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SUPERIOR COURT OF WASHINGTON
FOR PIERCE COUNTY

[REDACTED]
Plaintiff,

vs.

HOWMEDICA OSTEONICS CORP., A
NEW JERSEY CORPORATION D/B/A
STRYKER ORTHOPAEDICS,

Defendant.

NO. 15-2-07576-0

FIRST AMENDED -
COMPLAINT FOR DAMAGES

Comes now plaintiff, **[REDACTED]** ("Plaintiff"), and for cause of action against defendant, **HOWMEDICA OSTEONICS CORP., a New Jersey Corporation d/b/a STRYKER ORTHOPAEDICS** ("Defendant" or "Stryker"), and alleges as follows:

1. This action arises out of Defendant's development, testing, assembling, designing, manufacturing, packaging, labeling, preparing, distribution, marketing, supplying, and selling the Accolade TMZF Hip Stem and the LFIT Anatomic V40 Femoral Head (collectively the "Accolade", "Accolade System", or the "Defective Product").

FIRST AMENDED -
COMPLAINT FOR DAMAGES - 1

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PARTIES, VENUE AND JURISDICTION

2. At all times relevant to this Complaint, Plaintiff was and is a resident of Pierce County, Washington.

3. At all times relevant to this Complaint, Defendant was and is a New Jersey corporation with its principal place of business at 325 Corporate Drive, Mahwah, Bergen County, New Jersey 07430. At all times material hereto, Defendant regularly did business in the State of Washington, including Pierce County, where Defendant's agents and/or employees selected and provided the specific Acocolade manufactured by Defendant and delivered to Plaintiff's operating room at St. Clare Hospital, which Defective Product was responsible for Plaintiff's injuries.

4. Plaintiff's injuries were sustained in Pierce County, Washington and jurisdiction and venue are proper in Pierce County, Washington.

GENERAL ALLEGATIONS

TOTAL HIP ARTHROPLASTY

5. Total Hip Arthroplasty (hereafter "THA") is the term used to describe surgery wherein is 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.

6. 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

1 what remains of the femoral bone. The portion of the stem, which is housed inside the
2 femur, may be affixed to the bone via use of bone cement or by a porous coating on the
3 synthetic surface into which the natural bone will grow. The top of the synthetic metal
4 stem, referred to as the "neck", is not housed inside the femur and remains completely
5 exposed inside the body. A synthetic ball, whether made of metal, plastic, or ceramic, is
6 then attached to the neck of the synthetic stem.

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

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

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

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

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

23 **STRYKER HIP SYSTEM**

1 12. Defendant designs and manufactures various medical devices and implants.

2 13. According to Stryker's website,¹

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

10 14. Further Stryker's website² also claims,

11 Stryker is the worldwide market leader in Total Hip Replacement
12 products. The company has achieved this position through
13 innovations and by meeting requirements for hip arthroplasty
14 products that help restore patients to normal daily activities.

15 15. Regarding femoral components of a primary total hip arthroplasty
16 procedure, Stryker's website³ claims,

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

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

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

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

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

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

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

7 21. Defendant further claimed the Accolade stem maximizes the patient's hip
8 range of motion, increased stability, and prevented dislocation.

9 22. Defendant's promotional materials stated the Accolade stem was designed
10 to be utilized with LFIT Anatomic V40 femoral heads.

11 23. The LFIT Anatomic V40 femoral head is made from a cobalt/chromium
12 alloy.

13 24. Defendant claims that laboratory testing of these materials demonstrated
14 their compatibility without concern for corrosion or fretting.

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

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

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

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

4 29. These sales agents were responsible for answering any questions or
5 concerns surgeons, like Plaintiff's, had regarding the Accolade.

6 30. At all times relevant to this complaint, Plaintiff's orthopedic surgeon,
7 nurses, and hospital staff relied on information and assistance given by Defendant and its
8 sales agents.

9 **THE RECALL OF THE STRYKER REJUVENATE HIP SYSTEM**

10 31. In 2012, Defendant recalled its Rejuvenate and ABG II modular hip
11 systems.

12 32. The Rejuvenate and ABG II modular hip systems utilized the same TMZF
13 titanium metal in the femoral stem as the Accolade.

14 33. Similar to the Accolade, the modular neck of the Rejuvenate and ABG II
15 were manufactured from cobalt/chromium.

16 34. Patients of the Rejuvenate and ABG II experience failures of the devices,
17 including but not limited to, reports of severe pain, metallosis, psuedotumors, loosening,
18 and tissue destruction.

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

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

23 37. The scientific community has known for decades the combination of

1 titanium and cobalt/chromium results in significant fretting and corrosion when dissimilar
2 metals are combined.

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

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

10 40. Prior to marketing and selling the Accolade, the Rejuvenate and the ABG
11 II, Defendant knew or should have known that the laboratory testing it claimed
12 demonstrated the compatibility of the Titanium and Cobalt/Chromium was incomplete,
13 inconclusive, incorrect, and/or irrelevant when judging the clinical safety and effectiveness
14 of the hip systems.

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

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

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

22 44. Defendant did not take proper action in response to surgeon reports and
23 warnings.

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

4 46. On June 29 2012, Defendant finally recalled the Rejuvenate and ABG II
5 Systems.

6 47. According to Defendant the recall was due to the increased likelihood for
7 adverse local tissue reactions (hereafter "ALTR") caused by fretting and corrosion around
8 the taper neck junction of the modular stem and neck.

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

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

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

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

22 52. Upon information and belief, Defendant abandoned its use of the TMZF
23 titanium throughout its product lines.

1 **THE EFFECT OF IMPLANT FRETTING**
2 **AND CORROSION ON THE HUMAN BODY**

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

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

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

10 56. The resulting metal wear may result in the formation of pseudotumors,
11 tissue necrosis, osteolysis, aseptic loosening of the acetabular component, and various
12 systemic medical issues that may include cancer, autoimmune disorders, visual/auditory
13 disruptions, among many others.

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

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

21 59. Evidence of fretting corrosion of the modular taper junction is visualized by
22 irregular black material on the surface of the metal contained within the junction. Further,
23

1 the black material is typically associated with surface irregularities on the metal taper
2 surface in contact with the opposite metal surface, consistent with crevice corrosion.

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

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

7
8 **PLAINTIFF'S IMPLANT AND REVISION**

9 62. Plaintiff experienced a history of pain in her left hip that caused her to be
10 treated by Dr. Steven Teeny M.D. (hereafter "Dr. Teeny").

11 63. Dr. Teeny determined Plaintiff needed a THA of the left hip.

12 64. On January 8, 2007, Dr. Teeny performed a THA on Plaintiff's left hip at
13 St. Clare Hospital in Lakewood, Washington.

14 65. During this THA, Dr. Teeny implanted Plaintiff with a number of hip
15 implant components designed and manufactured by Defendant.

16 66. One of these components was the Accolade TMZF Stem, Reference
17 Number 6021-0230, ID Number 10030293CP.

18 67. Another of these components was the LFIT Anatomie V40 Femoral Head,
19 Reference Number 6260-9-032, with possible Lot Number 19G44902.

20 68. In preparation for the January 8, 2007 surgery, Dr. Teeny, or someone at his
21 direction contacted Defendant, or an agent and/or employee of Defendant, to notify it of
22 the need for the Stryker hip system components, including the Accolade System.

1 69. Defendant or Defendant's agent and/or employees selected and provided the
2 specific Accolade manufactured by Defendant and delivered them to the operating room at
3 St. Clare Hospital.

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

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

15 72. Prior to Plaintiff's THA surgery, sales representatives of Defendant
16 provided information to Plaintiff's orthopedic surgeon, including but not limited to, the
17 advantages of the Accolade System compared to its competitors, information regarding the
18 design rationale for the Accolade System, surgical techniques on how to implant the
19 Accolade System, and demonstrations on how to implant the Accolade System and the
20 components that could best be mated with the Accolade System, including providing a
21 variety of scenarios involving the various instrumentation used in implanting the Accolade
22 System.
23

1 73. Defendant's sales representative agents were responsible for answering any
2 questions or concerns Plaintiff's orthopedic surgeon had regarding the Accolade System.

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

7 75. At all times relevant to this complaint, Plaintiff's orthopedic surgeon,
8 nurses and hospital staff relied on information and assistance from Defendant and its sales
9 representative agents.

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

12 77. A July 2, 2012 tests of Plaintiff's left hip revealed a loose acetabular
13 component.

14 78. Thereafter, Dr. Teeny recommended surgery to replace plaintiff's Accolade
15 Hip components in Plaintiff's left hip.

16 79. On or about July 10, 2012, Plaintiff underwent a revision surgery on her left
17 hip, performed by Dr. Teeny at St. Clare Hospital.

18 80. During the revision surgery, Dr. Teeny noted extensive damage to
19 Plaintiff's hip:

20
21 "Immediately upon entering the joint, a thick squirt of green, thick
22 fluid was expressed seemingly under pressure. This was
23 immediately sent to laboratory for a gram stain and evaluation with
some synovial tissue for evaluation which showed minimal chronic
inflammation. No acute inflammation. No signs of

1 polymorphonuclear leukocytes. With that in mind, the feeling was it
2 had a clinical picture of an ALVAL type reaction... We did a partial
3 capsulectomy and capsulotomy which allowed us to express the
4 femoral head. A bone tamp was used to remove it. It noted a large
5 amount of corrosion material at the trunnion and some deep, what
6 appeared to be corrosion materials deep inside the femoral head as
7 well, even after head was removed.The cup itself was
8 completely loose. ...More green purulent-like material was found
9 behind the cup along with quite a bit of necrotic bone so that a fair
10 portion of the posterior wall, some of the superior wall, some of the
11 anterior wall and inferiorly all with significant bone loss. There was
12 necrotic bone almost in a layer around the cup as well."

13 81. During the revision surgery, Dr. Teeny removed the defective LFIT
14 AnatomicV40 head and replaced it with a ceramic head.

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

18 83. The Accolade System was unsafe to an extent beyond that which would be
19 contemplated by the order consumer, and the risks associated with it were more dangerous
20 than the risks associated with other hip replacement devices that were available to treat
21 Plaintiff's condition.

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

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

86. Plaintiff suffered personal injuries, including experiencing great physical

1 pain and suffering as a result of the defective Accolade System and will have great pain
2 and suffering in the future.

3 87. As a result of the necessary revision surgery on July 10, 2012, Plaintiff has
4 experienced disfigurement, including but not limited to additional scar tissue in her right
5 hip, and experienced additional, lengthy, and protracted rehabilitation, preventing her from
6 performing activities of daily living, and now Plaintiff has a right hip implant that has
7 decreased longevity.

8 88. As a direct and proximate result of the failed Accolade System, Plaintiff
9 suffered time loss from employment, loss of wages and earnings and earning capacity.

10 89. As a direct and proximate result of the failed Accolade System, Plaintiff
11 experienced mental and emotional distress and suffering, including reduction in the
12 capacity to enjoy life, and is likely to experience emotional trauma and distress in the
13 future.

14 **COUNT I – PRODUCT LIABILITY CLAIM – DESIGN DEFECT**

15 90. Plaintiff re-alleges each and every allegation contained in the preceding
16 paragraphs.

17 91. Defendant designed, manufactured, marketed, advertised, and sold the
18 defective product at issue in addition to providing training materials to sales agents and
19 surgeons on properly selecting and implanting the defective product. As such, Defendant
20 is a product seller and manufacturer within the meaning of RCW 7.72. et seq., - The
21 Washington Products Liability Act. The action brought herein against Defendant is
22 brought pursuant to the Washington Products Liability Act and to Breach of Warranty and
23

1 common law negligence.

2 92. The Accolade System was not reasonably safe to an extent beyond that
3 which would be contemplated by the ordinary consumer.

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

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

10 95. Defendant admits that prior to the design, marketing, advertising, and sale
11 of the product, multiple safer alternatives existed. For example, Defendant admitted that
12 one safer alternative involved a ceramic-metal junction instead of a metal-metal junction.

13 96. Defendant acted in an unreasonable manner in designing the Accolade
14 System.

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

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

21 99. At the time and on the occasion in question, the Accolade System was being
22 properly used for the purpose for which they were intended and such devices were in fact
23

1 defective, unsafe, and unreasonably dangerous.

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

5 101. As a direct and proximate result of the aforementioned risks, dangers, and
6 defects, Plaintiff was caused to suffer damages, said damages set forth in greater detail in
7 Paragraphs 81 through 89, and incorporated herein by reference.

8
9 **COUNT II – PRODUCT LIABILITY CLAIM – MANUFACTURING DEFECT**

10 102. Plaintiff re-alleges and incorporates by reference paragraphs 1 through 89 as
11 if fully set forth herein.

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

15 104. The product was unsafe or unreasonably dangerous as manufactured.

16 105. Defendant knew or should have known that unless the devices were
17 carefully and properly designed, manufactured, promoted, marketed, distributed, supplied,
18 sold and serviced, that they would constitute an unreasonable risk of substantial bodily
19 harm to those who used them for the purposes for which they were made and intended.
20

21 106. Defendant acted in an unreasonable manner in manufacturing the Accolade
22 System.

23 107. There was no substantial change in the condition of the Defective Product

1 from the time it left Defendant's possession to the time it was sold to and implanted in
2 Plaintiff.

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

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

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

13 111. As a direct and proximate result of the aforementioned risks, dangers, and
14 defects, Plaintiff was caused to suffer damages, said damages set forth in greater detail in
15 Paragraphs 1 through 89, and incorporated herein by reference.
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18 **COUNT III – PRODUCT LIABILITY CLAIM – FAILURE TO WARN**

19 112. Plaintiff re-alleges and incorporates by reference paragraphs 1 through 89 as
20 if fully set forth herein.

21 113. Defendant designed, manufactured, marketed, advertised, and sold the
22 Defective Product at issue in addition to providing training materials to sales agents and
23 surgeons on properly selecting and implanting the Defective Product.

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

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

9 116. Defendant failed to warn Plaintiff of the unreasonable danger posed to
10 Plaintiff by the Accolade System.

11 117. Defendant knew that Plaintiff, as an anticipated user of the Defective
12 Product, would likely not know, and in fact did not know, of the danger posed by the
13 device.

14 118. Defendant deliberately concealed or failed to disclose to Plaintiff, her
15 surgeon, the public, and the FDA, knowledge of the dangers of the Defective Product
16 Defendant acquired after the product was introduced for sale.

17 119. Defendant had a duty to warn Plaintiff of the dangers of the Accolade
18 System prior to and after the sale and implant of the Defective Product in Plaintiff.

19 120. Defendant failed to fulfill its duty to warn Plaintiff of the dangers of the
20 Accolade System.

21 121. Defendant further had a duty to warn Plaintiff, or plaintiff's surgeon, if any
22 of Plaintiff's medical history or conditions were contraindications for the use and implant
23

1 of the Accolade System.

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

5 123. There was no substantial change in the condition of the Defective Product
6 from the time it left Defendant's possession to the time it was sold to and implanted in
7 Plaintiff.

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

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

14 126. As a direct and proximate result of the aforementioned risks, dangers, and
15 defects, Plaintiff was caused to suffer damages, said damages set forth in greater detail in
16 Paragraphs 81 through 89, and incorporated herein by reference.

17
18 **COUNT IV - NEGLIGENCE**

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20 127. Plaintiff re-alleges and incorporates by reference paragraphs 1 through 89
21 above as if fully set forth herein.

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

1 manner.

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

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

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

10 132. As a proximate result of the negligence as set forth above, Plaintiff suffered
11 personal injuries and damages, said injuries and damages set forth in greater detail in
12 Paragraphs 81 through 89, and incorporated herein by reference.

13
14 **COUNT V - BREACH OF IMPLIED WARRANTY OF MERCHANT ABILITY**

15 133. Plaintiff re-alleges and incorporates by reference Paragraphs 1 through 89
16 above as if fully set forth herein.

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

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

22 136. Plaintiff was a foreseeable use of the Accolade System.

1 137. Plaintiff purchase the Accolade System from Defendant through her
2 surgeon agent.

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

5 139. Plaintiff used the product for its ordinary and intended purpose.

6 140. The Accolade System failed while being used for its ordinary and intended
7 purpose.

8 141. As a result of Defendant's breach of implied warranty of merchantability,
9 Plaintiff was caused to suffer and continues to suffer personal injuries and damages, said
10 injuries and damages set forth in greater detail in Paragraphs 81 through 89, and
11 incorporated herein by reference.

12
13 **COUNT VI - BREACH OF EXPRESS WARRANTY**

14 142. Plaintiff re-alleges and incorporates by reference Paragraphs 1 through 89
15 above as if fully set forth herein.

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

18 144. Plaintiff was a foreseeable user of the Accolade System.

19 145. Plaintiff purchased the Accolade System from Defendant through her
20 surgeon agent.

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

1 147. Plaintiff used the product for its ordinary and intended purpose.
2 148. The Accolade System failed while being used for its ordinary and intended
3 purpose.
4 149. Defendant explicitly warranted that patients, including Plaintiff, receiving
5 an Accolade System should have no concerns about the modular components fretting or
6 corroding.
7 150. Such representations by Defendant were meant to induce Plaintiff, through
8 her physician, to purchase the Accolade Systems.
9 151. The Accolade Systems and each of their component parts did not conform
10 to representations made by Defendant in many ways, including, but not limited to, the fact
11 that the modular components caused corrosion and fretting.
12 152. The mode of the Accolade System's failure in Patient was corrosion and
13 fretting of the components. This was precisely the mode of failure that patients should not
14 have been concerned about, according to Defendant's marketing.
15 153. Within a reasonable time after Plaintiff knew or should have known of the
16 failure of the Accolade System parts of the Accolade Systems, Plaintiff gave notice to
17 Defendant of such failure.
18 154. As a result of Defendant's breach of warranty, Plaintiff was caused to suffer
19 and continues to suffer personal injuries and damages, said injuries and damages set forth
20 in greater detail in Paragraphs 81 through 89, and incorporated herein by reference.
21

22 **PRAYER FOR RELIEF**

23 WHEREFORE, Plaintiff prays for judgment against Defendant, in amounts to be

1 proved at the time of trial, to fairly compensate Plaintiff for the damages set forth above,
2 together with costs, attorney's fees, pre- and post-judgment interest, and such other and
3 further damages as are proven at trial or for such relief as the Court deems just under the
4 circumstances.

5 Dated this 9th, day of April, 2015

6
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8 

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