SUPERIOR COURT OF WASHINGTON
FOR KING COUNTY

ALAN ROSSI, MD; JAMES MILLARD; and ELLEN PARDEE; Plaintiffs, *v.* BIOMET, INC.; BIOMET ORTHOPEDICS, LLC; BIOMET U.S. RECONSTRUCTION, LLC; BIOMET MANUFACTURING, LLC; ZIMMER BIOMET HOLDINGS, INC; NORTHWEST BIOMET, INC.; JAMES REIFF, II; JOHN CUCKLER, M.D.; and ALABAMA MEDICAL CONSULTANTS, INC. Defendants.	)	No.: COMPLAINT FOR PERSONAL INJURY

COMPLAINT

Plaintiffs, ALAN ROSSI, MD; JAMES MILLARD; and ELLEN PARDEE; ("Plaintiffs"), bring suit against Defendants; BIOMET, INC.; BIOMET ORTHOPEDICS, LLC; BIOMET U.S. RECONSTRUCTION, LLC; BIOMET MANUFACTURING, LLC; AND ZIMMER BIOMET HOLDINGS, INC (hereafter collectively referred to as "Biomet"); NORTHWEST BIOMET, INC. and JAMES REIFF, II (hereafter collectively referred to as "Distributor"); and JOHN CUCKLER, M.D. and ALABAMA MEDICAL CONSULTANTS, INC. (hereafter collectively referred to as "Cuckler"), and states as follows:

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PARTIES, VENUE AND JURISDICTION

1. This is a lawsuit regarding a defective metal on metal hip replacement system implanted in each of the Plaintiffs which was designed, developed, manufactured, labelled, promoted, marketed, sold, and supplied by Defendants.

2. The particular hip replacement system at issue in this case is the "Biomet

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Magnum Metal on Metal Hip Replacement System" (hereafter referred to as the "Magnum").

3. Plaintiffs were all implanted with the Magnum hip replacement system in the State of Washington.

4. At all times relevant to this Complaint, Defendant BIOMET, INC, was and is an Indiana-based multinational corporation, with its corporate headquarters in Warsaw, Indiana and facilities world-wide. Further, at all times relevant to this Complaint, Defendants BIOMET ORTHOPEDICS, LLC; BIOMET U.S. RECONSTRUCTION, LLC; and BIOMET MANUFACTURING, LLC each are and have been wholly owned subsidiaries of Defendant BIOMET, INC. In June of 2015, BIOMET, INC, was purchased by ZIMMER BIOMET HOLDINGS, INC, also having its world-wide corporate headquarters in Warsaw, Indiana. From June of 2015 to present, all activities relating to the product at issue in this case were directed and controlled by ZIMMER BIOMET HOLDINGS, INC. Hereafter, these defendants are referred to collectively as "Biomet Defendants" or simply "Biomet."

5. At all times relevant to this Complaint, JAMES REIFF, II was a citizen of the State of Washington residing at 4440 193rd Avenue, Issaquah, Washington.

6. At all times relevant to this Complaint, NORTHWEST BIOMET, INC. was a citizen of the State of Washington with its principal place of business at 13221 Southeast 26th Street, Suite B, Bellevue, Washington.

7. At all times relevant to this Complaint, JAMES REIFF, II, individually and operating through his company NORTHWEST BIOMET, INC., had an exclusive agreement with the Biomet Defendants for educating orthopedic surgeons about available Biomet hip replacement systems and the advantages, benefits, indications, templating, surgical implantation, and follow-up of those Biomet hip replacement systems in the State of Washington. Hereafter,

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these defendants will be referred to collectively as "Distributor."

8. The information that Distributor provided about Biomet hip replacement systems far exceeded the information provided on Magnum packaging or labeling.

9. Distributor's sales representatives selected the components and tools to have present in the operating room when the Plaintiffs were surgically implanted with the Magnum.

10. At all times relevant to this Complaint, Plaintiffs' surgeons relied upon information provided by Distributors' sales representatives in selecting the Magnum hip replacement for implantation into the Plaintiffs' bodies.

11. Distributor profited from the promotion, sale, and servicing of the Magnum hip replacements at issue in the instant case.

12. At all times relevant to this Complaint, Defendant JOHN CUCKLER, M.D. was and is a citizen of the State of Florida.

13. At all times relevant to this Complaint, Defendant ALABAMA MEDICAL CONSULTANTS, INC. was and is an Alabama corporation with its principal place of business in Naples, Florida, and as such is a citizen of the State of Florida.

14. At all times relevant to this Complaint, Defendant JOHN CUCKLER, M.D., personally and through his company, ALABAMA MEDICAL CONSULTANTS, INC., received royalties and financially profited from his design, development, and promotion of the Magnum metal on metal hip replacement system. Hereafter, these defendants will be referred to, collectively, as "Cuckler."

15. Cuckler profited from the promotion, sale, and servicing of the Magnum hip replacements at issue in the instant case.

16. Cuckler consented to the jurisdiction of the courts of the State of Washington.

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17. Jurisdiction is proper in the courts of the State of Washington because the Distributor defendants are both citizens of the State of Washington, Cuckler has consented to be sued in the State of Washington, and all Plaintiffs were implanted with the Magnum hip replacement in the State of Washington.

18. Venue is proper in the Superior Court of Washington in and for King County in that both the principal place of business and the residence of the Distributor defendants are in King County.

19. Suit is brought on behalf of each of the Plaintiffs to this matter for damages in excess of $75,000.

STATEMENT OF FACTS

A. The Biomet Magnum is different than the typical hip replacement

20. A hip replacement surgery replaces the natural head and socket of the hip joint with artificial components.

21. The majority of hip replacements implanted world-wide over the past several decades have utilized a replacement hip joint consisting of a metal head making contact with an ultra-heavy duty plastic cup inside a metal shell.

22. This typical hip replacement consisting of a metal-plastic interface has been refined to the point that ultra-heavy duty plastic hip replacements have a greater than 99.5 percent success rate per year.

23. The Biomet Magnum instead uses a metal replacement head interfacing directly with a metal shell; there is no plastic liner in the Magnum. Accordingly, this type of hip system is commonly referred to as a metal on metal hip replacement.

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B. Metal on metal hip replacements were tried decades ago and abandoned

24. In the 1960s and early 1970s, hip replacement manufacturers first began to market metal on metal hip replacements to surgeons.

25. Unfortunately, these early metal on metal hip replacements experienced a high rate of heavy metal poisoning and failure.

26. When the metal shell and metal head of these implants rubbed together, they released toxic cobalt and chromium debris into the body.

27. The cobalt and chromium debris resulted in patients suffering heavy metal poisoning, causing tissue death.

28. As a result, the medical community abandoned metal on metal hip replacements in the 1970s.

C. Biomet and Cuckler revived abandoned metal on metal hip replacements with Magnum

29. Despite the prior failure of metal on metal hip replacements to perform as intended, Biomet and Cuckler entered into an agreement to begin designing metal on metal hip replacements in the 1990s.

30. As a result of this collaboration, the Magnum hip replacement was created and began being sold in the United States in 2004.

D. Biomet and Cuckler employed loophole to avoid testing Magnum

31. Despite their knowledge that early metal on metal hip replacements were a failure and resulted in heavy metal poisoning, Biomet and Cuckler conducted extremely limited testing of the Magnum before selling it for implantation into the bodies of patients.

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32. To avoid comprehensive testing of the Magnum hip replacement, Biomet and Cuckler claimed to United States regulators that the Magnum should be "grandfathered-in" because it was substantially similar to hip replacements sold prior to May 28, 1976. [1]

33. This loophole required no testing for safety or efficacy.

E. Defendants claimed that the Magnum was a "lifetime hip" and suitable for use in younger, more active patients

34. Defendants claimed that without the plastic liner to wear out, the Biomet Magnum should last a patient's lifetime.

35. Defendants claimed that the Biomet Magnum was suitable for implantation in younger, more active patients.

36. Defendants promoted the Magnum as a "lifetime hip."

F. Biomet falsely claimed it conducted extensive testing of Magnum

37. Despite the fact that Biomet conducted no clinical testing of the Magnum hip replacement, it has continuously claimed "[t]he Magnum-Magnum™ Large Metal Articulation System offers optimal joint mechanic restoration and ultra low-wear rates in vivo" citing to a 1996 article about previously abandoned types of metal on metal hip replacements.[2]

38. In a 2004 publication titled "Metal Ions – A Scientific Review," Biomet falsely concludes that: "Extensive research and years of clinical trials have failed to prove any cause for concern associated with the ion levels exhibited from metal-on-metal implants."[3]

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[1] *See*, https://www.accessdata.fda.gov/cdrh_docs/pdf4/K042037.pdf containing Biomet Manufacturing Corp.'s 510(k) Summary of Safety and Effectiveness (Last accessed Nov. 2, 2017).
[2] *See*, http://www.biomet.com/campaign/trueAlternativeBearings/BOI03400MagnumDesignRationale.pdf (Last accessed Nov. 2, 2017).
[3] *See* http://www.grossortho.com/images/stories/pdf/currenttopics/MetalIonWhitePaper.pdf. (Last accessed Nov. 2, 2017).

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39. In fact, in a heading on page 7 of the publication, Biomet goes so far as to claim that: "Cobalt and Chromium may be beneficial to the body as established by research and listed by the US government."[4]

40. The 2004 publication by "Biomet Orthopedics, Inc., the Most Responsive Company in Orthopedics," is still available to orthopedic surgeons and the public online today at http://www.grossortho.com/images/stories/pdf/currenttopics/MetalIonWhitePaper.pdf. (Last accessed Nov. 2, 2017).

G. Cuckler conducted secret Magnum marketing campaign in exchange for millions of dollars

41. In conjunction with the promotion of the Magnum hip replacement, Cuckler gave speeches and published articles such as "The Rationale for Metal-on-Metal Total Hip Arthroplasty" published in 2005, claiming that there were "no adverse physiologic effects" to metal on metal hip replacements.

42. At the time that Cuckler published the above article, Biomet was paying Cuckler a percentage of the sale price of Magnum metal on metal hip replacement systems sold in the United States, something Cuckler failed to mention in the article promoting such hip replacements.

43. Pursuant to a Deferred Prosecution Agreement with the Department of Justice, in 2008, Biomet made public that Cuckler received payments from Biomet of between $3.0 and $3.1 million dollars in just the previous year. Extrapolating the one year that Biomet's payments to Cuckler are publically available, leads to the conclusion that Cuckler has received tens of millions of dollars from Biomet.

[4] *Id.*

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H. Thousands of Magnum hip replacements are implanted in Washington citizens

44. Defendants' promotion of the Magnum hip replacement was extremely successful.

45. In Washington State alone, thousands of Magnum metal on metal hip replacements were sold by Defendants and surgically implanted into the bodies of patients.

46. These hip replacements implanted in Washington citizens were designed by Cuckler and Biomet; promoted by Cuckler, Biomet, and Distributor; sold by Biomet and Distributor; and implantation and follow-up instruction was provided to surgeons by Cuckler, Biomet, and Distributor.

I. Defendants continue to claim that the Magnum is safe and successful

47. Defendants sold Magnum hip replacements for implantation into the bodies of patients up to the year 2014.

48. Defendants ceased selling Biomet Magnum metal on metal hip replacement in 2014.

49. However, Defendants have continued to reassure surgeons and the public that the heavy metal poisoning seen with other metal on metal hip replacements is not an issue with the Magnum.

50. To this day, Defendants continue to claim to orthopedic surgeons and the public that the Magnum is a safe and successful product.

J. In 2010 Johnson & Johnson voluntarily recalled almost identical hip replacement

51. Approximately the same time as Defendants began selling the Magnum, Johnson & Johnson began selling the DePuy ASR.

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52. The DePuy ASR was almost identical to the Magnum in its primary design features.

53. Like the Magnum, the DePuy ASR was a monoblock metal on metal hip replacement system with its cobalt chromium alloy head articulating against its cobalt chromium alloy shell.

54. In the summer of 2010, in response to "higher than expected revision rates," Johnson & Johnson conducted a world-wide recall of the DePuy ASR hip replacement.

55. Johnson & Johnson advised surgeons to conduct detailed testing and follow-up of patients with DePuy ASR hip replacements.

56. As a result of the testing and follow-up, dangerously high heavy metal levels were discovered in a significant percentage of patients necessitating surgery to remove the metal on metal hip replacements.

57. Heavy metal poisoning and tissue death from the toxic heavy metals released by the ASR was widely reported in the medical literature.

58. The Defendants were aware of the reports and studies discussing the injuries suffered by metal on metal patients as a result of this very similar product.

K. Defendants' response to the recall of the almost identical product: Sell more Magnums!

59. In response to the 2010 voluntary world-wide recall of an almost identical hip replacement, Defendants did not:

a. Recall Defendants' almost identical Magnum hip replacement.
b. Suspend the sales of their almost identical hip replacement pending a full investigation.
c. Conduct comprehensive testing of the Magnum to ensure it was not prone to causing heavy metal poisoning.

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d. Warn surgeons of the design similarities and the need to inform and carefully follow-up their patients.

60. Instead, Defendants increased promotion of Magnum, attempting to capture market share lost by Johnson & Johnson due to its voluntary recall.

61. Defendants devised marketing strategies to differentiate the Magnum from the recalled ASR hip replacement and other metal on metal hip replacements.

62. Defendants promoted these marketing strategies to surgeons and the public to reassure them that the Magnum did not cause heavy metal poisoning.

L. In 2010, Netherlands hospital warns Biomet of high rate of pseudotumors with Magnum

63. At the same time that Defendants were reassuring orthopedic surgeons and the public of the safety of the Magnum, they were receiving reports of just the opposite.

64. Isala Klinieken ("Isala") located in Zwolle, The Netherlands, has historically had a long and close relationship with Biomet.

65. From 2005 to 2007, Isala implanted patients with Biomet Magnum metal on metal hip replacements.

66. In 2010, Isala reported to Biomet that when it performed CT scans of over 100 patients' hips, more than a third had pseudotumors adjacent to the Magnum hip replacement.

M. Biomet warned that CT/MRI scanning was necessary to see tissue death from Magnum heavy metal poisoning

67. Isala reported to Biomet that the necessity for revision surgery was not identified until Isala conducted the CT scanning of their Magnum patients.

68. Isala warned that by the time that swelling, pain, and clicking indicating tissue

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death resulting from the heavy metal poisoning became apparent, the patient may have already suffered extensive injury.

69. In 2010, Isala informed Biomet that it had ceased implanting Biomet Magnum hip replacements in its patients.

70. Isala encouraged Biomet to adopt a comprehensive screening protocol using CT and MRIs of all patients with Biomet Magnums implanted in their bodies and warned that without such an enhanced protocol, patients may be at risk.

71. The Isala Klinieken reported some of its finding regarding the Magnum in a British medical journal.[5]

72. Despite all of these critical warnings provided by the Isala Klinieken, Defendants failed to inform surgeons or patients in the State of Washington of the study, ignored the need for follow-up screening, and instead continued to promote the Magnum for implantation into the bodies of patients.

N. Finland university reports severe adverse reactions from Magnum heavy metal debris

73. Likewise, Turku University in Turku, Finland has historically had a long and close relationship with Biomet.

74. From 2005 to 2012, the Biomet Magnum metal on metal hip replacement was the most commonly implanted hip replacement at Turku University.

75. In 2013, Turku University reported to Biomet that when the University examined a sample of their patients implanted with the Magnum, over half of the patients were

[5] Bosker B, Ettema H, Boomsma M, et al. High incidence of pseudotumour formation after large-diameter metal-on-metal total hip replacement: a prospective cohort study. *J Bone Joint Surg Br.* 2012 Jun;94(6):755-61.

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experiencing ARMD or "Adverse Reaction to Metal Debris" from the Magnum.

76. MRIs of the sample of Turku University Magnum patients revealed that over half had a psuedotumor or fluid collection in their hip.

77. Despite its long and close relationship with Biomet, in a 2013 publication of the Nordic Orthopedic Federation, Turku University stated that "ARMD is common after … Magnum total hip arthroplasty, and we discourage the use of this device." [6]

78. Defendants failed to inform surgeons or patients in the State of Washington of this study, that Turku University had discouraged use of the Magnum, the need for surgeons to screen their patients for Adverse Reaction to Metal Debris, and instead continued to promote the Magnum for implantation into the bodies of patients.

O. Biomet used Olympic gymnast Mary Lou Retton as Magnum spokesperson

79. As part of the promotion of the Magnum hip replacement, Biomet hired Olympic gold-metal gymnast, Mary Lou Retton, as a spokesperson.

80. Mary Lou Retton had received a Magnum hip replacement in 2005.

81. Biomet heavily promoted to surgeons and the public that the Magnum hip allowed "younger, more active patients, like Mary Lou" to "return to her normal activities, including her workout schedule."[7]

82. Mary Lou Retton was used by Defendants to promote the Magnum in brochures, in newspapers, on radio and television, and in-person to orthopedic surgeons and the public. [8]

83. A heading on Biomet's website proclaims "Mary Lou lives pain-free, and so

[6] Mokka J, Junnila M, Seppänen M, et al. Adverse reaction to metal debris after ReCap-MAGNUM-Magnum large-diameter-head metal-on-metal total hip arthroplasty. *Acta Orthopaedica*. 2013;84(6):549-554.
[7] *See*, http://www.biomet.com/fileLibrary/Patient_Education/PatientEdBrochures/Hip/English/Mary%20Lou%20Retton%20-%20Magnum%20Magnum.pdf (Last accessed Nov. 2, 2017).
[8] *See*, http://www.biomet.com/news/getFile.cfm?id=113&rt=inline&type=pr (Last accessed Nov. 2, 2017).

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should you."[9]

P. Mary Lou Retton has sued Biomet over defective Magnum hip replacement

84. Unfortunately, Mary Lou Retton, like the Plaintiffs in this action, is a Magnum victim.

85. While initially "pain-free," Mary Lou Retton suffered heavy metal poisoning from the Magnum hip replacement necessitating the surgical removal and replacement of the metal on metal hip replacement.

86. Mary Lou Retton was so severely injured by the Magnum metal on metal hip replacement, that despite her status as a celebrity spokesperson for the product, she too has sued the company.

Q. Despite knowing of the failure of the Magnum in Mary Lou Retton for years, Biomet continues to claim her a success story

87. Biomet has failed to inform surgeons and the public that Mary Lou Retton suffered heavy metal poisoning and had to have her Magnum surgically removed.

88. Biomet continues to cite to Mary Lou Retton as a patient success story.

89. Biomet has known of the failure of Mary Lou Retton's hip replacement for years, but has continued to promote to surgeons and the public a false story.

R. Australian government required Biomet to recall Magnum

90. Australia has a world-leading implant registry which keeps track of every orthopedic hip replacement sold, implanted, and replaced in Australia.

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[9] *See*, http://www.biomet.com/fileLibrary/Patient_Education/PatientEdBrochures/Hip/English/Mary%20Lou%20Retton%20-%20Magnum%20Magnum.pdf (Last accessed Nov. 2, 2017).

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91. Biomet ceased selling the Magnum in Australia in 2011.

92. In 2014, the Australian government communicated to Biomet that it was seeing excessive failure rates of the Magnum in Australian patients.

93. In 2015, the Australian government issued a "Hazard Alert" recalling the Biomet Magnum due to a "higher than expected revision rate."

94. Because Biomet had already ceased selling the Magnum in Australia, the Australian government's recall of the Magnum consisted of the "Hazard Alert" and mandating Biomet notify implanting surgeons in Australia of the recall and excessive revision rate.

95. Defendants have failed to disclose to orthopedic surgeons or the public in the State of Washington that the Magnum hip replacement was recalled in Australia and that the Australian government issued a "Hazard Alert" regarding the Magnum.

S. Magnum is a ticking time-bomb implanted in thousands of Washington's citizens' bodies

96. The Biomet Magnum is inherently defective.

97. When implanted in patients, it is prone to release toxic levels of cobalt and chromium.

98. Patients thus can suffer heavy metal poisoning, resulting in elevated levels of cobalt and chromium in the blood, pseudotumors, tissue necrosis, osteolysis, muscle wasting, and other severe injuries.

99. The Defendants' failure to warn surgeons and patients that the Magnum metal on metal hip replacements that were surgically implanted in patients' bodies may be releasing toxic heavy metals has left thousands of Washington patients with ticking time-bombs in their hips.

100. Based on the studies discussed above and others, hundreds, if not thousands, of

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Washington patients have already suffered undiagnosed pseudotumors, tissue death, bone death, etc. as a result of poisoning from the toxic heavy metals released from the Magnum.

T. Washington State is facing a public health disaster from unmonitored Magnums

101. As a result of Defendants' failure to warn surgeons and patients of the necessity for immediate testing and screening of implanted Magnum hip replacements, the number of patients poisoned and severely injured by the Magnum will greatly increase.

102. The State of Washington is facing a public health disaster from unmonitored Magnum metal on metal hip replacements.

U. Plaintiffs have each suffered heavy metal poisoning from Magnum

103. Each of the Plaintiffs to this action were implanted with the Magnum hip replacement, suffered heavy metal poisoning, tissue necrosis, and pain.

104. As a result, the Plaintiffs to this action lost their mobility, needlessly suffered severe pain, were forced to undergo unnecessary revision surgeries, surgical trauma, and extensive rehabilitation.

V. Alan Rossi, MD suffered complicated revision of Magnum necessitating stem revision

105. Dr. Rossi was implanted with the Magnum in Everett, Washington, on February 9, 2009.

106. By 2015, the Magnum had failed to the extent that Dr. Rossi was given the preoperative diagnosis of "failed metal on metal total hip arthroplasty" and an MRI revealed a "large fluid-filled cyst" near the Magnum.

107. On November 3, 2015, Dr. Rossi underwent a revision surgery in Wenatchee,

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Washington, to remove the defective Magnum hip replacement and the large cyst.

108. Upon surgically opening Dr. Rossi, the surgeon encountered a "large fluid-filled cyst with thick mature walls extending down to the hip joint."

109. The surgeon was then able to remove the Magnum head, but was unable to loosen the adapter as it "was essentially welded in place."

110. The surgeon had to significantly open the incision, and using a hammer, chisel the well-fixed stem out of the femur.

111. When the surgeon was finally able to remove the stem, he was forced to wire the fractured femur back together around the revision stem.

112. Anesthesia was initially via a spinal anesthetic, but due to the unexpected length of the surgery, general anesthesia had to be administered.

113. According to the revision operative report, Dr. Rossi lost approximately 1400 ml of blood during the surgery.

114. Rather than the small scar from the initial hip replacement, the complicated nature of the revision surgery left Dr. Rossi with a severe 11 inch scar.

115. Dr. Rossi then suffered an extremely long and painful recovery and rehabilitation from the replacement not only of the Magnum head, but the traumatic removal and replacement of a well-fixed stem.

W. James Millard required bilateral Magnum revisions but damage was so severe that surgeon could not safely remove one of the Magnum implants

116. Mr. Millard was implanted with Magnum hip replacements in Olympia, Washington, on December 14, 2009, on the right side and on July 2, 2012, on the left side.

117. By 2017, both Magnums had failed to the extent that Mr. Millard was scheduled

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to undergo bilateral revision surgeries to remove and replace the Magnum hip replacements.

118. Surgery to revise the left Magnum occurred on June 14, 2017, in Olympia, Washington, with the preoperative diagnosis of "[f]ailed total hip arthroplasty attributable to metal ion toxicity" and the postoperative being the same.

119. Surgery to revise the right Magnum occurred on February 12, 2017, in Olympia, Washington, with the preoperative diagnosis of "[f]ailing right total hip arthroplasty attributable to metal-on-metal and toxicity."

120. Upon surgically opening Mr. Millard, the surgeon identified "scarred synovial tissue removed to the size of several centimeters squared."

121. Following the removal of the scarred synovial tissue, the surgeon attempted to remove the femoral head from the stem stating in the operative report, "[s]everal hundred attempts were made peripherally around the femoral head with the bone tamp with significant force."

122. The surgeon goes on to state in the revision operative report:

> I even tried to rotate the femoral head relative to the stem by tapping tangentially on the inset markers at the underside of the femoral head, none of which would disengage the head or loosen it. Then we attempted pounding it on to the stern to loosen it. This also failed.
> After 45 minutes of attempted removal techniques, I felt it was safer to abandon any further attempts so as not to risk fracturing the femur.

123. The surgeon was then forced to close Mr. Millard's wound with staples, leaving the failing Magnum hip replacement in his body.

124. Mr. Millard was thus forced to recover from two revision surgeries, the second unsuccessful in removing the defective Magnum hip replacement, leaving the defective Magnum hip still implanted in his body.

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X. Ellen Pardee suffered heavy metal tissue death that partially destroyed her iliotibial band

125. Ms. Pardee was implanted with the Magnum in Bellevue, Washington, on March 2, 2010.

126. By 2017, her Magnum had failed to the extent that Ms. Pardee was given the preoperative diagnosis of "[failure] of metal-on-metal left total hip replacement due to adverse local tissue reaction and large pseudocyst."

127. In the revision operative report, the surgeon stated "[w]orkup with MRI showed that the patient had a large cystic mass in the posterolateral aspect of her hip, consistent with a pseudotumor related to adverse local tissue reaction from her metal-on-metal prosthesis."

128. Upon surgically opening Ms. Pardee, the surgeon noted the following:

> After a small area was entered, a large amount of turbid yellow fluid came out from a cystic structure directly underneath the iliotibial band. Fluid was collected for culture and sensitivity. The iliotibial band and gluteal fascia were opened along the entire length of the incision. There was an extremely large cystic mass with yellowish-brown caseating lining that was very friable. There was a 4-5 mm thick capsule around it. It measured approximately 5 inches in length, was approximately 2.5 inches wide and tracked down to the hip capsule.
> A tedious and meticulous dissection was carried down along the outside of the capsule, tracking it down into the posterolateral aspect of the hip joint. The capsule of the tumor was involved with the iliotibial band and had partially destroyed the iliotibial band in the distal portion of the wound. It involved the posterior aspect of the hip abductor tendon mass and all the muscles in the posterior aspect of the hip in the area of the small rotators were involved.

129. The surgeon then removed the Magnum head and cup.

130. Ms. Pardee then underwent a long and painful recovery and rehabilitation from the replacement of the Magnum head and cup.

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DAMAGES AND CAUSES OF ACTION

131. As a direct and proximate result of the defective Magnum hip replacement, Plaintiffs suffered injuries, including but not limited to significant pain, tissue destruction, bone destruction, metal wear, metal poisoning, loss of enjoyment of life, and limitation of daily activities.

132. Plaintiffs expect to continue suffering such injuries in the future as a result of the injuries received from the Magnum.

133. As a direct and proximate result of the defective Magnum, Plaintiffs incurred medical expenses and expect to incur additional medical expenses in the future.

134. As a direct and proximate result of the defective Magnum, Plaintiffs incurred lost earning potential, income and earnings.

135. As a direct and proximate result of the defective Magnum, Plaintiffs experienced emotional trauma and distress and are likely to experience emotional trauma and distress in the future.

136. Plaintiffs are not at fault for their own injuries rendering Defendants jointly liable under Wash. Rev Code Section 4.22.070.

COUNT ONE – ALL DEFENDANTS – FAILURE TO WARN
[Pursuant to Wash. Rev. Code Section 7.72.010(4)]

137. Plaintiffs re-allege and incorporate by reference the paragraphs above as if fully stated herein.

138. At the time that Defendants designed, developed, promoted and manufactured the Magnum, such device contained defects that made it unreasonably dangerous beyond the expectations of the ordinary consumer, and was unfit for its intended use.

139. The Magnum reached Plaintiffs without substantial change in the condition in

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which it was designed, developed, promoted, manufactured, and sold.

140. At the time and on the occasions in question, the Magnum was being properly used for the purpose for which it was intended, and such device was in fact defective, unsafe and unreasonably dangerous.

141. The foreseeable risk of harm from the defects in the Magnum could have been reduced or avoided by providing adequate instructions or warnings.

142. Defendants had a continuing, post-sale duty to warn regarding the unreasonable risk of harm associated with the Magnum.

143. Defendants had sufficient notice about specific dangers associated with the Magnum.

144. Defendants failed to provide adequate instructions or warnings regarding the defects in the Magnum which were known by Defendants or should have been known by Defendants and could have been provided.

145. Defendants failed to exercise reasonable care to inform Plaintiffs, Plaintiff's doctors, and the medical community about dangers regarding the Magnum that Defendants knew or should have known before and after the Magnum was sold.

146. As a direct and proximate result of the lack of reasonable and adequate instructions or warnings regarding the defects in the Magnum, the Plaintiffs suffered the injuries described above.

COUNT TWO – ALL DEFENDANTS – DESIGN AND MANUFACTURING DEFECT
[Pursuant to Wash. Rev. Code Section 7.72.010(4)

147. Plaintiffs re-allege and incorporate by reference the paragraphs above as if fully stated herein.

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148. At the time that Defendants designed, developed, and promoted the Magnum implanted in Plaintiffs, and at the time the Magnum was manufactured, the likelihood that the product would cause Plaintiffs' harm or similar harms, and the seriousness of those harms, outweighed the burden on Defendants to design a product that would have prevented those harms and the adverse effect that an alternative design that was practical and feasible would have on the usefulness of the product.

149. The Magnums implanted in Plaintiffs contained a manufacturing defect in that it differed from Defendant's design.

150. Defendants were aware that they were unable to adequately conform the manufacturing process to the Magnum's design.

151. The Magnum was unreasonably dangerous beyond the expectations of the ordinary consumer, and was unfit for its intended use.

152. The Magnum reached Plaintiffs without substantial change in the condition in which it was sold.

153. At the time and on the occasions in question, the Magnum was being properly used for the purpose for which it was intended, and such device was in fact defective, unsafe and unreasonably dangerous.

154. A number of feasible alternative designs existed at the time Plaintiffs were implanted with the Magnum, including hip replacements utilizing ultra-heavy duty plastic.

155. As a direct and proximate result of the defects in the Magnum, Plaintiffs suffered the injuries as described above.

COUNT THREE – ALL DEFENDANTS – BREACH OF WARRANTY
[Pursuant to Wash. Rev. Code Section 7.72.010(4)]

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156. Plaintiffs re-allege and incorporate by reference the paragraphs above as if fully stated herein.

157. Defendants expressly warranted that the Magnum was reasonably fit for its intended purpose as a hip replacement system. These warranties included, without limitation, the allegations above as well as the following:

a. The Magnum produced less wear than competing devices;
b. The Magnum was a clinically safe system;
c. The Magnum was stronger and designed to last longer than competing devices;
d. The Magnum did not exhibit high rates of revisions;
e. Fluid film lubrication would prevent contact of the ball and cup during articulation;
f. The Magnum was a safer alternative to metal on plastic hips using ultra-heavy duty plastic liners.

158. Plaintiff were reasonably foreseeable users of the Magnum.

159. Defendant's warranties regarding the Magnum related to material facts regarding the safety and efficacy of the Magnum.

160. Defendant's warranties were part of the basis of the bargain for Plaintiffs' Magnums.

161. Defendant's warranties proved to be untrue.

162. As a direct and proximate result of the breach of the warranties regarding the Magnum, Plaintiffs suffered the injuries as described above.

COUNT FOUR – ALL DEFENDANTS – INTENTIONAL MISREPRESENTATION [Pursuant to Wash. Rev. Code Section 7.72.010(4)]

163. Plaintiffs re-allege and incorporate by reference the paragraphs above as if fully stated herein.

164. As stated above, Defendants made misrepresentations of material facts about the

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Magnum or intentionally concealed information about the Magnum from Plaintiffs, Plaintiffs' orthopedic surgeons, and the medical community prior to and after Plaintiff was implanted with the Magnum.

165. Additional misrepresentations and concealment included, but were not limited to:

a. Falsely representing the Magnum as reducing wear and providing higher function for patients than other available hip systems.
b. Falsely representing that the Magnum is a safer and stronger alternative when compared with other available hip systems.
c. Falsely representing that the Magnum provided fluid film lubrication.
d. Failing to disclose the clinical significance and safety concerns regarding heavy metal poisoning.
e. Failing to disclose patterns and trends of failure Magnum implants.

166. The above representations and omissions were material and were made with the intent to persuade and induce Plaintiffs, Plaintiffs' surgeons, and the medical community to choose the Magnum hip system.

167. Defendants made the above representations or omissions knowing the misrepresentations were false or were ignorant of the truth of the assertion.

168. Defendants made the above misrepresentations or omissions with the intention of inducing Plaintiffs and Plaintiffs' orthopedic surgeon to purchase the Magnum.

169. Plaintiffs and Plaintiffs' orthopedic surgeons relied upon and were induced to act in reliance on Defendants' misrepresentations or omissions and in fact purchased the Magnum based on these misrepresentations or omissions.

170. As a direct and proximate result of the breach of the warranties regarding the Magnum, Plaintiffs suffered injuries as described above.

COUNT FIVE – BIOMET AND CUCKLER DEFENDANTS – NEGLIGENCE
[Pursuant to Wash. Rev. Code Section 7.72.010(4)]

171. Plaintiffs re-allege and incorporate by reference the paragraphs above as if fully

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stated herein.

172. Biomet and Cuckler designed, tested, distributed, manufactured, advertised, sold, and marketed the Magnum for implantation into consumers such as Plaintiff by physicians and surgeons.

173. Biomet and Cuckler were negligent and careless in the design, testing, distribution, manufacture, advertising, sale and marketing of the Magnum.

174. Biomet and Cuckler had a duty to perform adequate evaluation on the safety and efficacy of the Magnum. This included by reasonably gathering information regarding complaints and revisions and conducting adequate analysis on the information gathered.

175. Biomet and Cuckler further had a duty to share the results of its evaluation so that Plaintiffs, Plaintiffs' orthopedic surgeons, and the orthopedic community could be adequately apprised of the risks of the Magnum.

176. Biomet and Cuckler failed to adequately evaluate the safety and efficacy of the Magnum.

177. Biomet and Cuckler failed to adequately share the results of its evaluations of the Magnum with Plaintiffs, Plaintiffs' orthopedic surgeons, or the orthopedic community.

178. Biomet and Cuckler's failures to discharge their duties were a direct and proximate cause of Plaintiffs' injuries as described above.

COUNT SIX – DISTRIBUTOR DEFENDANTS – NEGLIGENCE
[Pursuant to Wash. Rev. Code Section 7.72.010(4)]

179. Plaintiffs re-allege and incorporate by reference the paragraphs above as if fully stated herein.

180. Distributor marketed, advertised, sold, and distributed the Magnum for

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implantation into consumers such as Plaintiff by surgeons.

181. Sales representatives working for Distributor were responsible for educating and continuously guiding surgeons regarding the proper patient selection, surgical planning, component selection, surgical technique, and post-surgery follow-up.

182. Surgeons, such as the Plaintiffs' surgeons, reasonably relied upon Distributor to properly perform these functions and Distributor had a duty to do so.

183. Distributor failed to properly perform these functions as described above and their failure to discharge these duties were a direct and proximate cause of Plaintiffs' injuries as described above.

COUNT SEVEN – ALL DEFENDANTS – UNFAIR TRADE PRACTICES
[Pursuant to Wash. Rev. Code Section 19.86.010]

184. Plaintiffs re-allege and incorporate by reference the paragraphs above as if fully stated herein.

185. The acts by Defendants in this cause of action include, but are not limited to, the following deceptive and unfair acts:

a. Representing the Magnum as a device clinically proven to be safe and effective.
b. Representing the Magnum to be of a higher quality and more desirable product than other available alternatives.
c. Failing to disclose adequate information about the safety and efficacy of the Magnum either before or after Plaintiffs' purchase.
d. Knowingly providing inadequate warnings about the Magnum's dangerous propensities.

186. Such acts occurred in the course of trade or commerce in the State of Washington.

187. Such acts affected, and still affect, the public interest of all the citizens of the State of Washington.

188. Such acts caused injury to Plaintiffs as described above.

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DEMAND FOR JURY TRIAL

189. Plaintiffs respectfully request that a jury be impaneled to hear this cause of action and to award such damages as the jury finds to be fair and reasonable under the circumstances.

WHEREFORE, Plaintiffs respectfully demand judgment against Defendants for compensatory damages and any other relief the Court deems just and proper.

Dated this 27th day of November, 2017.

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