IN THE CIRCUIT COURT OF THE SEVENTEENTH JUDICIAL CIRCUIT
IN AND FOR BROWARD COUNTY, FLORIDA

RAYMOND MOORE; ROBERT BLOOM; and ROBERT QUINN; Plaintiffs, *v.* BIOMET, INC.; BIOMET ORTHOPEDICS, LLC; BIOMET U.S. RECONSTRUCTION, LLC; BIOMET MANUFACTURING, LLC; ZIMMER BIOMET HOLDINGS, INC; ORTHOPEDICS, INC., JAMES H. BARR; JOHN CUCKLER, M.D.; and ALABAMA MEDICAL CONSULTANTS, INC.; Defendants.	)	No.:

COMPLAINT

Plaintiffs, RAYMOND MOORE; ROBERT BLOOM; and ROBERT QUINN; ("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"); ORTHOPEDICS, INC. and JAMES H. BARR (hereafter collectively referred to as "Distributor"); and JOHN CUCKLER, M.D. and ALABAMA MEDICAL CONSULTANTS, INC. (hereafter collectively referred to as "Cuckler"), and states as follows:

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PARTIES, VENUE AND JURISDICTION

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

2. The particular hip replacement system at issue in this case is the "Biomet M2a Magnum Metal on Metal Hip Replacement System" (hereafter referred to as the "Magnum"). Biomet's M2a hip replacement system line consisted of several different metal on metal hip replacement systems, with sales primarily compromised of the Biomet M2a-38 and Biomet Magnum.

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

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 H. BARR was a citizen of the State of Florida.

6. At all times relevant to this Complaint, ORTHOPEDICS, INC. was a citizen of the State of Florida with its principal place of business in either Broward or Dade County, Florida.

7. At all times relevant to this Complaint, JAMES H. BARR, individually and operating through his company ORTHOPEDICS, 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 South Florida. 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 Magnum packaging or labeling.

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

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

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

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

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

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

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

16. Jurisdiction is proper in the courts of the State of Florida because the Distributor defendants and Cuckler defendants are all citizens of the State of Florida, all Plaintiffs are citizens of the State of Florida, and all Plaintiffs were implanted with the Magnum hip replacement in the State of Florida.

17. Venue is proper in the Seventeenth Judicial Circuit Court in and for Broward County, Florida as Plaintiffs' causes of action accrued in Broward County.

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

STATEMENT OF FACTS

A. <u>The Biomet Magnum is different than the typical hip replacement</u>

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

20. 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.

21. 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.

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

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

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

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

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

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

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

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

28. 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.

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

D. Biomet and Cuckler employed loophole to avoid testing Magnum

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

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

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

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

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

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

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

F. Biomet falsely claimed it conducted extensive testing of Magnum

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

[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 Apr. 17, 2018).
[2] *See*, http://www.biomet.com/campaign/trueAlternativeBearings/BOI03400MagnumDesignRationale.pdf (Last accessed Apr. 17, 2018).

37. 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]

38. 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]

39. 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 Apr. 17, 2018).

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

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

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

42. Pursuant to a Deferred Prosecution Agreement with the United States Department of Justice, in 2008, Biomet made public that Cuckler received payments from Biomet of between

[3] *See* http://www.grossortho.com/images/stories/pdf/currenttopics/MetalIonWhitePaper.pdf. (Last accessed Apr. 17, 2018).
[4] *Id.*

$3.0 and $3.1 million dollars in just the previous year. Extrapolating the one year that Biomet's payments to Cuckler are publically available, leads to the conclusion that Cuckler has received tens of millions of dollars from Biomet.

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

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

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

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

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

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

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

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

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

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

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

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

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

53. 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.

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

55. 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.

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

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

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

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

a. Recall Defendants' almost identical Magnum hip replacement.

b. Suspend the sales of their almost identical hip replacement pending a full investigation.
c. Conduct comprehensive testing of the Magnum to ensure it was not prone to causing heavy metal poisoning.
d. Warn surgeons of the design similarities and the need to inform and carefully follow-up their patients.

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

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

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

L. In 2010, Netherlands researchers warn Biomet of pseudotumors from Magnum

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

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

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

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

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

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

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

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

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

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

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

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

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

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

[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.

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

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

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

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

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

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

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

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

[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 Apr. 17, 2018).

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

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

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

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

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

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

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

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

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

88. 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.

[8] *See*, http://www.biomet.com/news/getFile.cfm?id=113&rt=inline&type=pr (Last accessed Apr. 17, 2018).
[9] *See*, http://www.biomet.com/fileLibrary/Patient_Education/PatientEdBrochures/Hip/English/Mary%20Lou%20Retton%20-%20Magnum%20Magnum.pdf (Last accessed Apr. 17, 2018).

R. Australian government required Biomet to recall Magnum

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

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

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

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

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

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

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

95. The Biomet Magnum is inherently defective.

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

97. 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.

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

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

T. Florida is facing a public health disaster from unmonitored Magnums

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

101. Florida is facing a public health disaster from unmonitored Magnum metal on metal hip replacements.

U. Plaintiffs have each suffered heavy metal poisoning from the Magnum

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

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

V. Raymond Moore suffered extensive tissue death from Magnum heavy metal poisoning

104. Mr. Moore was implanted with a Biomet Magnum at Holy Cross Hospital in Ft. Lauderdale, Florida on July 12, 2011.

105. By 2017, the Magnum had failed to the extent that Mr. Moore had to have the Magnum surgically removed from his body.

106. The orthopedic surgeon performing the surgical removal and re-replacement of the Magnum on October 24, 2017, wrote in the operative report:

> … a Biomet metal-on-metal hip system and over the course of these past 5-1/2 to 6 years what has happened is that the patient experiencing pain and burning sensation, elevated metal ions in his blood, have normal MRI subtraction imaging studies confirming a reactive synovial response around the hip joint, all prompting the need for a revision to excise the reactive tissue that is a soft tissue response to the metal-on-metal and the need for revision whereby the articulating surfaces are replaced with a more standard articulating surface.

107. The surgeon went on write in the revision operative report that as a result of the damage from the heavy metal poisoning, he conducted a "extensive soft tissue repair" and put Mr. Moore in a post-surgery hip abduction brace due to the extent of the damage.

108. Mr. Moore then underwent a long and painful recovery and rehabilitation from the removal of the failed Biomet Magnum hip replacement.

W. Robert Bloom suffered pseudotumor and extensive tissue death from Magnum heavy metal poisoning and post revision infection requiring second revision

109. Mr. Bloom was implanted with a Biomet Magnum hip replacement at Holy Cross Hospital in Broward County, Florida, on August 13, 2009.

110. By 2017, the Magnum had failed to the extent that Mr. Bloom underwent the surgically removal of the Magnum on November 20, 2017.

111. During the surgery to remove the Magnum, the orthopedic surgeon found a large pseudotumor that he removed in addition to the Magnum.

112. Unfortunately, following the surgical removal of the Magnum, Mr. Bloom's hip became infected, and on December 20, 2017, he was forced to under a second revision surgery.

113. Mr. Bloom was thus forced to endure a long and painful recovery from two unnecessary revision surgeries.

X. Robert Quinn developed metallosis from toxic heavy metals released from Biomet Magnum

114. Mr. Quinn was implanted with a Biomet Magnum hip replacement on June 19, 2007.

115. By 2015, his Magnum had failed to the extent that Mr. Quinn was forced to have the Magnum surgically removed from his body.

116. In the revision operative report, the surgeon stated that Mr. Quinn "presents with significant metallosis findings from a previous metal-on-metal articulation."

117. Upon surgically opening Mr. Bloom, the surgeon noted "[a]s we entered the hip, we found a significant amount of metallosis debris and fluid consistent with that diagnosis."

118. The surgeon then removed and replaced the Magnum head and taper adapter.

119. Mr. Bloom then underwent a long and painful recovery and rehabilitation from the removal of the failed Biomet Magnum hip replacement.

DAMAGES AND CAUSES OF ACTION

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

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

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

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

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

COUNT ONE – ALL DEFENDANTS
STRICT LIABILITY FAILURE TO WARN

125. Plaintiffs re-allege and incorporate by reference paragraphs 1 to 124 above as if fully stated herein.

126. At the time Defendants designed, manufactured, promoted, marketed, sold, supplied, distributed and/or serviced the products at issue in this Complaint, such products contained defects that made them unreasonably dangerous beyond the expectations of the ordinary consumer, and were unfit for their intended use.

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

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

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

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

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

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

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

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

COUNT TWO – ALL DEFENDANTS
DESIGN AND MANUFACTURING DEFECT

135. Plaintiffs re-allege and incorporate by reference paragraphs 1 to 124 above as if fully stated herein.

136. At the time that defendants designed, manufactured, promoted, marketed, sold, supplied, distributed and/or serviced the products at issue in this Complaint, such components contained defects that made them unreasonably dangerous beyond the expectations of the ordinary consumer, and were unfit for their intended use.

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

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

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

COUNT THREE – BIOMET DEFENDANTS
BREACH OF IMPLIED WARRANTY

140. Plaintiffs re-allege and incorporate by reference paragraphs 1 to 124 above as if fully stated herein.

141. Biomet Defendants impliedly warranted that the products at issue in this Complaint and its component parts were merchantable and fit for the ordinary and intended purposes for which hip systems are used.

142. Plaintiffs were each a foreseeable user of the products at issue in this Complaint.

143. Plaintiffs' surgeons, as purchasing agents, purchased the product at issue in this Complaint for Plaintiffs from Biomet Defendants.

144. At all times relevant to this Complaint, Plaintiffs were in privity with the Biomet Defendants.

145. Plaintiffs used the product at issue in this Complaint for its ordinary and intended purpose.

146. The products at issue in this Complaint failed while being used for their ordinary and intended purpose.

147. As a direct and proximate result of Biomet Defendant's breach of implied warranty, Plaintiffs suffered injuries as described above.

COUNT FOUR – BIOMET DEFENDANTS
BREACH OF EXPRESS WARRANTY

148. Plaintiffs re-allege and incorporates by reference paragraphs 1 to 124 above as if fully stated herein.

149. Biomet Defendants sold and Plaintiffs purchased, through Plaintiffs' purchasing agent surgeons, the products at issue in this Complaint.

150. At all times relevant to this Complaint, Plaintiffs were in privity with Biomet Defendants.

151. Biomet Defendants expressly warranted by affirmation, promise, description, and sample to Plaintiffs and Plaintiffs' physicians that the products at issue in this Complaint were of a quality and character suitable for implantation and extended safe use in Plaintiffs.

152. Such representations by Biomet Defendants were meant to induce Plaintiffs, through Plaintiffs' physicians, to purchase the products at issue in this Complaint.

153. The products at issue in this Complaint did not conform to the representations made by Biomet Defendants.

154. Biomet Defendants breached the express warranty it provided with the products at issue in this Complaint.

155. As a direct and proximate result of Biomet Defendant's breach of express warranty, Plaintiffs suffered injuries as described above.

COUNT FIVE – ALL DEFENDANTS – MISREPRESENTATION

156. Plaintiffs re-allege and incorporate by reference paragraphs 1 to 124 above as if fully stated herein.

157. Defendants made statements concerning material facts which Defendants may have believed to be true but which in fact were false, or otherwise omitted material facts.

158. Defendants were negligent in making such statements because they should have known the statements were false or omitted material information.

159. In making these statements, Defendants intended or expected that another would rely on the statements.

160. Plaintiffs, through their surgeon agents, justifiably relied on the false statements.

161. As a direct and proximate result of the misrepresentations regarding the Magnum, Plaintiffs suffered injuries as described above.

COUNT SIX – ALL DEFENDANTS – NEGLIGENCE

162. Plaintiffs re-allege and incorporate by reference paragraphs 1 to 124 above as if fully stated herein.

163. Defendants, as the designers, manufacturers, promoters, marketers, sellers, suppliers, distributors, and/or servicers of the Biomet Magnum hip replacement system, owed a duty to use reasonable care in the design, manufacture, promotion, marketing, selling, supplying, distribution, and/or service of Plaintiffs' hip replacements.

164. Defendants, in breach of the duties described above, negligently and carelessly designed, manufactured, promoted, marketed, sold, supplied, distributed and/or serviced the products at issue in this Complaint.

165. Further, Defendants owed Plaintiffs a duty to provide reasonable complete and accurate information to Plaintiff, Plaintiff's orthopedic surgeon, and the orthopedic community regarding the products at issue in this Complaint.

166. Defendants breached this duty by failing to adequately warn Plaintiff, Plaintiff's orthopedic surgeon, and the orthopedic community regarding the products at issue in this Complaint.

167. As a direct and proximate result of Biomet Defendants' breaches of duty, Plaintiffs needlessly suffered injuries as described above.

COUNT SEVEN – BIOMET AND CUCKLER DEFENDANTS
INFORMATION NEGLIGENTLY SUPPLIED FOR THE GUIDANCE OF OTHERS

168. Plaintiffs re-allege and incorporate by reference paragraphs 1 to 124 above as if fully stated herein.

169. Plaintiffs' purchase of the Magnum was a business transaction.

170. The Biomet and Cuckler Defendants all had a pecuniary interest in the design, development, promotion, and testing of the Mangum.

171. The Biomet and Cuckler Defendants supplied false information for the guidance of others regarding the selection of the Magnum as a safe and effective hip replacement option, as alleged above.

172. The Biomet and Cuckler Defendants failed to exercise reasonable care or competence in obtaining and communicating the information supplied for the guidance of others regarding the Magnum.

173. Plaintiffs and Plaintiffs' orthopedic surgeon agents, were within the limited group of persons for whose benefit and guidance the Biomet and Cuckler Defendants intended to supply the information.

174. The Biomet and Cuckler Defendants intended for their information to influence either the transaction in which Plaintiffs, through Plaintiffs' orthopedic surgeon agents, purchased the Magnum or a substantially similar transaction.

175. Plaintiffs, individually and through Plaintiffs' orthopedic surgeon agents, justifiably relied upon the information provided by Biomet and Cuckler Defendants.

176. As a direct and proximate result of the Biomet and Cuckler Defendants' false information, Plaintiffs suffered pecuniary loss, as described above.

DEMAND FOR JURY TRIAL

177. 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 19th day of April, 2018.

/s/ *Altom M. Maglio*

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