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

BARBARA R. SINGER; and JASON F. LYONS Plaintiffs, vs. 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. 19-2-15517-5 COMPLAINT FOR PERSONAL INJURY

COMPLAINT

Plaintiffs, BARBARA R. SINGER and JASON F. LYONS, ("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 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 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 each implanted with the Biomet M2a metal on metal hip replacement 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

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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.

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.,

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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.

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 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 Plaintiffs for damages in excess of $75,000.

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.

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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 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 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.

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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 extremely limited testing of the M2a before selling it for implantation into the bodies of patients.

32. To avoid comprehensive testing of the M2a hip replacement, 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.

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 replacement, it has continuously claimed "[t]he M2a-Magnum™ Large Metal Articulation System offers optimal joint mechanic restoration and ultra low-wear rates in vivo" citing to a

[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 May 1, 2019).

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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]

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 May 1, 2019).

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 replacement systems 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

[2] *See*, http://www.biomet.com/campaign/trueAlternativeBearings/BOI03400MagnumDesignRationale.pdf (Last accessed May 1, 2019).
[3] *See* http://www.grossortho.com/images/stories/pdf/currenttopics/MetalIonWhitePaper.pdf. (Last accessed May 1, 2019).
[4] *Id*.

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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 publicly 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 replacement 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. Approximately the same time as 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 sales of their almost identical hip replacement pending a full investigation.
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

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

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

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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.

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.

[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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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 … M2a 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. Biomet used Olympic gymnast Mary Lou Retton as M2a spokesperson

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 a M2a hip replacement in the mid-2000's.

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]

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[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 May 1, 2019).

[8] *See*, http://www.biomet.com/news/getFile.cfm?id=113&rt=inline&type=pr (Last accessed May 1, 2019).

[9] *See*,

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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 replacement.

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.

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 replacement 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.

http://www.biomet.com/fileLibrary/Patient_Education/PatientEdBrochures/Hip/English/Mary%20Lou%20Retton%20-%20Magnum%20Magnum.pdf (Last accessed May 1, 2019).

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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.

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

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

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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.

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. <u>M2a is a ticking time-bomb implanted in thousands of Washington's citizens' bodies</u>

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, osteolysis, muscle wasting, 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

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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 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.

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

V. Plaintiffs 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. As a result of the heavy metal poisoning by the Biomet M2a, Plaintiffs had to undergo an additional surgical procedure to surgically remove the defective hip replacement and replace it with one with a heavy duty plastic liner.

115. Plaintiffs then each had to undergo an extensive recovery and rehabilitation.

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

W. Barbara Singer underwent a painful revision surgery for her failed left total hip arthroplasty, and may require revision of her right total hip arthroplasty

117. Ms. Singer was implanted with the M2a Magnum system into her right hip on November 5, 2007, and into her left hip on January 30, 2008. She was in her early 60's at the

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time, and looked forward to continuing an active lifestyle.

118. Before her surgeries, Ms. Singer met with her surgeon, P. Brodie Wood, MD. During the pre-surgical discussion, Dr. Wood recommended the M2a metal-on-metal bearing technology, relying on Biomet's representations that the product featured superior longevity and reduced wear. During the meeting, Dr. Wood indicated that the Biomet metal-on-metal product was ideal for active, younger patients, because they would not wear out and she would not need to undergo a second surgery later in life. As a result, they chose the Biomet product.

119. Ms. Singer was not aware that the Biomet product had not been clinically tested for safety and efficacy by Biomet before being released to the market.

120. Ms. Singer was not informed about the surprising lack of clinical awareness regarding the risks of metal ion wear presented by the Biomet metal-on-metal product.

121. Ms. Singer was not aware of the serious concerns raised by those responsible for understanding the clinical safety of metal-on-metal bearings, including the unresolved concerns raised by members of the August, 2001 FDA panel responsible for the pre-clinical review of metal-on-metal hip products.

122. Ms. Singer was not aware that Biomet and Dr. Cuckler had entered into unethical financial arrangements for the promotion of metal-on-metal hip implants, leading to criminal charges and, eventually, Deferred Prosecution Agreements.

123. Ms. Singer was not aware of serious breakdowns in Biomet's adverse event reporting systems, which were necessary to accurately track the safety and performance of the Magnum product.

124. Dr. Wood implanted Ms. Singer's left and right Biomet hip products in excellent positions, performing both surgeries at WSP Providence St. Peter Hospital, in Olympia,

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Washington.

125. Despite Dr. Wood's excellent positioning of the M2a products, Ms. Singer later developed problems associated with metallosis. In June, 2018, Dr. Wood arranged for blood tests to check Ms. Singer's metal levels. The June 25, 2018 test report revealed unusually high levels of both chromium and cobalt ions in Ms. Singer's blood.

126. As Ms. Singer could not discern which Biomet hip was more painful, she was advised to elect which hip she preferred for revision. Ultimately, Ms. Singer was scheduled for a revision surgery to remove and replace the failed M2a hip product on the left side.

127. On October 5, 2018, a follow up blood test revealed that the already high metal ion levels in Ms. Singer's blood were increasing.

128. On December 10, 2018, Dr. Wood surgically removed and replaced the failed left M2a hip product, in order to eradicate the high ion levels in her blood and address concerns with metal-on-metal ion toxicity. Upon surgically opening Ms. Singer's hip area, Dr. Wood observed significant metallosis around and on the tissues surrounding the Biomet product. A pathology report confirmed the existence of numerous pigment-laden macrophages consistent with metallosis.

129. Dr. Wood replaced the M2a head and added a ceramic component to the left hip replacement, rendering the hip replacement no longer metal on metal.

130. Ms. Singer has undergone a long and painful recovery and rehabilitation from the surgical revision of the failed left Biomet M2a hip implant, including a severe hematoma that has complicated her recovery and her quality of life to this date.

131. Ms. Singer fears that an additional surgical revision will be required for the Biomet M2a product that remains in her right hip. On March 18, 2019, Ms. Singer's post-

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revision metal tests showed high levels of chromium and cobalt persisting in her blood. Ms. Singer is scheduled for a follow up blood test to determine whether an additional revision is warranted to address the persistence of high metal ions.

X. Jason Lyons underwent two painful revision surgeries for his failed right and left total hip arthroplasties

132. Mr. Lyons was implanted with the M2a into his right hip on January 31, 2012, and his left hip on May 8, 2012. Dr. James E. Clark, MD properly implanted both of the M2a devices at Overlake Medical Center in Kirkland, Washington.

133. At time of the implants, Mr. Lyons was in his early 40's. Relying on the Biomet representations about the "lifetime" M2a bearing system, Dr. Clark recommended the Biomet M2a hip product to Mr. Lyons. He described the M2a Magnum as a product with a large metal-on-metal bearing surface that was superior to other hip products, and for which metal ion problems were not a significant concern. Dr. Clark assured Mr. Lyons that the M2a product was designed to last a lifetime, making it well suited for younger and more active patients.

134. Prior to the surgeries, Biomet promoted its M2a hip replacements with Olympic gymnastics champion Mary Lou Retton, who appeared before surgeons at Biomet sponsored events, and appeared before the general public on televised advertisements throughout the country. The advertisements promoted the Biomet M2a hip system as a life-changing and superior product for younger and more active patients.

135. Before his surgeries, Jason Lyons saw the Mary Lou Retton advertisements and was further reassured that the Biomet M2a product had a proven safe bearing surface that would last a lifetime.

136. Mr. Lyons did not realize that the Biomet product had not been clinically tested

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for safety and efficacy by Biomet before being released to the market.

137. Mr. Lyons was not informed about the surprising lack of clinical awareness regarding the risks of metal ion wear presented by the Biomet metal-on-metal product.

138. Mr. Lyons was not aware of the serious concerns raised by those responsible for understanding the clinical safety of metal-on-metal bearings, including the unresolved concerns raised by members of the August, 2001 FDA panel responsible for the pre-clinical review of metal-on-metal hip products.

139. Mr. Lyons was not aware that Biomet and Dr. Cuckler had entered into unethical financial arrangements for the promotion of metal-on-metal hip implants, leading to criminal charges and, eventually, Deferred Prosecution Agreements.

140. Mr. Lyons was not aware of serious breakdowns in Biomet's adverse event reporting systems, which were necessary to accurately track the safety and performance of the Magnum product.

141. Mr. Lyons' Biomet M2a hip product did not last a lifetime.

142. Within six years of implant, Mr. Lyons was suffering from disabling metal wear damage to his body. Large painful masses developed near both Biomet implants. Fluid aspirated from his left hip and an MRI indicated that Mr. Lyons had developed pseudotumors.

143. On October 19, 2018 Mr. Lyons underwent a left hip revision arthroplasty by Dr. Benjamin Bengs at the Providence Saint John's Health Center in Santa Monica, California. The surgery was necessary to address Mr. Lyons' failed left Biomet hip replacement product.

144. Upon surgically re-opening Mr. Lyons' left hip area, Dr. Bengs observed significant pseudotumor fluid, which he then removed from Mr. Lyons' body.

145. During the procedure, Dr. Bengs replaced the left Biomet M2a head and cup, and

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replaced them with polyethylene and metal components, rendering the hip replacement no longer metal on metal.

146. On December 4, 2018 Mr. Lyons returned to Providence Saint John's Health Center, and underwent a right hip revision arthroplasty by Dr. Bengs. As with the left side, the surgery was necessary to address "metal-on-metal metallosis" arising from the failed Biomet hip replacement product on Mr. Lyon's right side.

147. Upon surgically opening Mr. Lyons' right hip area, Dr. Bengs observed extensive damage to the tissues surrounding the hip area. Dr. Bengs observed that Mr. Lyons' "posterior capsule was for the most part no longer there." As with the left side, significant fluid surrounded the joint area, and a developing pseudotumor was evidently "destroying the posterior capsular structures" of Mr. Lyons left hip.

148. During the procedure, Dr. Bengs replaced the right Biomet M2a head and cup, adding a ceramic head component, rendering the right hip replacement no longer metal on metal.

149. The metallosis damage to Mr. Lyon's hip area is permanent and has caused persistent and painful anterior dislocation of his right hip prosthesis.

150. Mr. Lyons has undergone long and painful recoveries and rehabilitation from the surgical revisions of his failed Biomet M2a hip implants. He has suffered irreparable and ongoing damage from the defective Biomet products.

DAMAGES AND CAUSES OF ACTION

151. 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

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activities.

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

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

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

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

156. Plaintiffs are not at fault for her 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)]

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

158. 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.

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

160. 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.

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

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

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

164. 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.

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

166. As a direct and proximate result of the lack of reasonable and adequate instructions or warnings regarding the defects in the M2a, Plaintiffs suffered the injuries described above.

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

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

168. 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

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have on the usefulness of the product.

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

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

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

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

173. 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.

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

175. 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)]

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

177. 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;

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b. The M2a bearing surfaces were all carefully tested consistent with the Design Rationale for the product;
c. The M2a was a clinically safe system;
d. The M2a was stronger and designed to last longer than competing devices;
e. The M2a did not exhibit high rates of revisions;
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.

178. Plaintiffs were reasonably foreseeable users of the M2a.

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

180. Defendant's warranties were part of the basis of the bargain for Plaintiffs' purchase of the M2a.

181. Defendants' warranties proved to be untrue.

182. 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)]

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

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

185. Defendants possessed (and possess) superior knowledge about the level of clinical testing and safety of the Biomet M2a system, including the lack of reliable support for representations about the asserted clinical safety and failure rates of the M2a system.

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186. The Plaintiffs and their surgeons are not able to discover Defendants' superior and specialized knowledge and experience about Biomet M2a product complaints, failures and revisions, and their systems for reporting and analyzing the same.

187. Defendants have failed in their duty to disclose known material facts to the plaintiffs and/or plaintiffs' surgeons regarding the M2a, including but not limited to:

a. Biomet and Northwest Biomet's failure to properly report, analyze and track M2a product failures and revision rates, as required for purposes of assessing product safety;
b. Biomet's failure to conduct an interdepartmental review or health hazard evaluation to confirm and warn consumers and the orthopedic community about the root causes of adverse product events involving metallosis, pseudotumors, and necrosis, even though clinics, studies and regulatory bodies around the world were identifying the need to proactively address such hazards;
c. Biomet's failure to test M2a bearing surfaces using the techniques Biomet deemed necessary for product safety, as articulated in its own Design Rationale;
d. Biomet's unethical and unlawful practice of paying millions of dollars in royalties to prominent surgeons who were responsible for gaining acceptance of the M2a products throughout the orthopedic community;
e. Biomet and Northwest Biomet's failure to alert surgeons to the problems of and potential solutions for cold welding, which greatly increase the risk of harm and damage to patients undergoing revisions of M2a products;
f. Biomet's abuse of the 510(k) process to clear the sale of the M2a without FDA approval, by grandfathering the M2a based on older predicate devices that had themselves failed because of metal wear related issues.

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

a. Falsely representing the M2a had resolved the metal ion wear problems that had plagued similar metal-on-metal hip products, including the predicate systems on which it was based.
b. Falsely representing the M2a as reducing wear and providing higher function for patients than other available hip systems.
c. Falsely representing the M2a metal-on-metal bearing system as a lifetime hip product.
d. Falsely representing that the M2a is a safer and stronger alternative when compared with other available hip systems.
e. Falsely representing that the M2a provided fluid film lubrication.
f. Failing to disclose the clinical significance and safety concerns regarding heavy metal poisoning.

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g. Failing to disclose patterns and trends of failure M2a implants.

189. For example, approximately six months before adopting the Magnum as his preferred device, Olympia surgeon Dr. Peter Brodie Wood attended a dinner presentation on the Magnum hosted by Biomet and Northwest Biomet representatives at a Tacoma, Washington restaurant, believed to be El Gaucho.

190. Northwest Biomet executive James Reiff helped arrange the Tacoma presentation, as well as other presentations of Biomet information on the Magnum to surgeons throughout Washington.

191. The Tacoma presentation included a projected presentation of Biomet representations about the superiority of the Magnum metal-on-metal bearing surface. In addition, an east coast surgeon presented on his experience with the Magnum, and how his use of the Magnum expanded to include virtually "all patients", including the obese.

192. The Magnum was described as a "lifetime" hip with highly polished bearing surfaces that were scientifically proven to have eliminated the risks of bearing wear. The Northwest Biomet presentation indicated that the risks from wear, including metal ions, were insignificant.

193. Northwest Biomet sales representative Keith Conklin helped coordinate the presentation of Biomet's information on the Magnum to surgeons throughout Washington, including Dr. Wood. Pursuant to Biomet guidance, Northwest Biomet and Keith Conklin continued to distribute Biomet representations about the Magnum to Washington surgeons, including Dr. Wood. The information is reflected in the Magnum Design Rationale, product brochures, and other alleged scientific and clinical information set forth in Biomet Field Communications.

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194. The information presented at the Tacoma dinner and within the Biomet communications included false representations that the Magnum bearing system had resulted in a "lifetime" hip, with "self-polishing" features that virtually eliminated wear problems when compared to other devices, such as competing polyethylene products.

195. The information provided by Biomet, via Northwest Biomet, to Dr. Wood included Biomet's photograph of metal and plastic wear piles, with text explaining that the Magnum metal-on-metal bearing was safer than competing products because it produced ultra low-wear rates *in vivo*. Dr. Wood understood that Biomet followed careful practices necessary for maintaining low wear and optimal clearance for each and every Magnum. Dr. Wood was told that the Magnum was "self-polishing", with ultra-low wear characteristics that actually got better over time in the human body.

196. The misleading and incomplete information presented by Biomet, Northwest Biomet, James Reiff and his sales representatives effectively convinced many orthopedic surgeons in Washington to accept the Magnum in their practices, and convinced the Plaintiffs' surgeons to recommend implantation of the Magnum in Plaintiffs' bodies.

197. For example, the information convinced Dr. Wood to focus his orthopedic practice on the Magnum. Within six months of the Tacoma meeting, Dr. Wood had made the Biomet Magnum a preferred hip replacement product and, over the ensuing years, he became one of the top utilizers of the Magnum in hip replacement surgeries in Washington, and the nation. In turn, Dr. Wood's sales representative Keith Conklin was recognized as the most successful sales representative in the State of Washington.

198. In contrast to the reassuring representations about the Magnum's safety and efficacy, Biomet and its representatives (including Northwest Biomet, Reiff and Conklin)

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failed to alert Dr. Wood and other Washington surgeons to many serious concerns and unknowns with the clinical safety of Biomet's M2a systems, including a growing awareness of problems with metal wear, metallosis, pseudotumors, cold welding, and the need for a head removal tool to minimize patient harm during revisions.

199. Prior to implanting the Magnums, Plaintiffs' surgeons were not alerted to ongoing concerns and uncertainties about the clinical performance of the M2a bearing system by those who were studying the product; that the Magnum was being sold for implantation without the level of clinical testing and review required for other medical devices subject to FDA approval; that rather than an objective presentation of information, sales representatives were being instructed not to raise or discuss ongoing concerns with metal ions when providing product information to local surgeons; for surgeons raising questions about metal ions, sales representatives were instructed to describe the problems as merely "theoretical" and to "change the subject"; and Northwest Biomet and its sales representatives were recklessly failing to fulfill its obligation to timely report the failure or revision of any M2a product to the proper authorities, thereby impeding proper assessment of product failure rates.

200. 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 and to fail to properly follow-up regarding the M2a hip replacement system.

201. Defendants made the above representations or omissions knowing the misrepresentations were false or were ignorant of the truth of the assertions.

202. The above representations and omissions are reflected in Biomet's system for marketing the M2a product in Washington through its local distributor, Northwest Biomet, Inc., and its executive James Reiff. Together, these defendants directed the aggressive

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promotion of the M2a products to Washington's orthopedic community through a series of written publications, brochures, and field communications which reflect the representations and omissions detailed above. Through this marketing effort, Defendants established acceptance of Biomet's representations about the M2a product's safety among surgeons in Washington's orthopedic community.

203. Defendants made the above misrepresentations or omissions with the intention and knowledge that their efforts would influence Washington surgeons and consumers in their decisions to select the Biomet M2a hip replacement system for surgical implantation.

204. 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 or omissions.

205. As a direct and proximate result of the breach of the warranties 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)]

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

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

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

209. Biomet and Cuckler had a duty to perform adequate evaluation on the safety and efficacy of the M2a. This included by reasonably gathering and reporting information

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regarding complaints and revisions and conducting adequate analysis on the information gathered.

210. 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.

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

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

213. Instead of acknowledging the uncertainties and dangers of the M2a system, Biomet and Cuckler broadcast misrepresentations about the alleged safety and superiority of M2a metal on metal bearing surfaces throughout the orthopedic community, and through local distributors such as Northwest Biomet, knowing such information would be used to guide the group of Washington surgeons and consumers who would be searching for artificial hip replacement systems.

214. Biomet, Cuckler and Northwest Biomet supplied the false information about the M2a system for the guidance of this group of surgeons and consumers, despite awareness that they lacked the level of knowledge about M2a clinical safety that they professed to have.

215. The Plaintiffs and their surgeons justifiably relied upon the misrepresentations and omissions about the M2a's clinical safety in their determination that the M2a was safe and appropriate for implantation in Plaintiffs' bodies.

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

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

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

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

219. 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.

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

221. 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]

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

223. 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 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 propensities.

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

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

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

DEMAND FOR JURY TRIAL

227. 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 12th day of June, 2019.

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