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	SUPERIOR COURT OF NEW JERSEY LAW DIVISION: BERGEN COUNTY
	CIVIL ACTION
[redacted] Plaintiff, v.	**IN RE: STYKER REJUVENATE HIP STEM and ABG II MODULAR HIP CASE NO. 296**
HOWMEDICA OSTEONICS CORP. a New Jersey Corporation d/b/a STRYKER ORTHOPAEDICS, Defendant.	DOCKET NO.: **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 Minnesota 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. THA 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 affixation by screws, the use of bone cement, a porous metal coating on the back of the cup into which the natural bone will grow, or by a combination of the three.

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 can be 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 sections 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 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 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 REJUVENATE HIP SYSTEM

13. Defendant Stryker 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. In late 2009 and early 2010, Stryker began marketing and selling the The Stryker Rejuvenate™ SPT Modular Stem ("Rejuvenate Stem") and the Rejuvenate™ Modular Neck (hereafter "Rejuvenate Neck") together as part of its Rejuvenate Modular Hip System (hereafter "Rejuvenate System").

17. The Rejuvenate Stem is a synthetic metal stem made from a Titanium alloy. Specifically, the metal composition is: Ti-12Mo-6Zr-2Fe.

18. The Rejuvenate Stem's design utilizes a porous coating into which the host bone is intended to fuse.

19. The Rejuvenate Neck is a synthetic metal neck designed to attach to the top of the Rejuvenate Stem. Despite the Rejuvenate Stem being composed of a Titanium alloy, the Rejuvenate Neck is composed of a Cobalt and Chromium alloy (CoCr).

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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.

20. The Rejuvenate System is "modular" because it is designed with two separate but connecting pieces: The neck and stem.

21. Most primary THA stems do not utilize a "modular" design; the stem and neck of most primary THA stems are designed as one whole, continuous piece. Accordingly, most primary THA stems do not share the Rejuvenate System's trait of being composed of two different pieces. That the Rejuvenate System's two pieces do not share the same metal composition is a further differentiator.

22. Regarding femoral components of a primary total hip arthroplasty procedure, Styker'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.

23. Stryker marketed the Rejuvenate System as a system which "represents the latest evolution in the OmniFit and Secur-Fit product lines, which have a successful published clinical history for over 15 years."

24. Neither the OmniFit nor the Secur-Fit products incorporated a modular stem design. Both the OmniFit and Secur-Fit employ the traditional one-piece stem design.

25. Further, Stryker touted the "Proven Modularity" of the Rejuvenate System, stating:

> The modular junction construct is designed to maintain strength and durability. The Rejuvenate System combines the material characteristics of TMZF (Ti-12Mo-6Zr-2Fe) and Cobalt Chrome (CoCr) for the stem and neck implants respectively. **Laboratory testing demonstrates the compatibility of these materials without concern for fretting and corrosion.** (Emphasis added).

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

26. Upon information and belief, Stryker also utilized print, television, internet, and e-mail marketing to disseminate information promoting purported advantages of the Rejuvenate 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 Rejuvenate System in patients needing a THA procedure.

28. Upon information and belief, Stryker 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 Rejuvenate System during a THA procedure.

29. Upon information and belief, Stryker 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, like Plaintiff's, had regarding the Rejuvenate System.

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

THE RECALL OF THE STRYKER REJUVENATE HIP SYSTEM

32. The perceived benefits of utilizing a modular design for the femoral component of a primary THA included greater surgeon customization of a femoral component according to a patient's anatomy.

33. The known risks of utilizing a modular design for the femoral components of a primary THA included wear, fretting, and corrosion that occurs at the juncture of the modular components.

34. Despite Stryker's claims of the advantages of the Rejuvenate System, the product is and always was deeply flawed and defective.

35. Since its inception in the US Market, the Rejuvenate System experienced an unreasonably high rate of failures.

36. Upon information and belief, prior to Plaintiff's implant and revision surgeries, Defendant was aware of problems and defects with the Rejuvenate System, including, but not limited to, fretting and corrosion in, near, and around the junction of the Rejuvenate Stem and Rejuvenate Neck.

37. Prior to marketing and selling the Rejuvenate System, Defendant was aware of published research which showed that modular neck femoral components present a high risk of metal fretting and crevice corrosion which could result in adverse local tissue reactions, as well other ailments.

38. Despite published research to the contrary, Defendant promoted the Rejuvenate System as having "Proven Modularity" based on "(l)aboratory testing [which] demonstrates the compatibility of these [Titanium alloy and Cobalt-Chrome] materials without concern for fretting and corrosion."

39. Prior to marketing and selling the Rejuvenate System, Defendant was aware that no published research supported its "Proven Modularity" claim regarding the Rejuvenate System.

40. Prior to marketing and selling the Rejuvenate System, Defendant was aware that no published research supported their claim that "Laboratory testing demonstrates the compatibility of these materials without concern for fretting and corrosion."

41. Prior to marketing and selling the Rejuvenate System, Defendant knew or should have known that its "Proven Modularity" claim regarding the Rejuvenate System was not true.

42. Prior to marketing and selling the Rejuvenate System, Defendant knew or should have known that the laboratory testing it claimed demonstrated the compatibility of the Rejuvenate Neck and Rejuvenate Stem was incomplete, inconclusive, incorrect, and/or irrelevant when judging the *clinical* safety and effectiveness of the Rejuvenate System.

43. Prior to marketing and selling the Rejuvenate System, Defendant knew or should have known that the Rejuvenate System was not a clinically safe prosthesis.

44. Despite knowing, or being in a position where it should have known of the unreasonable risks associate with the Rejuvenate System, Defendant began to market and sell the Rejuvenate System in late 2009 and early 2010.

45. During the marketing and sale of the Rejuvenate System, Defendant knew or should have known that the Rejuvenate System was not a clinically safe prosthesis.

46. After Defendant began marketing and selling the Rejuvenate System, Defendant quickly began receiving a high number of reports and warnings from surgeons regarding failed Rejuvenate Necks and Stems.

47. Defendant did not take proper action in response to surgeon reports and warnings.

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

49. On June 29 2012, Stryker finally recalled the Rejuvenate System. According to Stryker, the recall was due to the increased likelihood for adverse local tissue reactions (hereafter "ALTR") caused by fretting and corrosion around the taper neck junction of the modular stem and neck.

50. After recalling the Rejuvenate System, Stryker sponsored a manuscript titled, "Evaluation of painful total hip replacements / modular metal taper junctions."

51. The purported intent of this manuscript, available on Stryker'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."

52. While downplaying the rate of clinical occurrence of failures, this manuscript admits the danger associated with modular stems:

> With the additional taper junction, the modular neck femoral components provide an additional interface that may, in rare situations, be a potential source for metal fretting and crevice corrosion.

53. This admission is in stark contrast to the marketing of the Rejuvenate System, which stated that the neck and stem of the Rejuvenate System were compatible "without concern for fretting and corrosion."

54. Further, Defendant admits in this manuscript, "It has been shown that ceramic-metal modular junctions have less fretting corrosion than metal-metal modular junctions."

55. All of the medical research cited in the manuscript in support of the above admissions *predates* Defendant's selling and marketing of the Rejuvenate System.

56. Accordingly, Defendant knew or should have known, prior to selling and marketing the Rejuvenate System, that designing a hip stem with an additional metal-metal junction, not found in almost any other hip stem, was unreasonably dangerous.

THE EFFECT OF IMPLANT FRETTING AND CORROSION ON THE HUMAN BODY

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

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

59. Fretting and corrosion may result in metal wear being released into the THA patient's body, both to local regions of the hip and systemically to various regions of the body.

60. 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 that may include cancer, autoimmune disorders, visual/auditory disruptions, among many others.

61. 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.

62. The longer the source of metal debris is present, the worse the soft tissue damage may be.

63. Evidence of fretting 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.

64. 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.

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

66. The extent of damage to a person's natural hip anatomy due to metal wear, fretting and corrosion may be so great as to decrease the likelihood of success of future revision surgeries.

THE FDA'S 510(k) CLEARANCE PROCESS

67. In late 2009, the U.S. Food and Drug Administration (hereafter "FDA") cleared the Rejuvenate System for sale through its 510(k) clearance process.

68. The 510(k) clearance process refers to Section 510(k) of the Medical Device Amendments of 1976 (hereafter "MDA") of the Federal Food, Drug, and Cosmetic Act. Under this process, device manufacturers are only required to notify the FDA at least 90 days before they market a device claimed to be "substantially equivalent" to a device the FDA approved for sale prior to 1976, when the MDA was enacted.

69. No clinical testing is required under this process.

70. Subsequent amendments to the MDA allowed for 510(k) clearance for products deemed "substantially equivalent" to post-MDA, 510(k)-cleared devices. Through this domino

effect, devices deemed "substantially equivalent" to devices previously deemed "substantially equivalent" to devices approved for sale by the FDA prior to 1976 could be sold to patients in a matter of 90 days without any clinical testing.

71. Stryker's 510(k) application claimed the Rejuvenate System was substantially equivalent to devices previously cleared through the 510(k) process. Therefore, the Rejuvenate System's clearance for sale was based on its purported substantial yet indirect similarity to a medical device approved for sale by the FDA prior to 1976.

72. Clearance for sale under the 510(k) process does not equate to FDA approval of the cleared device.

73. In 2012, at the request of the FDA, the National Institute of Health (hereafter "NIH") conducted a thorough review of the 510(k) process, coming to the following major conclusions

> **The 510(k) clearance process is not intended to evaluate the safety and effectiveness of medical devices with some exceptions. The 510(k) process cannot be transformed into a pre-market evaluation of safety and effectiveness so long as the standard for clearance is substantial equivalence to any previously cleared device.**

74. The NIH explained, "The assessment of substantial equivalence does not require an independent demonstration that the new device provides a 'reasonable assurance of safety and effectiveness.'" Further, the NIH even pointed out that the classification of predicate devices approved for sale prior to the 1976 MDA "did not include any evaluation of the safety and effectiveness of individual medical devices . . . Thus is common for devices to be cleared through the 510(k) program by being found substantially equivalent to devices that were never individually evaluated for safety and effectiveness, either through the original device classification program or through the 510(k) process.

PLAINTIFF'S IMPLANT AND REVISION

75. Plaintiff experienced a history of pain in her right hip that caused her to be treated by [redacted] (hereafter "Dr. [redacted]").

76. Dr. [redacted] determined Plaintiff needed a THA of the right hip.

77. On May 27 2010, Dr. [redacted] performed a THA on Plaintiff's right hip at St. Cloud Hospital in St. Cloud, Minnesota.

78. During this THA, Dr. [redacted] implanted Plaintiff with a number of hip implant components designed and manufactured by Stryker Orthopaedics (hereafter "Stryker").

79. One of these components was the Rejuvenate Stem, Size 8, Reference Number SPT-08000S, Lot Number MHT0TE.

80. Another of these components was the Rejuvenate Neck, Reference Number NLS-340000B, Lot Number 29491602.

81. In preparation for the May 27, 2010 surgery, Dr. [redacted] 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 Rejuvenate System.

82. Defendant or Defendant's agent and/or employees selected and provided the specific Rejuvenate System manufactured by Stryker and delivered them to the operating room at St. Cloud Hospital.

83. 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.

84. Defendant trained and educated its sales staff regarding the Rejuvenate System, including 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 Rejuvenate System, and training on how to sell to orthopedic surgeons, including training on the advantage of the Rejuvenate System over its competitors.

85. 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 Rejuvenate System compared to its competitors, information regarding the design rationale for the Rejuvenate System, surgical techniques on how to implant the Rejuvenate System, and demonstrations on how to implant the Rejuvenate System and the components that could best be mated with the Rejuvenate System, including providing a variety of scenarios involving the various instrumentation used in implanting the Rejuvenate System.

86. Defendant's sales representative agents were responsible for answering any questions or concerns Plaintiff's orthopedic surgeon had regarding the Rejuvenate System.

87. 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 Rejuvenate System instead of one of the competing hip replacements.

88. 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 representative agents.

89. After being implanted with the Rejuvenate System, Plaintiff experienced significant pain in her right hip and sought follow-up treatment with Dr. [redacted].

90. A July 27, 2012 MRI of Plaintiff's right hip revealed, among other things, 1) A large amount of fluid build-up around the femoral neck and extending to the ilipsoas bursa and pelvis; 2) a markedly thickened rind of abnormal soft tissue along the periphery of the femoral neck, presumed to represent necrotic soft tissue; and 3) Complete disruption of tendons.

91. An August 1, 2012 metal ion test revealed a Cobalt serum level of 13, which is more than 13 times the maximum normal reference amount for this test.

92. An August 1, 2012 a metal ion test revealed a Chromium serum level of 5.7, which is 19 times the maximum normal reference amount for this test.

93. Cobalt and Chromium are both known toxins and carcinogens.

94. Thereafter, Dr. [redacted] recommended surgery to replace Plaintiff's Rejuvenate System components in Plaintiff's left hip.

95. On or about September 12, 2012, Plaintiff underwent a revision surgery on her right hip, performed by Dr. [redacted] at St. Cloud Hospital in St. Cloud, Minnesota.

96. During the revision surgery, Dr. [redacted] noted **extensive damage to Plaintiff's hip**:

> Upon entering the fascia, a significant amount of metal stained fluid was encountered. There was no abductor or external rotator attachment remaining on the trochanter. All this tissue was dead and detached, and there was a complete bald proximal trochanter . . . The neck was removed from the stem and there was the typical black sludge corrosion at this interface. There was erosion of the proximal femoral bone as well. The femoral component was well fixed. Debridement of all the dead necrotic tissue was performed, which included the majority of the external rotators in the vicinity of the hip and posterior capsule. The entirety of the abductor minimus and the majority of the remaining gluteus medius had significant change and had atrophy and fatty degeneration and scarring with very few remaining muscle fibers identified. There was significant adductor musculature and vastus lateralis that was necrotic as well and was debrided.

97. Dr. [redacted] noted that Plaintiff lost 450mL of blood during the revision operation, three times as much as Plaintiff lost during her implant surgery.

98. Based on Dr. [redacted] findings, the metal-metal juncture of Plaintiff's Rejuvenate System had fretted and corroded, causing extensive fluid build-up, muscle death, metal poisoning, bone loss, and tendon damage.

99. Upon information and belief, the modular juncture in Plaintiff's Rejuvenate System failed and caused the damage noted by Dr. [redacted] during revision surgery.

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

101. The Rejuvenate 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 that were available to treat Plaintiff's condition.

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

103. As a direct and proximate result of the failed Rejuvenate System, Plaintiff was caused to incur medical expenses, and expects to incur additional medical expenses in the future.

104. Plaintiff suffered personal injuries, including experiencing great pain and suffering as a result of the defective Rejuvenate System. Plaintiff continues to experience pain and suffering and will experience additional pain and suffering in the future.

105. As a result of the necessary revision surgery on September 12, 2012, Plaintiff has additional scar tissue in her right hip, required an additional lengthy and protracted rehabilitation, preventing her from performing activities of daily living, and now Plaintiff has a right hip implant that has decreased longevity.

106. As a direct and proximate result of the defective Rejuvenate System, Plaintiff has suffered dislocations and undergone multiple revision surgeries.

107. As a direct and proximate result of the failed Rejuvenate System, Plaintiff lost wages, income and earnings, and will suffer future lost wages, income and earnings.

108. As a direct and proximate result of the failed Rejuvenate System, Plaintiff has incurred expenses in order to make activities of daily living more handicap-accessible. Plaintiff will continue to incur such expenses in the future.

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

COUNT I
STRICT LIABILITY – DESIGN DEFECT

110. Plaintiff realleges and incorporates by reference Paragraphs 1 through 109 as if fully set forth herein.

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

112. The product was unreasonably dangerous as designed.

113. Defendant knew or should have known that unless the devices were carefully and properly designed, manufactured, promoted, marketed, distributed, supplied, sold and serviced, that 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. The product's known risks clearly outweighed the purported advantages, especially in light of the fact that the purported advantages were not clinically proven.

115. Defendant admits that prior to the design, marketing, advertising, and sale of the product, multiple safer alternatives existed. For example, Defendant admitted that one safer alternative involved a ceramic-metal modular junction instead of a metal-metal modular junction. Another safer alternative was to not use a modular stem at all, instead opting for one single continuous part just like almost all primary THA stems on the market, including the OmniFit and Secur-Fit.

116. Defendant acted in an unreasonable manner in designing the Rejuvenate System.

117. 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.

118. As designed, manufactured, promoted, marketed, distributed, supplied, sold and serviced, the Rejuvenate System was unreasonably dangerous to anyone who might use them for

the purposes for which they were intended and was, in fact, defective, unfit, dangerous, unsafe, unsuitable, and dangerous to be placed in Plaintiff's body.

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

120. The risks posed to Plaintiff by the Rejuvenate System were known by Defendant or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution.

121. As a direct and proximate result of the aforementioned risks, dangers, and defects, Plaintiff was caused to suffer damages, said damages set forth in greater detail in Paragraphs 102 through 109, and incorporated herein by reference.

COUNT II
STRICT LIABILITY – MANUFACTURING DEFECT

122. Plaintiff realleges and incorporates by reference paragraphs 1 through 109 as if fully set forth herein.

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

124. The product was unreasonably dangerous as manufactured.

125. Defendant knew or should have known that unless the devices were carefully and properly designed, manufactured, promoted, marketed, distributed, supplied, sold and serviced, that 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.

126. Defendant acted in an unreasonable manner in manufacturing the Rejuvenate System.

127. 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.

128. As designed, manufactured, promoted, marketed, distributed, supplied, sold and serviced, the Rejuvenate System was unreasonably dangerous to anyone who might use them for the purposes for which they were intended and was, in fact, defective, unfit, dangerous, unsafe, unsuitable, and dangerous to be placed in Plaintiff's body.

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

130. The risks posed to Plaintiff by the Rejuvenate System were known by Defendant or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution.

131. As a direct and proximate result of the aforementioned risks, dangers, and defects, Plaintiff was caused to suffer damages, said damages set forth in greater detail in Paragraphs 102 through 109, and incorporated herein by reference.

COUNT III
STRICT LIABILITY – FAILURE TO WARN

132. Plaintiff realleges and incorporates by reference paragraphs 1 through 109 as if fully set forth herein.

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

134. Defendant knew or should have known that unless the devices were carefully and properly designed, manufactured, promoted, marketed, distributed, supplied, sold and serviced,

that 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.

135. As designed, manufactured, promoted, marketed, distributed, supplied, sold and serviced, the Rejuvenate System was unreasonably dangerous to anyone who might use them for the purposes for which they were intended and was, in fact, defective, unfit, dangerous, unsafe, unsuitable, and dangerous to be placed in Plaintiff's body.

136. Defendant failed to warn Plaintiff of the unreasonable danger posed to Plaintiff by the Rejuvenate System.

137. 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.

138. 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.

139. Defendant had a duty to warn Plaintiff of the dangers of the Rejuvenate System prior to and after the sale and implant of the product in Plaintiff.

140. Defendant failed to fulfill its duty to warn Plaintiff of the dangers of the Rejuvenate System.

141. 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 Rejuvenate System.

142. 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 Rejuvenate System.

143. 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.

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

145. The risks posed to Plaintiff by the Rejuvenate System were known by Defendant or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution.

146. As a direct and proximate result of the aforementioned risks, dangers, and defects, Plaintiff was caused to suffer damages, said damages set forth in greater detail in Paragraphs 102 through 109, and incorporated herein by reference.

COUNT IV
NEGLIGENCE

147. Plaintiff realleges and incorporates by reference paragraphs 1 through 109 above as if fully set forth herein.

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

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

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

151. 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.

152. As a direct and proximate result of the aforementioned risks, dangers, and defects, Plaintiff was caused to suffer damages, said damages set forth in greater detail in Paragraphs 102 through 109, and incorporated herein by reference.

COUNT V
BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY

153. Plaintiff realleges and incorporates by reference paragraphs 1 through 109 above as if fully set forth herein.

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

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

156. Plaintiff was a foreseeable user of the Rejuvenate System.

157. Plaintiff purchased the Rejuvenate System from Defendants through her surgeon agent.

158. Plaintiff was and is in privity with Defendant regarding her purchase of the Rejuvenate System.

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

160. The Rejuvenate System failed while being used for its ordinary and intended purpose.

161. As a direct and proximate result of the aforementioned risks, dangers, and defects, Plaintiff was caused to suffer damages, said damages set forth in greater detail in Paragraphs 102 through 109, and incorporated herein by reference.

COUNT VI
BREACH OF EXPRESS WARRANTY

162. Plaintiff realleges and incorporates by reference paragraphs 1 through 109 above as if fully set forth herein.

163. Defendants designed, manufactured, marketed, sold, distributed, and serviced the Rejuvenate System at issue in this case.

164. Plaintiff was a foreseeable user of the Rejuvenate System.

165. Plaintiff purchased the Rejuvenate System from Defendant through her surgeon agent.

166. Plaintiff was and is in privity with Defendants regarding her purchase of the Rejuvenate System.

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

168. The Rejuvenate System failed while being used for its ordinary and intended purpose.

169. Defendants explicitly warranted that patients, including Plaintiff, receiving a Rejuvenate System should have no concerns about the modular components fretting or corroding.

170. Such representations by Defendant were meant to induce Plaintiff, through her physician, to purchase the Rejuvenate Systems.

171. The Rejuvenate Systems and each of their 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.

172. The mode of the Rejuvenate System's failure in Patient was corrosion and fretting of the modular components. This was precisely the mode of failure that patients should not have been concerned about, according to Defendants' marketing.

173. Within a reasonable time after Plaintiff knew or should have known of the failure of the Rejuvenate System parts of the Rejuvenate Systems, Plaintiff gave notice to Defendant of such failure.

174. As a direct and proximate result of the aforementioned risks, dangers, and defects, Plaintiff was caused to suffer damages, said damages set forth in greater detail in Paragraphs 102 through 109, and incorporated herein by reference.

PRAYER FOR RELIEF

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

DEMAND FOR JURY TRIAL

Plaintiff demands a trial by jury.

DESIGNATION OF TRIAL COUNSEL

Pursuant to R. 4:5-1(c) and R. 4:25-4, Plaintiff(s) hereby designates F. John Caldwell, Jr. as trial counsel.

RULE 4:5-1 CERTIFICATION

Plaintiff, by her attorneys, hereby certifies that the matter in controversy is not the subject of any other pending or contemplated judicial or arbitration proceedings. Plaintiff is not currently aware of any other parties that should be joined in this particular action. In addition, Plaintiff recognizes her continuing obligation to file and serve on all parties and the Court an amended certification if there is a change in the facts stated in this original certification.

Dated: May 6, 2013

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