITIVE DAMAGES

150. The previous paragraphs are included as if specifically stated herein.

151. Defendants' intentional and/or reckless failure to disclose information deprived Mr. Racine's physicians of necessary information to enable them to weigh the true risks of using the Physiomesh against its benefits.

152. Defendants' conduct is reprehensible; evidencing an evil hand guided by an evil mind, and actual malice with a sense of conscious and deliberate wrongdoing, evil and wrongful motive with an intent to defraud and injure with ill will to its potential customers, and was undertaken for pecuniary gain in reckless and conscious disregard for the substantial risk of death and physical injury to consumers, including Mr. Racine.

153. Defendants continued to manufacture and sell Physiomesh after obtaining knowledge and information that the product was defective and unreasonably unsafe. Defendants were aware of the probable consequences of implantation of the dangerous and defective Physiomesh, including the risk of failure and serious injury, such as suffered by Mr. Racine. Defendants willfully and deliberately failed to avoid those consequences, and in doing so, Defendants acted with conscious indifference, indifference to, and/or flagrant disregard of, the safety of those persons who might foreseeably have been harmed by the Physiomesh product, including Mr. Racine, justifying the imposition of punitive

damages.

154. Such conduct justifies an award of punitive or exemplary damages in an amount sufficient to punish Defendants' conduct and deter like conduct by Defendants and other similarly situated persons and entities in the future.

WHEREFORE, Plaintiff, Charles Racine, demands judgment against Defendants, Ethicon, Inc. and Johnson & Johnson, in an amount in excess of $75,000, plus interest, costs, and any and all other relief to which this Court finds him entitled.

Respectfully submitted,

_____/s/_____
Michael Paul Smith, Esq. #23685
Eugene A. Arbaugh, Jr., Esq. #25927
Smith, Gildea & Schmidt, LLC
600 Washington Ave, Suite 200
Towson, Maryland 21204
(410) 821-0070 (telephone)
(410) 821-0071 (facsimile)
Email: mpsmith@sgs-law.com
Email: earbaugh@sgs-law.com
Attorneys for Plaintiff

PRAYER FOR JURY TRIAL

Plaintiff, Charles Racine, hereby requests a trial by jury on the foregoing Complaint.

_____/s/_____
Michael Paul Smith, Esq. #23685
Eugene A. Arbaugh, Jr., Esq. #25927
Smith, Gildea & Schmidt, LLC
600 Washington Ave, Suite 200
Towson, Maryland 21204
(410) 821-0070 (telephone)
(410) 821-0071 (facsimile)
Email: mpsmith@sgs-law.com
Email: earbaugh@sgs-law.com
Attorneys for Plaintiff

JS 44 (Rev. 07/16)

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
Charles Racine

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

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Michael Paul Smith, Esquire
Smith, Gildea & Schmidt, LLC
600 Washington Ave, Suite 200, Towson, MD 21204

DEFENDANTS
Ethicon, Inc. and Johnson & Johnson

County of Residence of First Listed Defendant Somerset County
(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)*:
MD Code, Courts and Judicial Proceedings, § 6-103(b)
Brief description of cause:
Negligent design, manufacture, marketing, packaging, and labeling of a medical device known as Physiomesh.

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 04/13/2017

SIGNATURE OF ATTORNEY OF RECORD Michael P. Smith

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. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of Maryland

Charles Racine

Plaintiff(s)

v.

Ethicon, Inc. and Johnson & Johnson

Defendant(s)

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Ethicon, Inc.
Serve on: Johnson & Johnson
Resident Agent
One Johnson & Johnson Plaza
New Brunswick, NJ 8933

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: Michael Paul Smith, Esquire
Eugene A. Arbaugh, Jr., Esquire
Smith, Gildea & Schmidt, LLC
600 Washington Avenue, Ste. 200
Towson, MD 21204

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: 04/13/2017

Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____ was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

Print Save As... Reset

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of Maryland

Charles Racine

Plaintiff(s)

v.

Ethicon, Inc. and Johnson & Johnson

Defendant(s)

Civil Action No.

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Serve on: Johnson & Johnson
Resident Agent
One Johnson & Johnson Plaza
New Brunswick, NJ 8933

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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: Michael Paul Smith, Esquire
Eugene A. Arbaugh, Jr., Esquire
Smith, Gildea & Schmidt, LLC
600 Washington Avenue, Ste. 200
Towson, MD 21204

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: 04/13/2017

Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____ was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

Print Save As... Reset