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SUPERIOR COURT OF NEW JERSEY
LAW DIVISION: BERGEN COUNTY

CIVIL ACTION

[redacted]

Plaintiff,

v.

HOWMEDICA OSTEONICS CORP.
a New Jersey Corporation d/b/a
STRYKER ORTHOPAEDICS,

Defendant.

DOCKET NO.: L-6062-15

JURY TRIAL DEMANDED

COMPLAINT FOR DAMAGES AND DEMAND FOR JURY TRIAL

Plaintiff, [redacted] for her Complaint against Defendant, HOWMEDICA OSTEONICS CORP, d/b/a STRYKER ORTHOPAEDICS, alleges and states as follows:

PARTIES, VENUE AND JURISDICTION

1. At all times relevant to this Complaint, Plaintiff was and is a Washington, DC resident.

2. At all times relevant to this Complaint, Defendant HOWMEDICA OSTEONICS CORP. a New Jersey Corporation d/b/a STRYKER ORTHOPAEDICS (hereafter "Stryker" or "Defendant") was and is a New Jersey corporation with its principal place of business at 325 Corporate Drive, Mahwah, New Jersey 07430, in Bergen County, New Jersey, and as such is a citizen of the State of New Jersey.

3. Venue is proper in Bergen County in that at present and at all times relevant to this action the primary residence of Defendant was in Bergen County, New Jersey.

GENERAL ALLEGATIONS

TOTAL HIP ARTHROPLASTY

4. Total Hip Arthroplasty (hereafter "THA") is the term used to describe surgery wherein a patient's natural hip anatomy is replaced with synthetic components. THA is also commonly referred to as "hip replacement surgery." A patient may need a THA for a variety of medical reasons including degenerative bone disease and avascular necrosis.

5. The process involves traumatic surgery in which a surgeon saws and removes a considerable portion of bone, including the ball, from the top of the femur. In place of the removed bone, the surgeon places a metal shaft, called a "stem", down into what remains of the femoral bone. The portion of the stem, which is housed inside the femur, may be affixed to the bone via use of bone cement or by a porous coating on the synthetic surface into which the natural bone will grow. The top of the synthetic metal stem, referred to as the "neck", is not housed inside the femur and remains completely exposed inside the body. A synthetic ball, whether made of metal, plastic, or ceramic, is then attached to the neck of the synthetic stem.

6. The surgeon also replaces the anatomical hip socket, the acetabulum, with an artificial "cup" against which the new, synthetic ball articulates. In order to do so, the surgeon removes bone from the natural acetabulum until it is large enough to house a synthetic cup. The surgeon then places a synthetic cup into the hip socket. The cup affixes to the bone either through the use of bone cement or through the use of a porous metal coating on the back of the cup into which the natural bone will grow.

7. A successful THA results in a hip prosthesis that should last 20+ years in a patient.

8. If a hip prosthesis fails in a patient, the patient's surgeon may recommend a "revision" THA procedure in order to replace the failed hip components.

9. A revision THA is extremely traumatic to a patient, multitudes more so than a primary THA. The surgery is typically much longer, with greater blood loss, greater surgeon difficulty, and greater mortality rate. Further, the rehabilitation period for a revision THA is much longer.

10. In most revision THA procedures, the synthetic components that must be replaced are either the acetabular cup or the femoral ball or both.

11. In a smaller number of THA procedures, a surgeon may find it necessary to replace a femoral stem, as well.

12. The revision of a femoral stem is even more traumatic to a patient than the revision of an acetabular cup and/or ball. Typically, a patient's femur fuses with the synthetic stem embedded inside. In order to remove the synthetic stem, the surgeon must create a large incision down the patient's thigh, then cut and remove large section of the femoral bone to get access to the femoral implant. This process of removing the bone around the implant can be likened to peeling a banana. What is more, the process of separating the stem from bone is made more difficult because the two are likely fused together. Once the surgeon is able to access, remove, and replace the failed stem, the process of securing the new stem in place results in the use of a multitude of screws and metal wires to clamp the bone shut around the new implant. An

x-ray of a revised femoral implant can sometimes resemble barbed wire surrounding the bone. A patient's recovery from stem revision surgery is prolonged and painful.

STRYKER HIP SYSTEM

13. Defendant designs and manufactures various medical devices and implants.

14. According to Stryker's website[1],

> Stryker is one of the world's leading medical technology companies and is dedicated to helping healthcare professionals perform their jobs more efficiently while enhancing patient care. The Company offers a diverse array of innovative medical technologies, including reconstructive, medical and surgical, and neurotechnology and spine products to help people lead more active and more satisfying lives.

15. Further, Stryker's website[2] also claims,

> Stryker is the worldwide market leader in Total Hip Replacement products. The Company has achieved this position through innovation and by meeting requirements for hip arthroplasty products that help restore patients to normal daily activities.

16. Regarding femoral components of a primary total hip arthroplasty procedure, Stryker's website[3] claims,

> Building on over 30 years of clinical experience, Stryker Orthopaedics offers a wide range of primary femoral hip components designed to meet the needs of surgeons and patients. Time-tested design principles support our press-fit and cemented hip stem solutions. Additionally, Stryker Orthopaedics instrumentation platforms provide the orthopaedic surgeon flexibility to choose from many implant options, helping them to intraoperatively select the best implant for each patient.

17. In March of 2000, Defendant received FDA clearance to sell its Accolade hip system in the United States.

18. The Accolade stem is a monoblock, single piece artificial replacement that is designed to be implanted in the patient's femur.

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[1] http://www.stryker.com/en-us/corporate/AboutUs/index.htm; Accessed on April 25, 2013.
[2] http://www.stryker.com/en-us/products/Orthopaedics/HipReplacement/index.htm; Accessed on April 25, 2013.
[3] http://www.stryker.com/en-us/products/Orthopaedics/HipReplacement/Primary/index.htm; Accessed on April 25, 2013.

19. The Accolade stem is manufactured utilizing a proprietary titanium alloy consisting of titanium, molybdenum, zinc and iron ("TMZF")

20. Defendant marketed and promoted the Accolade stem as being stronger and less rigid than other titanium products on the market.

21. Defendant claimed and represented to orthopedic surgeons that the TMZF alloy had been tested and proven to resist the effects of corrosion and fretting.

22. Defendant further claimed the Accolade stem maximized a patient's hip range of motion, increased stability, and prevented dislocation.

23. Defendant's promotional materials stated the Accolade stem was designed to be utilized with LFIT Anatomic V40 formal heads.

24. The LFIT Anatomic V40 femoral head is made from a cobalt/chromium alloy.

25. Defendant claimed that laboratory testing of these materials demonstrated their compatibility without concern for corrosion or fretting.

26. Defendant utilized print, television, internet, and e-mail marketing to disseminate information promoting the purported advantages of the Accolade System.

27. This information was targeted to surgeons as agents of patients in order to convince surgeons, including Plaintiff's surgeon, to recommend the implant of the Accolade.

28. Upon information and belief, Defendant utilized educational programs via print, television, internet, e-mail, workshops (both in-person and online), and personal visits in order to educate surgeons, including Plaintiff's surgeon, on how to correctly implant the Accolade.

29. Upon information and belief, Defendant utilized sales agents to facilitate the marketing, sales, and education process. These agents were sometimes employees of Stryker but could also be independent contractors, as well.

30. These sales agents were responsible for answering any questions or concerns surgeons, including Plaintiff's surgeon, had regarding the Accolade.

31. At all times relevant to this Complaint, Plaintiff's orthopedic surgeon, nurses, and hospital staff relied on information and assistance given by Defendant and its sales agents.

RECALL OF THE STRYKER REJUVENATE HIP SYSTEM

32. In 2012, Defendant recalled its Rejuvenate and ABG II modular hip systems.

33. The Rejuvenate and ABG II modular hip systems utilized the same TMZF alloy in the femoral stem as the Accolade.

34. Similar to the Accolade, the modular neck of the Rejuvenate and ABG II was manufactured from cobalt/chromium.

35. Patients of the Rejuvenate and ABG II experienced failures of the devices, including but not limited to, reports of severe pain, metallosis, pseudotumors, loosening, and tissue destruction.

36. Upon information and belief, Defendant recalled the Rejuvenate and ABG II because of these reports and failures.

37. Upon information and belief, the revision rates for the Rejuvenate and ABG II have been reported to exceed 50%.

38. The scientific community has known for decades that the combination of titanium and cobalt/chromium results in significant fretting and corrosion when dissimilar metals are combined.

39. Upon information and belief, prior to Plaintiff's implant and revision surgery, Defendant was aware of problems and defects with the Accolade, including, but not limited to, fretting and corrosion.

40. Prior to marketing and selling the Accolade, Defendant was aware that no published research provided clinical support for its claim that "Laboratory testing demonstrates the compatibility of these materials without concern for fretting and corrosion."

41. Prior to marketing and selling the Accolade, the Rejuvenate and the ABG II, Defendant knew or should have known that the laboratory testing it claimed demonstrated the compatibility of titanium and cobalt/chromium was incomplete, inconclusive, incorrect, and/or irrelevant when judging the *clinical* safety and effectiveness of the hip systems.

42. Prior to marketing and selling the Accolade, Defendant knew or should have known that the Accolade was not a clinically safe hip prosthesis.

43. During the marketing and sale of the Accolade, Defendant knew or should have known that the Accolade was not a clinically safe hip prosthesis.

44. After Defendant began marketing and selling the Accolade, the Rejuvenate, and the ABG II, Defendant quickly began receiving a high number of reports and warnings from surgeons regarding failed Accolade, Rejuvenate and ABG II hip systems.

45. Defendant did not take proper action in response to surgeons' reports and warnings.

46. Despite knowing, or being in a position where it should have known of the unreasonable risks associated with the Accolade, Defendant continued to market and sell the Accolade System.

47. On June 29 2012, Defendant finally recalled the Rejuvenate and ABG II Systems.

48. According to Defendant the recall was due to the increased likelihood of adverse local tissue reactions (hereafter "ALTR") caused by fretting and corrosion around the tapered neck junction of the modular stem and neck.

49. After recalling the Rejuvenate and ABG II Systems, Defendant sponsored a manuscript titled, "Evaluation of painful total hip replacements / modular metal taper junctions."

50. The purported intent of this manuscript, available on Defendant's website, "is to discuss the clinical presentation, evaluation and workup of patients who present with persistent pain and symptoms after successful total hip arthroplasty with a metal taper junction suspected of fretting and/or corrosion."

51. This admission is in stark contrast to the marketing of the Accolade, which stated that the TMZF stem was compatible with a cobalt/chromium head "without concern for fretting and corrosion."

52. At the time Defendant recalled the Rejuvenate and ABG II, it redesigned the Accolade stem and abandoned the use of TMZF and switched to a new titanium alloy.

53. Upon information and belief, Defendant abandoned its use of TMZF throughout its product lines.

THE EFFECT OF IMPLANT FRETTING AND CORROSION ON THE HUMAN BODY

54. Patients with fretting and corrosion of the hip prosthesis typically present with symptoms of pain located in the anterior, lateral or posterior aspect of the hip.

55. These patients may or may not have pain at rest, but more consistently have pain with weight-bearing, motion, and loading of the hip joint on physical examination.

56. Fretting and corrosion may result in metal wear being released into the patient's body, both locally in the hip and systemically to other regions of the body.

57. The resulting metal wear may result in the formation of pseudotumors, tissue necrosis, osteolysis, aseptic loosening of the acetabular component, and various systemic medical issues including cancer, autoimmune disorders, and visual/auditory disruptions, among many others.

58. One of the main effects of the metal wear debris associated with corrosion and fretting is Adverse Local Tissue Reaction, or ALTR. This reaction may include tissue death, inflammation and infection and may occur in the peri-articular capsule, the abductor musculature, and tendinous insertion onto the greater trochanter, as well as other areas in the hip region.

59. The longer the source of metal debris is present in the patient's body, the worse the soft tissue damage may be.

60. Evidence of fretting and corrosion of the modular taper junction is visualized by irregular black material on the surface of the metal contained within the junction. Further, the black material is typically associated with surface irregularities on the metal taper surface in contact with the opposite metal surface, consistent with crevice corrosion.

61. ALTR may also create a substantial amount of intra-articular joint fluid, sometimes reported to be a brownish or grey color with a turbid consistency.

62. Patients displaying pain, elevated metal levels, and evidence of the conditions listed above will likely need a revision THA.

PLAINTIFF'S IMPLANT AND REVISION

63. Plaintiff experienced a history of pain in her left hip that caused her to be treated by Dr. Philip Bobrow M.D. (hereafter "Dr. Bobrow").

64. Dr. Bobrow determined Plaintiff needed a THA of the left hip.

65. On April 30, 2009, Dr. Bobrow performed a THA on Plaintiff's left hip at Sibley Memorial Hospital in Washington, DC.

66. During this THA, Dr. Bobrow implanted Plaintiff with a number of hip implant components designed and manufactured by Defendant.

67. One of these components was the Accolade TMZF Stem, Reference Number 6020-0335, Lot Number 27928503.

68. Another of these components was a Femoral Head, Reference Number 6260-9-036, with Lot Number MHETNT.

69. In preparation for the April 30, 2009 surgery, Dr. Bobrow or someone at his direction contacted Defendant or an agent and/or employee of Defendant, to notify it of the need for the Stryker hip system components, including the Accolade System.

70. Defendant or Defendant's agent and/or employees selected and provided the specific Accolade products manufactured by Defendant and delivered them to the operating room at Sibley Memorial Hospital.

71. Defendant utilized sales representatives who were responsible for educating Plaintiff's orthopedic surgeon regarding the claimed advantages of the products used, answering any questions Plaintiff's orthopedic surgeon asked regarding the products, assisting Plaintiff's orthopedic surgeon at surgery regarding the products, and selling the products to Plaintiff through her orthopedic surgeon-agent.

72. Defendant trained and educated its sales staff regarding the Accolade System by providing orthopedic and surgical training, product design rationale, surgical technique tips, training in the use of implanting tools, training in selecting the hip replacement components to mate with the Accolade System, and training in how to sell the product to orthopedic surgeons, including training on the advantage of the Accolade System over its competitors.

73. Prior to Plaintiff's THA surgery, sales representatives of Defendant provided information to Plaintiff's orthopedic surgeon, including but not limited to, the advantages of the Accolade System compared to its competitors, information regarding the design rationale for the Accolade System, surgical techniques on how to implant the Accolade System, and demonstrations on how to implant the Accolade System and the components that could best be mated with the Accolade System, including providing a variety of scenarios involving the various instrumentation used in implanting the Accolade System.

74. Defendant's sales representatives were responsible for answering any questions or concerns Plaintiff's orthopedic surgeon had regarding the Accolade System.

75. The above information was provided by Defendant's sales representatives to Plaintiff's orthopedic surgeon and was intended for the purpose of convincing and inducing Plaintiff's orthopedic surgeon to use the Accolade System instead of one of the competing hip replacements.

76. At all times relevant to this complaint, Plaintiff's orthopedic surgeon, nurses and hospital staff relied on information and assistance from Defendant and its sales representatives.

77. After being implanted with the Accolade System, Plaintiff experienced significant pain in her left hip and sought follow-up treatment with Dr. Bobrow.

78. Plaintiff had recurrent dislocation of the left hip and metallosis.

79. Thereafter, Dr. Bobrow recommended surgery to replace the failing Accolade Hip components in Plaintiff's left hip.

80. On March 3, 2014, Plaintiff underwent a revision surgery on her left hip, performed by Dr. Bobrow at Sibley Memorial Hospital.

81. During the revision surgery, Dr. Bobrow noted **extensive damage to Plaintiff's hip**, stating in part:

> "There was clear metallosis around the base of the metal head on the trunnion. Using***the head was removed and some black material was encountered from around the trunnion..."

82. Upon information and belief, the aforementioned defects caused Plaintiff's Accolade System to fail prematurely and necessitated revision surgery.

83. The Accolade System was more dangerous than an ordinary consumer would reasonably expect, and the risks associated with it were more dangerous than the risks associated with other hip replacement devices available to treat Plaintiff's condition.

84. Plaintiff suffered injuries as a result of the negligent design, manufacture, marketing and distribution of the Accolade System and component parts.

85. As a direct and proximate result of Defendant's failed Accolade System, Plaintiff was caused to incur medical expenses, and expects to incur additional medical expenses in the future.

86. Plaintiff also suffered personal injuries, including experiencing great pain and suffering as a result of the defective Accolade System.

87. As a further direct and proximate result of the failed Accolade System, Plaintiff experienced emotional trauma and distress, and is likely to experience emotional trauma and distress in the future.

88. The conduct of Defendant as set forth herein was outrageous, reckless and showed a conscious disregard or indifference to Plaintiff and/or others, entitling Plaintiff to an award of punitive damages to punish and deter Defendant from similar future conduct.

COUNT I
STRICT LIABILITY – DESIGN DEFECT

89. Plaintiff re-alleges and incorporates by reference all paragraphs above as if fully set forth herein.

90. Defendant designed, manufactured, marketed, advertised, and sold the defective product at issue, and provided training materials to sales agents and surgeons on properly selecting and implanting the defective product.

91. The product was unreasonably dangerous as designed.

92. Defendant knew or should have known that unless the devices were carefully and properly designed, manufactured, promoted, marketed, distributed, supplied, sold and serviced, they would constitute an unreasonable risk of substantial bodily harm to those who used them for the purposes for which they were made and intended.

93. The product's known risks clearly outweighed the purported advantages, especially in light of the fact that the purported advantages were not clinically proven.

94. Defendant has admitted that prior to the design, marketing, advertising, and sale of the product, multiple safer alternatives existed, such as a ceramic-metal junction instead of a metal-metal junction.

95. Defendant acted in an unreasonable manner in designing the Accolade System.

96. There was no substantial change in the condition of the product from the time it left Defendant's possession to the time it was sold to and implanted in Plaintiff.

97. As designed, manufactured, promoted, marketed, distributed, supplied, sold and serviced, the Accolade System was unreasonably dangerous to anyone who might use it for the purposes for which it was intended and was, in fact, defective, unfit, dangerous, unsafe, unsuitable, and dangerous for placement in Plaintiff's body.

98. At the time and on the occasion in question, the devices were being properly used for the purpose for which they were intended, but were in fact defective, unsafe, and unreasonably dangerous.

99. The risks posed to Plaintiff by the Accolade System were known or knowable by Defendant given the generally recognized and prevailing scientific and medical knowledge at the time of its manufacture and distribution.

100. As a direct and proximate result of the aforementioned risks, dangers, and defects, Plaintiff was caused to suffer damages, as set forth in Paragraphs 84 through 88 above and incorporated herein by reference.

COUNT II
STRICT LIABILITY – MANUFACTURING DEFECT

101. Plaintiff re-alleges and incorporates by reference paragraphs 1 through 88 above as if fully set forth herein.

102. Defendant designed, manufactured, marketed, advertised, and sold the defective product at issue, and provided training materials to sales agents and surgeons on properly selecting and implanting the defective product.

103. The product was unreasonably dangerous as manufactured.

104. Defendant knew or should have known that unless the devices were carefully and properly designed, manufactured, promoted, marketed, distributed, supplied, sold and serviced, they would constitute an unreasonable risk of substantial bodily harm to those who used them for the purposes for which they were made and intended.

105. Defendant acted in an unreasonable manner in manufacturing the Accolade System.

106. There was no substantial change in the condition of the product from the time it left Defendant's possession to the time it was sold to and implanted in Plaintiff.

107. As designed, manufactured, promoted, marketed, distributed, supplied, sold and serviced, the Accolade System was unreasonably dangerous to anyone who might use it for the purposes for which it was intended and was, in fact, defective, unfit, dangerous, unsafe, unsuitable, and dangerous for placement in Plaintiff's body.

108. At the time and on the occasion in question, the devices were being properly used for the purpose for which they were intended, but were in fact defective, unsafe, and unreasonably dangerous.

109. The risks posed to Plaintiff by the Accolade System were known or knowable by Defendant given the generally recognized and prevailing scientific and medical knowledge at the time of manufacture and distribution.

110. As a direct and proximate result of the aforementioned risks, dangers, and defects, Plaintiff was caused to suffer damages, as set forth in Paragraphs 84 through 88 above and incorporated herein by reference.

COUNT III
STRICT LIABILITY – FAILURE TO WARN

111. Plaintiff re-alleges and incorporates by reference paragraphs 1 through 88 above as if fully set forth herein.

112. Defendant designed, manufactured, marketed, advertised, and sold the defective product at issue, and provided training materials to sales agents and surgeons on properly selecting and implanting the defective product.

113. Defendant knew or should have known that unless the devices were carefully and properly designed, manufactured, promoted, marketed, distributed, supplied, sold and serviced, they would constitute an unreasonable risk of substantial bodily harm to those who used them for the purposes for which they were made and intended.

114. As designed, manufactured, promoted, marketed, distributed, supplied, sold and serviced, the Accolade System was unreasonably dangerous to anyone who might use it for the purposes for which it was intended and was, in fact, defective, unfit, dangerous, unsafe, unsuitable, and dangerous for placement in Plaintiff's body.

115. Defendant failed to warn Plaintiff of the unreasonable danger posed to Plaintiff by the Accolade System.

116. Defendant knew that Plaintiff, as an anticipated user of the product, would likely not know, and in fact did not know, of the danger posed by the device.

117. Defendant deliberately concealed or failed to disclose to Plaintiff, her surgeon, the public, and the FDA, knowledge of the dangers of the product Defendant acquired after the product was introduced for sale.

118. Defendant had a duty to warn Plaintiff of the dangers of the Accolade System before and after the sale and implant of the product in Plaintiff.

119. Defendant failed to fulfill its duty to warn Plaintiff of the dangers of the Accolade System.

120. Defendant further had a duty to warn Plaintiff, or plaintiff's surgeon, if any of Plaintiff's medical history or conditions were contraindications for the use and implant of the Accolade System.

121. Defendant failed to fulfill its duty to warn Plaintiff, or plaintiff's surgeon, if any of Plaintiff's medical history or conditions were contraindications for the use and implant of the Accolade System.

122. There was no substantial change in the condition of the product from the time it left Defendant's possession to the time it was sold to and implanted in Plaintiff.

123. At the time and on the occasion in question, the devices were being properly used for the purpose for which they were intended, but were in fact defective, unsafe, and unreasonably dangerous.

124. The risks posed to Plaintiff by the Accolade System were known or knowable by Defendant given the generally recognized and prevailing scientific and medical knowledge at the time of manufacture and distribution.

125. As a direct and proximate result of the aforementioned risks, dangers, and defects, Plaintiff was caused to suffer damages, as set forth in Paragraphs 84 through 88 above and incorporated herein by reference.

COUNT IV
NEGLIGENCE

126. Plaintiff re-alleges and incorporates by reference paragraphs 1 through 88 above as if fully set forth herein.

127. Defendant, in designing, manufacturing, marketing, selling, distributing, and servicing the Accolade System, had a duty to undertake these tasks in a reasonable manner.

128. Defendant owed a duty to provide reasonable warnings and accurate information to Plaintiff, her orthopedic surgeon, and the orthopedic community.

129. Defendant, in breach of the duties described above, negligently and carelessly designed, manufactured, marketed, sold, distributed, and serviced the Accolade System implanted in Plaintiff.

130. Defendant, in breach of the duties described above, provided inaccurate, incomplete, misleading and unreasonable information and warnings to Plaintiff, her orthopedic surgeon, and the orthopedic community.

131. As a proximate result of the negligence as set forth above, Plaintiff suffered personal injuries and damages, as set forth in Paragraphs 84 through 88 above and incorporated herein by reference.

COUNT V
BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY

132. Plaintiff re-alleges and incorporates by reference Paragraphs 1 through 88 above as if fully set forth herein.

133. Defendant designed, manufactured, marketed, sold, distributed, and serviced the Accolade System at issue in this case.

134. Defendant impliedly warranted that the aforementioned Accolade System and its component parts were merchantable and fit for the ordinary and intended purposes for which artificial hip systems are used.

135. Plaintiff was a foreseeable user of the Accolade System.

136. Plaintiff purchased the Accolade System from Defendant through her surgeon agent.

137. Plaintiff was and is in privity with Defendant regarding her purchase of the Accolade System.

138. Plaintiff used the product for its ordinary and intended purpose.

139. The Accolade System failed while being used for its ordinary and intended purpose.

140. As a result of Defendant's breach of implied warranty of merchantability, Plaintiff was caused to suffer and continues to suffer personal injuries and damages, as set forth in Paragraphs 84 through 88 above and incorporated herein by reference.

COUNT VI
BREACH OF EXPRESS WARRANTY

141. Plaintiff re-alleges and incorporates by reference Paragraphs 1 through 88 above as if fully set forth herein.

142. Defendant designed, manufactured, marketed, sold, distributed, and serviced the Accolade System at issue in this case.

143. Plaintiff was a foreseeable user of the Accolade System.

144. Plaintiff purchased the Accolade System from Defendant through her surgeon-agent.

145. Plaintiff was and is in privity with Defendant regarding her purchase of the Accolade System.

146. Plaintiff used the product for its ordinary and intended purpose.

147. The Accolade System failed while being used for its ordinary and intended purpose.

148. Defendant explicitly warranted that patients, including Plaintiff, receiving an Accolade System should have no concerns about the modular components fretting or corroding.

149. Such representations by Defendant were meant to induce Plaintiff, through her physician, to purchase the Accolade System.

150. The Accolade System and each of its component parts did not conform to representations made by Defendant in many ways, including, but not limited to, the fact that the modular components caused corrosion and fretting.

151. The mode of the Accolade System's failure in Plaintiff was corrosion and fretting of the components. According to Defendant's marketing, this was precisely the mode of failure that patients should not have been concerned about.

152. Within a reasonable time after Plaintiff knew or should have known of the failure of her implanted Accolade System, she gave notice to Defendant of such failure.

153. As a result of Defendant's breach of warranty, Plaintiff was caused to suffer and continues to suffer personal injuries and damages, said injuries and damages as set forth in Paragraphs 84 through 88 above and incorporated herein by reference.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment against Defendant for damages and for all such other relief as the Court may deem necessary, just and proper.

DEMAND FOR JURY TRIAL

Plaintiff demands a trial by jury.

Dated: Thursday, June 25, 2015.

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