IN THE SUPERIOR COURT OF THE STATE OF WASHINGTON,
IN AND FOR THE COUNTY OF KING

KRISTEN VITTONE; LESLIE MEDERS; And LARRY THOMA, 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.: 18-2-57874-4 SEA COMPLAINT FOR PERSONAL INJURY

COMPLAINT

Plaintiffs, KRISTEN VITTONE; LESLIE MEDERS; and LARRY THOMA ("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 at issue in this case is the "Biomet M2a Metal on Metal Hip Replacement" which includes both the Biomet M2a-38 and the Biomet M2a-Magnum (hereafter referred to as the "M2a").

3. Plaintiffs were all implanted with Biomet M2a metal on metal hip replacements 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."

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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, 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 M2a 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 M2a.

10. At all times relevant to this Complaint, Plaintiffs' surgeons relied upon information provided by Distributors' sales representatives in selecting the M2a hip replacement for implantation into the Plaintiffs' bodies.

11. Distributor profited from the promotion, sale, and servicing of the M2a 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.

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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 M2a 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 M2a hip replacements at issue in the instant case and directed his promotion of the M2a at surgeons and patients located in the State of Washington.

16. Cuckler, by and through his attorneys, consented to the jurisdiction of the courts of the State of Washington.

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, Cuckler directed his promotion of the M2a to surgeons and patients in the State of Washington, and all Plaintiffs were implanted with the M2a 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.

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STATEMENT OF FACTS

A. The Biomet M2a 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 M2a instead uses a metal replacement head interfacing directly with a metal shell; there is no plastic liner in the M2a. Accordingly, this type of hip system is commonly referred to as a metal on metal hip replacement.

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

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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 M2a

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 M2a hip replacement was created and began being sold in the United States in 2001.

D. Biomet and Cuckler employed loophole to avoid testing M2a

31. Despite their knowledge that early metal on metal hip replacements were a failure and resulted in heavy metal poisoning, Biomet and Cuckler conducted almost no testing of the M2a before selling it for implantation into the bodies of patients.

32. To avoid comprehensive testing of the M2a hip replacements, Biomet and Cuckler claimed to United States regulators that the M2a 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.

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[1] *See*, https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K011110 and https://www.accessdata.fda.gov/cdrh_docs/pdf4/K042037.pdf containing Biomet Manufacturing Corp.'s 510(k) Summary of Safety and Effectiveness (Last accessed Aug. 22, 2018).

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E. Defendants claimed that the M2a 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 M2a should last a patient's lifetime.

35. Defendants claimed that the Biomet M2a was suitable for implantation in younger, more active patients.

36. Defendants promoted the M2a as a "lifetime hip."

37. Defendants represented that the expected useful safe life of the M2a was well in excess of 20 years.

F. Biomet falsely claimed it conducted extensive testing of M2a

38. Despite the fact that Biomet conducted no clinical testing of the M2a hip replacements, it has continuously made claims such as "[t]he M2a-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]

39. 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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[2] *See*, http://www.biomet.com/campaign/trueAlternativeBearings/BOI03400MagnumDesignRationale.pdf (Last accessed Aug. 22, 2018).

[3] *See* http://www.grossortho.com/images/stories/pdf/currenttopics/MetalIonWhitePaper.pdf. (Last accessed Aug. 22, 2018).

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40. 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]

41. 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 Aug. 22, 2018).

G. Cuckler conducted secret M2a marketing campaign in exchange for millions of dollars

42. In conjunction with the promotion of the M2a 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.

43. At the time that Cuckler published the above article, Biomet was paying Cuckler a percentage of the sale price of M2a metal on metal hip replacements sold in the United States, something Cuckler failed to mention in the article promoting such hip replacements.

44. 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

[4] *Id.*

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to Cuckler are publically available, leads to the conclusion that Cuckler has received tens of millions of dollars from Biomet.

H. Thousands of M2a hip replacements are implanted in Washington citizens

45. Defendants' promotion of the M2a hip replacement was extremely successful.

46. In Washington State alone, thousands of M2a metal on metal hip replacements were sold by Defendants and surgically implanted into the bodies of patients.

47. 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 M2a is safe and successful

48. Defendants sold M2a hip replacements for implantation into the bodies of patients up to the year 2014 or 2015.

49. Defendants ceased selling Biomet M2a metal on metal hip replacements in 2014 or 2015.

50. 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 M2a.

51. To this day, Defendants continue to claim to orthopedic surgeons and the public that the M2a is a safe and successful product.

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

52. Soon after the Defendants began selling the M2a, Johnson & Johnson began selling the DePuy ASR.

53. The DePuy ASR was almost identical to the M2a in its primary design features.

54. Like the M2a, 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.

55. 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.

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

57. 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.

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

59. 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 M2as!

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

a. Recall Defendants' almost identical M2a hip replacement.
b. Suspend the sales of their almost identical hip replacement pending a full investigation.

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c. Conduct comprehensive testing of the M2a to ensure it was not prone to causing heavy metal poisoning.

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

61. Instead, Defendants increased promotion of M2a, attempting to capture market share lost by Johnson & Johnson due to its voluntary recall.

62. Defendants devised marketing strategies to differentiate the M2a from the recalled ASR hip replacement and other metal on metal hip replacements.

63. Defendants promoted these marketing strategies to surgeons and the public to reassure them that the M2a did not cause heavy metal poisoning.

L. In 2010, Netherlands hospital warns Biomet of high rate of pseudotumors with M2a

64. At the same time that Defendants were reassuring orthopedic surgeons and the public of the safety of the M2a, they were receiving reports of just the opposite.

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

66. Isala was in fact a Biomet funded study site.

67. Prior to 2007, Isala implanted patients with a significant number of Biomet M2a metal on metal hip replacements.

68. 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 M2a hip replacement.

M. <u>Biomet warned that CT/MRI scanning was necessary to see tissue death from M2a heavy metal poisoning</u>

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69. Isala reported to Biomet that the necessity for revision surgery was not identified until Isala conducted the CT scanning of their M2a patients.

70. Isala warned that by the time that swelling, pain, and clicking indicating tissue death resulting from the heavy metal poisoning became apparent, the patient may have already suffered extensive injury.

71. In 2010, Isala informed Biomet that it had ceased implanting Biomet M2a hip replacements in its patients.

72. Isala encouraged Biomet to adopt a comprehensive screening protocol using CT and MRIs of all patients with Biomet M2as implanted in their bodies and warned that without such an enhanced protocol, patients may be at risk.

73. The Isala Klinieken reported some of its finding regarding the M2a in a British medical journal.[5]

74. 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 M2a for implantation into the bodies of patients.

N. <u>Finland university reports severe adverse reactions from M2a heavy metal debris</u>

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

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[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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76. Like Isala, Turku University was a Biomet funded study site.

77. From 2005 to 2012, the Biomet M2a metal on metal hip replacement was the most commonly implanted hip replacement at Turku University.

78. In 2013, Turku University reported to Biomet that when the University examined a sample of their patients implanted with the M2a, over half of the patients were experiencing ARMD or "Adverse Reaction to Metal Debris" from the M2a.

79. MRIs of the sample of Turku University M2a patients revealed that over half had a psuedotumor or fluid collection in their hip.

80. 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]

81. Defendants failed to inform surgeons or patients in the State of Washington of this study, that Turku University had discouraged use of the M2a, the need for surgeons to screen their patients for Adverse Reaction to Metal Debris, and instead continued to promote the M2a for implantation into the bodies of patients.

O. <u>Biomet used Olympic gymnast Mary Lou Retton as M2a spokesperson</u>

82. As part of the promotion of the M2a hip replacement, Biomet hired Olympic gold-metal gymnast, Mary Lou Retton, as a spokesperson.

83. Mary Lou Retton had received M2a hip replacements in the mid-2000's.

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[6] Mokka J, Junnila M, Seppänen M, et al. Adverse reaction to metal debris after ReCap-M2A-Magnum large-diameter-head metal-on-metal total hip arthroplasty. *Acta Orthopaedica*. 2013;84(6):549-554.

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84. Biomet heavily promoted to surgeons and the public that the M2a hip allowed "younger, more active patients, like Mary Lou" to "return to her normal activities, including her workout schedule."[7]

85. Mary Lou Retton was used by Defendants to promote the M2a in brochures, in newspapers, on radio and television, and in-person to orthopedic surgeons and the public. [8]

86. A heading on Biomet's website proclaims "Mary Lou lives pain-free, and so should you."[9]

P. Mary Lou Retton has sued Biomet over defective M2a hip replacement

87. Unfortunately, Mary Lou Retton, like the Plaintiffs in this action, is a M2a victim.

88. While initially "pain-free," Mary Lou Retton suffered heavy metal poisoning from the M2a hip replacement necessitating the surgical removal and replacement of the metal on metal hip replacements.

89. Mary Lou Retton was so severely injured by the M2a metal on metal hip replacement, that despite her status as a celebrity spokesperson for the product, she too has sued the company.

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[7] *See*, http://www.biomet.com/fileLibrary/Patient_Education/PatientEdBrochures/Hip/English/Mary%20Lou%20Retton%20-%20M2a%20Magnum.pdf (Last accessed Nov. 2, 2017).
[8] *See*, http://www.biomet.com/news/getFile.cfm?id=113&rt=inline&type=pr (Last accessed Aug. 22, 2018).
[9] *See*, http://www.biomet.com/fileLibrary/Patient_Education/PatientEdBrochures/Hip/English/Mary%20Lou%20Retton%20-%20M2a%20Magnum.pdf (Last accessed Aug. 22, 2018).

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Q. Despite knowing of the failure of the M2a in Mary Lou Retton for years, Biomet continues to claim her a success story

90. Biomet has failed to inform surgeons and the public that Mary Lou Retton suffered heavy metal poisoning and had to have her M2a surgically removed.

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

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

R. Australian government required Biomet to recall M2a

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

94. Biomet ceased selling the M2a in Australia in 2011.

95. In 2014, the Australian government communicated to Biomet that it was seeing excessive failure rates of the M2a in Australian patients.

96. In 2015, the Australian government issued a "Hazard Alert" recalling the Biomet M2a due to a "higher than expected revision rate."

97. Because Biomet had already ceased selling the M2a in Australia, the Australian government's recall of the M2a consisted of the "Hazard Alert" and mandating Biomet notify implanting surgeons in Australia of the recall and excessive revision rate.

98. Defendants have failed to disclose to orthopedic surgeons or the public in the State of Washington that the M2a hip replacement was recalled in Australia and that the Australian government issued a "Hazard Alert" regarding the M2a.

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S. Since 2012 Biomet has had false M2a failure rate data posted on its website

99. From 2012 until today, Biomet had posted on its website under the heading "Important information regarding metal-on-metal hips" data purporting to show the success of Biomet's metal on metal hip replacements at http://www.biomet.com/wps/portal/internet/Biomet/Healthcare-Professionals/products/orthopedics/important-information-mom-hips (Last accessed Dec. 13, 2018.).

100. The "Important information regarding metal-on-metal hips" is clearly intended to reassure patients and surgeons that Biomet's metal on metal hip replacements are safe and performing as intended.

101. The "Important information regarding metal-on-metal hips" states "Biomet has been closely monitoring the available data regarding its [metal on metal] hip devices."

102. The "Important information regarding metal-on-metal hips" claims that there is no statistically significant difference between survivorship of the Biomet Magnum and the Biomet M2a-38 and hip replacements generally in the Australian National Joint Registry and the England and Wales National Joint Registry.

103. By 2015, at the latest, Biomet was aware that the Biomet Magnum and M2a-38 were failing at a statically significantly higher rate than hip replacements generally in the Australian National Joint Registry.

104. Likewise, for years Biomet has been aware that the Magnum and M2a-38 were failing at a significantly significant higher rate in the England and Wales National Joint Registry than hip replacements generally.

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105. Despite knowing that it would mislead orthopedic surgeons and the public concerning the safety of its metal on metal hip replacements, Biomet has continued to promote false information regarding the safety of its M2a hip replacement.

T. Biomet M2a are a ticking time-bomb implanted in thousands of Washington's citizens' bodies

106. The Biomet M2a is inherently defective.

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

108. Patients thus can suffer heavy metal poisoning, resulting in elevated levels of cobalt and chromium in the blood, pseudotumors, tissue necrosis, muscle wasting, bone loss, heart death, and other severe injuries.

109. The Defendants' failure to warn surgeons and patients that the M2a 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.

110. Based on the studies discussed above and others, hundreds, if not thousands, of Washington patients have already suffered undiagnosed tissue death and pseudotumors as a result of poisoning from the toxic heavy metals released from the M2a.

U. Washington State is facing a public health disaster from unmonitored M2as

111. As a result of Defendants' failure to warn surgeons and patients of the necessity for immediate testing and screening of implanted M2a hip replacements, the number of patients poisoned and severely injured by the M2a will greatly increase.

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112. The State of Washington is facing a public health disaster from unmonitored M2a metal on metal hip replacements.

V. Plaintiffs have each suffered heavy metal poisoning from M2a

113. Each of the Plaintiffs to this action were implanted with the M2a hip replacement, suffered heavy metal poisoning, tissue death, bone loss, and pain.

114. Within days of being implanted with the M2a hip replacements Plaintiffs began suffering heavy metal poisoning from the M2a hip replacements.

115. 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.

W. Kristen Vittone underwent a painful revision surgery for her failed right M2a, which revealed necrotic tissue and other signs of metallosis damage.

116. Ms. Vittone was implanted with the M2a into her right hip on November 26, 2007, by Thomas K. Stonecipher, MD at Providence Hospital, Everett Medical Center, in Everett, Washington.

117. In February 2017, Ms. Vittone's doctor discovered problems with the M2a when a test revealed elevated levels cobalt and chromium ions in her blood. Ms. Vittone's subsequent MRI revealed extra fluid accumulations around the hip. Accordingly she was scheduled for a revision surgery to remove and replace the failed M2a hip product.

118. On February 22, 2018, Ms. Vittone underwent right hip revision surgery by Charles F. Jung, MD, at Swedish Medical Center in Seattle, Washington. During the procedure,

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Dr. Jung confirmed the diagnosis of a failed right metal-on-metal hip replacement, with an inflammatory reaction, and removed brownish discolored synovial tissue beneath the fascia.

119. A surgical pathology report indicated that the excised synovial tissue reflected a "stromal reactive change" and "necrotic" [dead] tissue conditions. In addition, testing on the excised fascial tissue of Ms. Vittone's right hip revealed "[f]ragments of fibrous synovial-like tissue with dense hemosiderin-laden macrophages."

120. Dr. Jung was able to complete a right total hip acetabular revision and femoral head exchange, replacing defective components with ceramic head on a polyethylene liner, rendering it no longer a metal on metal hip replacement.

121. Ms. Vittone then suffered a long and painful recovery and rehabilitation from the removal and replacement of her right M2a. The failure of the hip and resulting revision has been very disruptive and damaging to Ms. Vittone's home and work life.

X. Leslie Meders' failed Biomet M2a led to metallosis and a series of painful and damaging surgical procedures

122. Ms. Meders was implanted with a M2a hip replacement in her left hip on June 10, 2008, by Ronald Wu, MD at PeaceHealth St. Joseph's Medical Center, in Bellingham, Washington.

123. In July of 2017, it was determined that Ms. Meders' M2a implant had failed to the extent that she had developed metallosis in her left hip area. She was referred to Dr. Ronald Wu who confirmed elevated metal levels as well as a large are of osteolysis behind the M2a. Dr. Wul determined that Ms. Meders should undergo surgery to remove and replace the Biomet M2a. Revision surgery was ultimately scheduled for February 20, 2018.

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124. On January 8, 2018, Ms. Meders was admitted to the St. Joseph hospital with worsening left him and back pain, and a large left hip abscess was discovered with fluid collections related to infection. These conditions were related to Ms. Meders' metallosis. On January 10, 2018, Ms. Meders underwent a difficult surgery to address the situation. During the surgery Dr. Leonard Klodychuk noted that Ms. Meders' M2a was dislocated. Dr. Klodychuk performed an extended trochanteric osteotomy to explant the infected component, which resulted in a trochanteric bone fracture. During the procedure a number of saw blades were broken trying to remove the Biomet stem. The cup itself was removed using the Biomet explant system.

125. On January 16, 2018, while drains for Ms. Meders' infection were being changed, it was noted that her spacer and implant had become dislocated. Ms. Meders was forced to undergo another surgery due to address a dislocation of the antibiotic spacer, and to exchange the femoral neck component of the implant. This complex surgery was performed by Dr. Leonard Kolodychuk, with Dr. Steven Bruce as cosurgeon.

126. On January 29, 2018, Ms. Meders underwent a third surgical procedure to drain a large post-operative seroma (a pocket of inflammatory fluid produced by injured and dying cells) in the area of the failed Biomet M2a impant. This surgery was performed by Dr. Jeffrey Krusniak.

127. Finally, Dr. Wu surgically completed the revision of the failed Biomet M2a implant that had been scheduled for February 20, 2018. at St. Joseph's Medical Center.

128. Ms. Meders was thus forced to undergo an arduous series of difficult surgeries, followed by an extremely long and painful recovery and rehabilitation. The aftermath of the failed implant and metallosis has negatively impacted her life in many ways.

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Y. Larry Thoma suffered extensive heavy metal tissue death and severe bone loss

129. On January 26, 2006, Mr. Thoma was implanted with the M2a in his left hip by Thomas Stonecipher, M.D., at Providence Everett Medical Center, in Everett Washington.

130. In September of 2018, Mr. Thoma had a fall. Imaging confirmed that the impact had shattered Mr. Thoma's left hip bone.

131. Mr. Thoma was scheduled with Dr. Mark Mildred for a revision surgery, which occurred on September 26, 2018 at PeaceHealth Sacred Heart Medical Center in Eugene, Oregon. During the surgery, Dr. Mildred observed a "Vancouver B2 periprosthetic fracture", a "greater trochanteric fracture", and "severe metallosis with near complete destruction of the postlateral cortex of the proximal femoral femur". During the procedure, Dr. Mildred removed and replaced the failed M2a and did his best to address the metallosis and associated damage.

132. Mr. Thoma then underwent a long and painful recovery and rehabilitation from the revision of the failed Biomet M2a. To this day, his life is impacted by the defective product.

DAMAGES AND CAUSES OF ACTION

133. As a direct and proximate result of the defective M2a 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.

134. Plaintiffs expect to continue suffering such injuries in the future as a result of the injuries received from the M2a.

135. As a direct and proximate result of the defective M2a, Plaintiffs incurred medical expenses and expect to incur additional medical expenses in the future.

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136. As a direct and proximate result of the defective M2a, Plaintiffs incurred lost earning potential, income and earnings.

137. As a direct and proximate result of the defective M2a, Plaintiffs experienced emotional trauma and distress and are likely to experience emotional trauma and distress in the future.

138. 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)]

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

140. At the time that Defendants designed, developed, promoted and manufactured the M2a, such device contained defects that made it unreasonably dangerous beyond the expectations of the ordinary consumer, and was unfit for its intended use.

141. The M2a reached Plaintiffs without substantial change in the condition in which it was designed, developed, promoted, manufactured, and sold.

142. At the time and on the occasions in question, the M2a was being properly used for the purpose for which it was intended, and such device was in fact defective, unsafe and unreasonably dangerous.

143. The foreseeable risk of harm from the defects in the M2a could have been reduced or avoided by providing adequate instructions or warnings.

144. Defendants had a continuing, post-sale duty to warn regarding the unreasonable risk of harm associated with the M2a.

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145. Defendants had sufficient notice about specific dangers associated with the M2a.

146. Defendants failed to provide adequate instructions or warnings regarding the defects in the M2a which were known by Defendants or should have been known by Defendants and could have been provided.

147. Defendants failed to exercise reasonable care to inform Plaintiffs, Plaintiff's doctors, and the medical community about dangers regarding the M2a that Defendants knew or should have known before and after the M2a was sold.

148. As a direct and proximate result of the lack of reasonable and adequate instructions or warnings regarding the defects in the M2a, 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)

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

150. At the time that Defendants designed, developed, and promoted the M2a implanted in Plaintiffs, and at the time the M2a 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.

151. The M2as implanted in Plaintiffs contained a manufacturing defect in that it differed from Defendant's design.

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152. Defendants were aware that they were unable to adequately conform the manufacturing process to the M2a's design.

153. The M2a was unreasonably dangerous beyond the expectations of the ordinary consumer, and was unfit for its intended use.

154. The M2a reached Plaintiffs without substantial change in the condition in which it was sold.

155. At the time and on the occasions in question, the M2a was being properly used for the purpose for which it was intended, and such device was in fact defective, unsafe and unreasonably dangerous.

156. A number of feasible alternative designs existed at the time Plaintiffs were implanted with the M2a, including hip replacements utilizing ultra-heavy duty plastic.

157. As a direct and proximate result of the defects in the M2a, Plaintiffs suffered the injuries as described above.

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

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

159. Defendants expressly warranted that the M2a 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 M2a produced less wear than competing devices;
b. The M2a was a clinically safe system;
c. The M2a was stronger and designed to last longer than competing devices;
d. The M2a was a lifetime hip replacement;
e. The M2a did not exhibit high rates of revisions;

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f. Fluid film lubrication would prevent contact of the ball and cup during articulation;
g. The M2a was a safer alternative to metal on plastic hips using ultra-heavy duty plastic liners.

160. Plaintiff were reasonably foreseeable users of the M2a.

161. Defendant's warranties regarding the M2a related to material facts regarding the safety and efficacy of the M2a.

162. Defendant's warranties were part of the basis of the bargain for Plaintiffs' M2as.

163. Defendant's warranties proved to be untrue.

164. As a direct and proximate result of the breach of the warranties regarding the M2a, Plaintiffs suffered the injuries as described above.

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

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

166. As stated above, Defendants made misrepresentations of material facts about the M2a and intentionally concealed information about the M2a from Plaintiffs, Plaintiffs' orthopedic surgeons, and the medical community prior to and after Plaintiff was implanted with the M2a.

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

a. Falsely representing the M2a as reducing wear and providing higher function for patients than other available hip systems.
b. Falsely representing that the M2a is a safer and stronger alternative when compared with other available hip systems.
c. Falsely representing that the M2a 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 of M2a hip replacements.
f. Failing to disclose heavy metal poisoning of patients with M2a hip replacements.

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168. 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 M2a hip replacements and to continue to utilize M2a hip replacements.

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

170. Defendants made the above misrepresentations and omissions with the intention of inducing Plaintiffs and Plaintiffs' orthopedic surgeon to purchase M2a hip replacements and to continue to do so.

171. Plaintiffs and Plaintiffs' orthopedic surgeons relied upon and were induced to act in reliance on Defendants' misrepresentations or omissions and in fact purchased the M2a based on these misrepresentations and omissions and were delayed in following-up on heavy metal poisoning from the M2a hip replacements based upon Defendants' misrepresentations and omissions.

172. As a direct and proximate result of the misrepresentations and omissions regarding the M2a, Plaintiffs suffered injuries as described above.

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

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

174. Biomet and Cuckler designed, tested, distributed, manufactured, advertised, sold, and marketed the M2a for implantation into consumers such as Plaintiff by physicians and surgeons.

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175. Biomet and Cuckler were negligent and careless in the design, testing, distribution, manufacture, advertising, sale and marketing of the M2a.

176. Biomet and Cuckler had a duty to perform adequate evaluation on the safety and efficacy of the M2a. This included by reasonably gathering information regarding complaints and revisions and conducting adequate analysis on the information gathered.

177. 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 M2a.

178. Biomet and Cuckler failed to adequately evaluate the safety and efficacy of the M2a.

179. Biomet and Cuckler failed to adequately share the results of its evaluations of the M2a with Plaintiffs, Plaintiffs' orthopedic surgeons, or the orthopedic community.

180. 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)]

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

182. Distributor marketed, advertised, sold, and distributed the M2a for implantation into consumers such as Plaintiff by surgeons.

183. 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.

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

185. 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]

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

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

a. Representing the M2a as a device which was clinically proven to be safe and effective.
b. Representing the M2a 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 M2a either before or after Plaintiffs' purchase.
d. Knowingly providing inadequate warnings about the M2a's dangerous propensity to heavy metal poisoning.

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

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

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

DEMAND FOR JURY TRIAL

191. 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.

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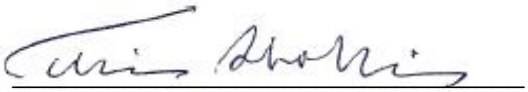
WHEREFORE, Plaintiffs respectfully demand judgment against Defendants for compensatory damages and any other relief the Court deems just and proper.

Dated this 20th day of December, 2018.



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