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

PALMER SANDENO; JACQUELINE LANGE;
and BEVERLY BELKA

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. 18-2-22160-9 SEA

COMPLAINT

Plaintiffs PALMER SANDENO; JACQUELINE LANGE; and BEVERLY BELKA
("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 state as follows:

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W. Jacqueline Lange suffered extensive tissue death and bone loss from the M2a and her surgeon was required to fracture and wire together her femur during surgery	19
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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.”

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

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

6 7. At all times relevant to this Complaint, JAMES REIFF, II, individually and
7 operating through his company NORTHWEST BIOMET, INC., had an exclusive agreement
8 with the Biomet Defendants for educating orthopedic surgeons about available Biomet hip
9 replacement systems and the advantages, benefits, indications, templating, surgical implantation,
10 and follow-up of those Biomet hip replacement systems in the State of Washington. Hereafter,
11 these defendants will be referred to collectively as “Distributor.”

12 8. The information that Distributor provided about Biomet hip replacement systems
13 far exceeded the information provided on M2a packaging or labeling.

14 9. Distributor’s sales representatives selected the components and tools to have
15 present in the operating room when the Plaintiffs were surgically implanted with the M2a.

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

19 11. Distributor profited from the promotion, sale, and servicing of the M2a hip
20 replacements at issue in the instant case.

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

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

4 14. At all times relevant to this Complaint, Defendant JOHN CUCKLER, M.D.,
5 personally and through his company, ALABAMA MEDICAL CONSULTANTS, INC., received
6 royalties and financially profited from his design, development, and promotion of the M2a metal
7 on metal hip replacement system. Hereafter, these defendants will be referred to, collectively, as
8 “Cuckler.”

9
10 15. Cuckler profited from the promotion, sale, and servicing of the M2a hip
11 replacements at issue in the instant case and directed his promotion of the M2a at surgeons and
12 patients located in the State of Washington.

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

15 17. Jurisdiction is proper in the courts of the State of Washington because the
16 Distributor defendants are both citizens of the State of Washington, Cuckler has consented to be
17 sued in the State of Washington, Cuckler directed his promotion of the M2a to surgeons and
18 patients in the State of Washington, and all Plaintiffs were implanted with the M2a hip
19 replacement in the State of Washington.

20
21 18. Venue is proper in the Superior Court of Washington in and for King County in
22 that both the principal place of business and the residence of the Distributor defendants are in
23 King County.

24 19. Suit is brought on behalf of each of the Plaintiffs to this matter for damages in
25 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.

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

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

5
6 **C. Biomet and Cuckler revived abandoned metal on metal hip replacements with M2a**

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

10 30. As a result of this collaboration, the M2a hip replacement was created and began
11 being sold in the United States in 2001.

12
13 **D. Biomet and Cuckler employed loophole to avoid testing M2a**

14
15 31. Despite their knowledge that early metal on metal hip replacements were a failure
16 and resulted in heavy metal poisoning, Biomet and Cuckler conducted almost no testing of the
17 M2a before selling it for implantation into the bodies of patients.

18 32. To avoid comprehensive testing of the M2a hip replacements, Biomet and
19 Cuckler claimed to United States regulators that the M2a should be “grandfathered-in” because it
20 was substantially similar to hip replacements sold prior to May 28, 1976.¹

21 33. This loophole required no testing for safety or efficacy.
22

23
24 ¹ See, <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K011110> and
25 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).

1 40. In fact, in a heading on page 7 of the publication, Biomet goes so far as to claim
2 that: “Cobalt and Chromium may be beneficial to the body as established by research and listed
3 by the US government.”⁴

4 41. The 2004 publication by “Biomet Orthopedics, Inc., the Most Responsive
5 Company in Orthopedics,” is still available to orthopedic surgeons and the public online today at
6 <http://www.grossortho.com/images/stories/pdf/currenttopics/MetalIonWhitePaper.pdf>. (Last
7 accessed Aug. 22, 2018).
8

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

11 42. In conjunction with the promotion of the M2a hip replacement, Cuckler gave
12 speeches and published articles such as “The Rationale for Metal-on-Metal Total Hip
13 Arthroplasty” published in 2005, claiming that there were “no adverse physiologic effects” to
14 metal on metal hip replacements.
15

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

19 44. Pursuant to a Deferred Prosecution Agreement with the Department of Justice, in
20 2008, Biomet made public that Cuckler received payments from Biomet of between \$3.0 and
21 \$3.1 million dollars in just the previous year. Extrapolating the one year that Biomet’s payments
22
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24

25 ⁴ *Id.*

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

3
4 **H. Thousands of M2a hip replacements are implanted in Washington citizens**

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

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

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

12
13 **I. Defendants continue to claim that the M2a is safe and successful**

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

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

18 50. However, Defendants have continued to reassure surgeons and the public that the
19 heavy metal poisoning seen with other metal on metal hip replacements is not an issue with the
20 M2a.

21 51. To this day, Defendants continue to claim to orthopedic surgeons and the public
22 that the M2a is a safe and successful product.
23
24
25

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

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

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

5 54. Like the M2a, the DePuy ASR was a monoblock metal on metal hip replacement
6 system with its cobalt chromium alloy head articulating against its cobalt chromium alloy shell.

7 55. In the summer of 2010, in response to “higher than expected revision rates,”
8 Johnson & Johnson conducted a world-wide recall of the DePuy ASR hip replacement.

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

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

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

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

18
19
20 **K. Defendants’ response to the recall of the almost identical product: Sell more M2as!**

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

- 23 a. Recall Defendants’ almost identical M2a hip replacement.
24 b. Suspend the sales of their almost identical hip replacement pending a full
25 investigation.

- 1 c. Conduct comprehensive testing of the M2a to ensure it was not prone to
2 causing heavy metal poisoning.
3 d. Warn surgeons of the design similarities and the need to inform and
4 carefully follow-up their patients.

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

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

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

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

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

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

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

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

19 68. In 2010, Isala reported to Biomet that when it performed CT scans of over 100
20 patients’ hips, more than a third had pseudotumors adjacent to the M2a hip replacement.

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

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

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

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

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

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

13 74. Despite all of these critical warnings provided by the Isala Klinieken, Defendants
14 failed to inform surgeons or patients in the State of Washington of the study, ignored the need for
15 follow-up screening, and instead continued to promote the M2a for implantation into the bodies
16 of patients.
17

18
19 **N. Finland university reports severe adverse reactions from M2a heavy metal debris**

20 75. Likewise, Turku University in Turku, Finland has historically had a long and
21 close relationship with Biomet.
22

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

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

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

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

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

9 80. Despite its long and close relationship with Biomet, in a 2013 publication of the
10 Nordic Orthopedic Federation, Turku University stated that “ARMD is common after ...
11 Magnum total hip arthroplasty, and we discourage the use of this device.”⁶

12 81. Defendants failed to inform surgeons or patients in the State of Washington of
13 this study, that Turku University had discouraged use of the M2a, the need for surgeons to screen
14 their patients for Adverse Reaction to Metal Debris, and instead continued to promote the M2a
15 for implantation into the bodies of patients.
16

17 **O. Biomet used Olympic gymnast Mary Lou Retton as M2a spokesperson**

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

20 83. Mary Lou Retton had received M2a hip replacements in the mid-2000’s.
21
22
23

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

1 84. Biomet heavily promoted to surgeons and the public that the M2a hip allowed
2 “younger, more active patients, like Mary Lou” to “return to her normal activities, including her
3 workout schedule.”⁷

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

6 86. A heading on Biomet’s website proclaims “Mary Lou lives pain-free, and so
7 should you.”⁹

8
9 **P. Mary Lou Retton has sued Biomet over defective M2a hip replacement**

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

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

14 89. Mary Lou Retton was so severely injured by the M2a metal on metal hip
15 replacement, that despite her status as a celebrity spokesperson for the product, she too has sued
16 the company.
17

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22 ⁷ See, http://www.biomet.com/fileLibrary/Patient_Education/PatientEdBrochures/Hip/English/Mary%20Lou%20Retton%20-%20M2a%20Magnum.pdf (Last accessed Nov. 2, 2017).

23 ⁸ See, <http://www.biomet.com/news/getFile.cfm?id=113&rt=inline&type=pr> (Last accessed Aug. 22, 2018).

24 ⁹ See, http://www.biomet.com/fileLibrary/Patient_Education/PatientEdBrochures/Hip/English/Mary%20Lou%20Retton%20-%20M2a%20Magnum.pdf (Last accessed Aug. 22, 2018).
25

1 **S. Biomet M2a are a ticking time-bomb implanted in thousands of Washington's**
2 **citizens' bodies**

3 99. The Biomet M2a is inherently defective.

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

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

9 102. The Defendants' failure to warn surgeons and patients that the M2a metal on
10 metal hip replacements that were surgically implanted in patients' bodies may be releasing toxic
11 heavy metals has left thousands of Washington patients with ticking time-bombs in their hips.

12 103. Based on the studies discussed above and others, hundreds, if not thousands, of
13 Washington patients have already suffered undiagnosed tissue death and pseudotumors as a
14 result of poisoning from the toxic heavy metals released from the M2a.
15

16 **T. Washington State is facing a public health disaster from unmonitored M2as**
17

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

21 105. The State of Washington is facing a public health disaster from unmonitored M2a
22 metal on metal hip replacements.
23
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1 **U. Plaintiffs have each suffered heavy metal poisoning from M2a**

2
3 106. Each of the Plaintiffs to this action were implanted with the M2a hip replacement,
4 suffered heavy metal poisoning, tissue death, bone loss, and pain.

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

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

10
11 **V. Palmer Sandeno underwent bilateral M2a revisions but surgeon could not safely**
12 **remove one of the M2a implants**

13 109. Mr. Sandeno was implanted with the M2a into his left hip on November 1, 2004,
14 by Peter Brodie Wood, MD at Providence St. Peter Hospital in Olympia, Washington.

15 110. By late 2017, the M2a had failed to the extent that Mr. Sandeno had “markedly
16 elevated ions of cobalt and chromium and pain and discomfort in his left hip” and was scheduled
17 for revision surgery to remove and replace the M2a from his left hip.

18 111. On January 8, 2018, Mr. Sandeno underwent a revision surgery by Peter Brodie
19 Wood, MD at Providence St. Peter Hospital in Olympia, Washington.

20 112. Upon surgically opening Mr. Sandeno, the Dr. Wood encountered a “abududent
21 metalosis” which he was not fully able to clean out.

22 113. Dr. Wood was able to remove the metal head and add a polyethylene component
23 to the hip replacement, rendering it no longer a metal on metal hip replacement.

1 114. Mr. Sandeno was also implanted with the M2a into his right hip on October 25,
2 2006, by Peter Brodie Wood, MD at Providence St. Peter Hospital in Olympia, Washington.

3 115. On February 23, 2018, due to “possible early failure of right total hip arthroplasty
4 owing to increased metal ion buildup,” Dr. Wood conducted a revision surgery to attempt to
5 remove the head from the M2a and implant a polyethylene component.

6 116. Dr. Wood cut open Mr. Sandeno’s hip, exposed the M2a head, and attempted to
7 remove the head from M2a.

8 117. Unfortunately, he discovered that the M2a head was cold-welded in place.

9 118. Despite having a special tool created by Biomet to remove heads that had been
10 cold welded and spending over an hour attempting to remove the head, Dr. Wood was unable to
11 do so.

12 119. Dr. Wood was then forced to end the surgery leaving the M2a hip replacement in
13 Mr. Sandeno.

14 120. Mr. Sandeno has then suffered an extremely long and painful recovery and
15 rehabilitation from the removal and replacement of his left M2a and the aborted removal of his
16 right M2a which he continues to go through today.

17
18
19 **W. Jacqueline Lange suffered extensive tissue death and bone loss from the M2a and**
20 **her surgeon was required to fracture and wire together her femur during surgery**

21 121. Ms. Lange was implanted with a M2a hip replacement in her right hip in
22 December 5, 2005, by Gregory M. Engel, MD at Overlake Hospital Medical Center in Bellevue,
23 Washington.

1 122. By 2018, her M2a had failed to the extent that Ms. Lange was scheduled to
2 undergo surgery to remove and replace the M2a.

3 123. The revision surgery was performed on March 6, 2018, by Jonah Hulst, MD at
4 Overlake Hospital Medical Center in Bellevue, Washington.

5 124. Upon surgically opening Ms. Lange's body, Dr. Hulst encountered extensive
6 tissue death and bone loss.

7 125. He was unable to remove the well fixed M2a stem from Ms. Lange's femur and
8 had to surgically cut open her femur to remove the stem.

9 126. Dr. Hulst was then forced to use wires to attempt to repair the femur.

10 127. Ms. Lange was thus forced to recover from an incredibly extensive and
11 complicated surgery and an extremely long and painful recovery and rehabilitation which she
12 continues to go through today.

13
14 **X. Beverly Belka suffered extensive heavy metal tissue death and severe bone loss**

15
16 128. Ms. Belka was implanted with the M2a in her right hip at St. Joseph's Hospital in
17 Bellingham, Washington by Ronald Woo, MD on November 2, 2004.

18 129. By 2016, her M2a had failed to the extent that Ms. Belka was scheduled by Dr.
19 Woo for surgery to remove and replace the failed M2a.

20 130. Upon surgically opening Ms. Belka's hip replacement and visualizing the tissue
21 and bone, Dr. Woo found that she had suffered extensive tissue death and severe bone loss from
22 the heavy metal poisoning.

23 131. Dr. Woo replaced the M2a head and added a polyethylene component to the hip
24 replacement, rendering the hip replacement no longer metal on metal.
25

1 132. Ms. Belka then underwent a long and painful recovery and rehabilitation from the
2 revision of the failed Biomet M2a.

3 **DAMAGES AND CAUSES OF ACTION**

4 133. As a direct and proximate result of the defective M2a hip replacement, Plaintiffs
5 suffered injuries, including but not limited to significant pain, tissue destruction, bone
6 destruction, metal wear, metal poisoning, loss of enjoyment of life, and limitation of daily
7 activities.

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

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

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

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

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

19 **COUNT ONE – ALL DEFENDANTS – FAILURE TO WARN**

20 **[Pursuant to Wash. Rev. Code Section 7.72.010(4)]**

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

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

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

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

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

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

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

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

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

20 148. As a direct and proximate result of the lack of reasonable and adequate
21 instructions or warnings regarding the defects in the M2a, the Plaintiffs suffered the injuries
22 described above.
23
24

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

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

6 150. At the time that Defendants designed, developed, and promoted the M2a
7 implanted in Plaintiffs, and at the time the M2a was manufactured, the likelihood that the
8 product would cause Plaintiffs' harm or similar harms, and the seriousness of those harms,
9 outweighed the burden on Defendants to design a product that would have prevented those harms
10 and the adverse effect that an alternative design that was practical and feasible would have on the
11 usefulness of the product.

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

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

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

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

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

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

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

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

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

7 159. Defendants expressly warranted that the M2a was reasonably fit for its intended
8 purpose as a hip replacement system. These warranties included, without limitation, the
9 allegations above as well as the following:

- 10 a. The M2a produced less wear than competing devices;
11 b. The M2a was a clinically safe system;
12 c. The M2a was stronger and designed to last longer than competing devices;
13 d. The M2a was a lifetime hip replacement;
14 e. The M2a did not exhibit high rates of revisions;
15 f. Fluid film lubrication would prevent contact of the ball and cup during
 articulation;
16 g. The M2a was a safer alternative to metal on plastic hips using ultra-heavy
 duty plastic liners.

17 160. Plaintiff were reasonably foreseeable users of the M2a.

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

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

21 163. Defendant's warranties proved to be untrue.

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

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

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

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

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

- 10 a. Falsely representing the M2a as reducing wear and providing higher function for
11 patients than other available hip systems.
12 b. Falsely representing that the M2a is a safer and stronger alternative when
13 compared with other available hip systems.
14 c. Falsely representing that the M2a provided fluid film lubrication.
15 d. Failing to disclose the clinical significance and safety concerns regarding heavy
16 metal poisoning.
17 e. Failing to disclose patterns and trends of failure of M2a hip replacements.
18 f. Failing to disclose heavy metal poisoning of patients with M2a hip replacements.

19 168. The above representations and omissions were material and were made with the
20 intent to persuade and induce Plaintiffs, Plaintiffs’ surgeons, and the medical community to
21 choose M2a hip replacements and to continue to utilize M2a hip replacements.

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

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

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

6 172. As a direct and proximate result of the misrepresentations and omissions
7 regarding the M2a, Plaintiffs suffered injuries as described above.
8

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

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

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

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

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

21 177. Biomet and Cuckler further had a duty to share the results of its evaluation so that
22 Plaintiffs, Plaintiffs' orthopedic surgeons, and the orthopedic community could be adequately
23 apprised of the risks of the M2a.
24
25

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

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

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

7
8 **COUNT SIX – DISTRIBUTOR DEFENDANTS – NEGLIGENCE**
9 **[Pursuant to Wash. Rev. Code Section 7.72.010(4)]**

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

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

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

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

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

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

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

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

- 3 a. Representing the M2a as a device which was clinically proven to be safe and
4 effective.
5 b. Representing the M2a to be of a higher quality and more desirable product than
6 other available alternatives.
7 c. Failing to disclose adequate information about the safety and efficacy of the M2a
8 either before or after Plaintiffs' purchase.
9 d. Knowingly providing inadequate warnings about the M2a's dangerous
10 propensity to heavy metal poisoning.

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

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

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

15 DEMAND FOR JURY TRIAL

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

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

20 Dated this 4th day of September, 2018.

21 

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