IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF KANSAS

PATRICIA A. TRAFFAS, Plaintiff, v. BIOMET, INC.; BIOMET ORTHOPEDICS, LLC; BIOMET U.S. RECONSTRUCTION, LLC; BIOMET MANUFACTURING, LLC; ZIMMER BIOMET HOLDINGS, INC; JOHN CUCKLER, M.D.; and ALABAMA MEDICAL CONSULTANTS, INC., Defendants.	)	Case No. 2:19-cv-2115

COMPLAINT

Plaintiff, PATRICIA A. TRAFFAS, brings 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" or "Biomet Defendants"); JOHN CUCKLER, M.D. and ALABAMA MEDICAL CONSULTANTS, INC., (hereafter collectively referred to as "Cuckler" or "Cuckler Defendants"), 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 Plaintiff which was designed, developed, manufactured, labelled, promoted, marketed, sold, and supplied by Defendants.

2. The hip replacement system at issue in this case is the "Biomet M2a Metal on Metal Hip Replacement System" (hereafter referred to as the "M2a"). Biomet's M2a hip replacement system line consisted of several substantially similar metal on metal hip replacement systems, including the M2a "38", M2a "Magnum", and M2a "ReCap".

3. Plaintiff PATRICIA TRAFFAS was implanted with a M2a Magnum, in the State of Kasas and is a resident and citizen of the State of Kansas.

4. Hereinafter, Plaintiff PATRICIA TRAFFAS is referred as "Plaintiff".

5. At all times relevant to this Complaint, Defendant BIOMET, INC., was and is an Indiana citizen, 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.

6. In June of 2015, BIOMET, INC. was purchased by ZIMMER BIOMET HOLDINGS, INC. also an Indiana citizen, and/or merged with ZIMMER INC., multinational corporation 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., and/or Biomet Defendants doing business as Zimmer Biomet.

7. At all times relevant herein, Biomet Defendants were the agents of each other, and in doing the things alleged herein, each Biomet Defendant was acting within the course and scope of its agency and was subject to or under the supervision of its Biomet co-defendants.

8. Thus, the Biomet Defendants are severally and separately liable to the Plaintiff.

9. At all times relevant to this Complaint, Plaintiff's surgeon(s) relied upon information provided by Defendants in selecting the M2a hip replacement for implantation into Plaintiff's hip.

10. Defendant JOHN CUCKLER, M.D. ("Cuckler") is a citizen and resident of the State of Florida.

11. Defendant ALABAMA MEDICAL CONSULTANTS, INC. is an Alabama corporation with its principal place of business in Naples, Florida, and as such is a citizen of the State of Florida.

12. At all times relevant to this Complaint, Defendant JOHN CUCKLER, M.D., personally and through his company, ALABAMA MEDICAL CONSULTANTS, INC., financially profited from his design, development, and worldwide promotion of the M2a metal on metal hip

replacement system and received royalties on the net product sales of all M2a metal on metal hip replacement systems sold.

13. Cuckler Defendants further profited from the worldwide promotion, sale, and servicing of the M2a hip replacements at issue in the instant case by development of the instrumentation used by surgeons worldwide to implant the M2a systems; formulating training materials to instruct surgeons worldwide on how to implant the M2a systems; authoring the surgical technique for the M2a systems; participating in drafting marketing material regarding the M2a systems; authoring medical literature on the product; giving presentations at national and worldwide conferences to orthopedic surgeons promoting the M2a systems; and providing continuing education and guidance to corporate Biomet and surgeons worldwide including post market surveillance measures.

14. Cuckler Defendants contributed materially and substantially to the M2a's placement into the stream of commerce throughout the world, including every state in the United States and in Kansas.

15. Cuckler Defendants had direct contact with orthopedic surgeons in Kansas, through presentations given about the M2a Systems.

16. Cuckler Defendants had direct communications with sales representatives of Biomet, who sold the M2a Systems in Kansas, regarding the benefits of the M2a System.

17. Plaintiff's ability to investigate and uncover Defendants' wrongful conduct such that Plaintiff could discover a potential cause of action against Defendants was delayed on account of Defendants' fraudulent concealment.

18. Jurisdiction is proper in Federal Court because Plaintiff and all Defendants are diverse and because damages in this case exceed $75,000.

19. Venue is proper in the U.S. District Court for the District of Kansas.

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 referred to as a metal on metal hip replacement.

B. Metal On Metal Hip Replacements Were Tried Decades Ago, Failed, 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, among many other issues.

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 The M2a

29. Despite the prior failure of metal on metal hip replacements to perform as intended, Biomet and Cuckler Defendants 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 the early 2000s.

D. Biomet And Cuckler Employed Loophole To Avoid Testing M2a

31. Biomet and Cuckler knowingly and intentionally engaged in a corporate practice of recklessly rushing their M2a metal on metal implants to market without adequate time to design and test the implants to make reasonable assurances regarding their safety and efficacy.

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 clinical testing nor any testing, whatsoever, for safety or efficacy.

34. 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.

35. Biomet had explicit notice in 1995 from one of the world's foremost orthopedic surgeons that Biomet's protocols for testing its M2a metal on metal hip implants ignored known health risks related to heavy metal poisoning.

36. Despite the aforementioned knowledge, Biomet knowingly and intentionally failed

[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 Aug. 20, 2018).

to conduct any clinical or laboratory tests relating to the health risks associated with metal on metal hip replacement heavy metal poisoning prior to launching the M2a.

E. Defendants Fraudulently Misrepresented To The Public By Marketing The M2a As Having "Low Wear"

37. The M2a produces an exponentially larger number of smaller and more toxic wear particles than wear particles produced from plastic hip implants.

38. Defendants had actual knowledge by 2000 that heavy metal poisoning is related to the size and total number of these metal particles as opposed to the total weight of released metal particles. Further, Defendants had actual knowledge that these particles are toxic.

39. Plastic wear particles released from polyethylene implants are much larger and less reactive than heavy metal wear from metal on metal implants. Testing protocols for wear in polyethylene implants allows for measurement of the wear by total weight.

40. These same protocols, however, *explicitly* warn against the use of the protocols for measuring wear in metal on metal implants, like the M2a. This is, in large part, because the toxicity and reactivity of heavy metal wear is not related to weight, but particle size and count.

41. Defendants knowingly and intentionally conducted laboratory "wear testing" for the M2a in a way that was *only* designed for testing of plastic hip implants. Particularly, the test protocols only measured wear by total weight.

42. Defendants were fully aware that the M2a produced more toxic wear than polyethylene implants, regardless of total weight comparisons.

43. Despite the aforementioned knowledge, Defendants knowingly and intentionally marketed the M2a by claiming that it produced less wear than polyethylene (plastic) hip

replacements. Furthermore, Defendants knowingly and intentionally marketed the M2a by falsely associating its deceptively marketed "low wear" properties with safety and efficacy.[2] [3]

44. Biomet and Cuckler Defendants established channels for providing advice to orthopedic surgeons within Kansas by presenting information regarding the product at educational seminars and by educating the sales representatives who marketed and sold the product in Kansas.

F. Defendants Suppressed Reports Of Problems With The M2a And Deceived Surgeons Into Believing That Concerns About Heavy Metal Poisoning Were False

45. Defendants knowingly and intentionally spread false information claiming that decades of experience with previous metal on metal implants purportedly resulted in zero instances of heavy metal poisoning.[4]

46. Defendants engaged in a knowing and intentional scheme to hide clinical information relating to heavy metal poisoning from its own metal on metal hip replacements.

47. This scheme included explicit training to Biomet's sales representatives on how to deceptively convince surgeons that reports of heavy metal poisoning are all fake; merely a theoretical concern; and a scheme by competitors who do not sell metal on metal hip replacements to steal business.

48. Biomet Defendants, due to their sales representatives' role in the sale of particular implant components to orthopedic surgeons, have notice of every surgery in which Biomet components are implanted. This includes surgeries in which Biomet components are used to replace failed M2a implants. As a result, Biomet Defendants possess a unique set of clinical information through which the success or failure of their implants can be analyzed.

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[2] *See,* http://www.biomet.com/wps/wcm/connect/internet/acb6d5c6-e3e9-42e2-b3e6-83fd38a567f1/Y-BMT-735_021502_K.pdf?MOD=AJPERES, (Last accessed September 12, 2018).
[3] *See*, http://www.biomet.com/campaign/trueAlternativeBearings/BOI03400MagnumDesignRationale.pdf (Last accessed Aug. 20, 2018).
[4] *See* http://www.grossortho.com/images/stories/pdf/currenttopics/MetalIonWhitePaper.pdf. (Last accessed Aug. 20, 2018).

49. Unfortunately, Biomet Defendants engage in a corporate practice of under reporting and failing to properly analyze clinical information in their possession regarding implants which they sell.

50. In 2016 and 2018 this practice resulted in multiple "483" observations by the FDA regarding Biomet Defendants' failure to properly handle complaint reports and failure to properly analyze clinical information regarding product failures.

51. Biomet Defendants also marketed their metal on metal hip replacements based upon what it claimed was a low "reported adverse event rate" of ".056". However, Biomet Defendants were intentionally and knowingly failing to include large numbers of adverse events, especially those relating to heavy metal poisoning. Biomet was fully aware that this scheme artificially suppressed the "reported adverse event rate." Regardless, Biomet consistently used the figure in its marketing. Biomet was aware that this figure would be heavily relied upon by the medical community.

G. Defendants Claimed That The M2a Was A "Lifetime Hip" And Suitable For Use In Younger, More Active Patients

52. Defendants claimed that without the plastic liner to wear out, the Biomet M2a should last a patient's lifetime.

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

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

H. Biomet Falsely Claimed It Conducted Extensive Testing Of M2a

55. Despite the fact that Biomet never conducted any pre-market clinical testing of the M2a implants at issue, Biomet claimed that the implants had "clinically proven results" immediately upon marketing.[5]

56. Further, Biomet claimed that its M2a 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.[6]

57. 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."[7]

58. 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."[8]

I. Biomet And Cuckler Misrepresented About The Existence of Adverse Reactions To Heavy Metal Wear

59. Published medical literature existed prior to the marketing of M2a products which *explicitly* discussed adverse physiologic effects related to heavy metal wear from metal on metal hip implants.

60. Defendants knew or should have known about the existence of such literature.

61. Cuckler affirmatively chose to ignore the existence of such literature because he simply did not agree with the conclusions of such literature.

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[5] *See,* http://www.biomet.com/wps/wcm/connect/internet/acb6d5c6-e3e9-42e2-b3e6-83fd38a567f1/Y-BMT-735_021502_K.pdf?MOD=AJPERES, (Last accessed September 12, 2018).
[6] *See*, http://www.biomet.com/campaign/trueAlternativeBearings/BOI03400MagnumDesignRationale.pdf (Last accessed Aug. 20, 2018).
[7] *See* http://www.grossortho.com/images/stories/pdf/currenttopics/MetalIonWhitePaper.pdf. (Last accessed Aug. 20, 2018).
[8] *Id*.

62. In conjunction with the promotion of the M2a hip replacements, 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.

63. Biomet extensively cited Cuckler's statement in marketing for its M2a products.[9]

64. Defendants intentionally misrepresented the existence of literature regarding adverse reactions to heavy metal wear in order to market, and profit from the sale of M2a implants.

J. Cuckler Conducted Secret M2a Marketing Campaign In Exchange For Millions Of Dollars

65. At the time that Cuckler published "The Rationale for Metal-on-Metal Total Hip Arthroplasty", Biomet was paying Cuckler a percentage of the sale price of M2a metal on metal hip replacement systems sold in the United States. Cuckler failed to mention this in the article promoting such hip replacements.

66. In 2008, pursuant to a Deferred Prosecution Agreement with the United States Department of Justice, 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 received tens of millions of dollars from Biomet.

K. In 2010 Johnson & Johnson Voluntarily Recalled Almost Identical Hip Replacement

67. Approximately the same time as Defendants began selling the M2a, Johnson & Johnson began selling the DePuy ASR.

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

[9] *See e.g.*, http://www.biomet.com/campaign/trueAlternativeBearings/BOI03400MagnumDesignRationale.pdf (Last accessed Aug. 20, 2018).

69. 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.

70. 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.

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

72. 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.

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

74. 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.

L. Defendants' Response To The Recall Was To Try To Increase Its Sales of M2a

75. 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 replacements.
b. Suspend the sales of their almost identical hip replacement pending a full investigation.
c. Conduct comprehensive testing of the M2a implants to ensure they were not prone to causing heavy metal poisoning.
d. Warn surgeons of the design similarities and the need to inform and carefully follow-up with their patients.

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

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

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

M. In 2010, Dutch Researchers Warn Biomet Of Pseudotumors From M2a Implants

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

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

81. From 2005 to 2007, Isala implanted patients with Biomet's M2a Magnum metal on metal hip replacements.

82. 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 Magnum hip replacement.

N. Biomet Was Warned That Advanced Screening Protocols Were Necessary To See Tissue Death From M2a Heavy Metal Poisoning

83. Isala reported to Biomet that the necessity for revision surgery was not identified until Isala conducted advanced screening protocols of their M2a patients.

84. 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.

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

86. Isala encouraged Biomet to adopt an advanced screening protocol of all patients with Biomet M2a products implanted in their bodies and warned that without such, patients may be at risk without knowing it.

87. The Isala Klinieken reported some of its findings regarding the M2a Magnum in a British medical journal.[10]

88. Despite all of these critical warnings provided by the Isala Klinieken, Defendants failed to inform surgeons or patients in the United States of the study, ignored the need for follow-up screening, and instead continued to promote the M2a products for implantation into the bodies of patients.

O. Finland University Reports Severe Adverse Reactions From M2a Heavy Metal Debris

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

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

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

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

93. 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**." [11]

94. Defendants failed to inform surgeons or patients in the United States of the existence of this study, that Turku University had discouraged use of the M2a Magnum, and of the need for

[10] 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.

[11] 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. Emphasis added.

surgeons to screen their patients for Adverse Reaction to Metal Debris. Instead, Defendants continued to promote the M2a products for implantation into the bodies of patients.

P. Biomet Used Olympic Gymnast Mary Lou Retton As M2a Spokesperson

95. As part of the promotion of the M2a hip replacements, Biomet hired Olympic gold-medal gymnast Mary Lou Retton as a spokesperson.

96. Mary Lou Retton first received an M2a hip replacement in 2005.

97. 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."[12]

98. 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.[13]

99. A heading on Biomet's brochure proclaims, "Mary Lou lives pain-free, and so should you."[14]

Q. Mary Lou Retton Has Sued Biomet Over Defective M2a Hip Replacement

100. Unfortunately, Mary Lou Retton, like the Plaintiff in this action, is an M2a victim.

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

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

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

R. Despite Knowing Of The Failure Of The M2a In Mary Lou Retton For Years, Biomet Continues To Claim Her A Success Story

103. 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.

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

105. 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.

S. Australian Government Required Biomet To Recall M2a

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

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

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

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

110. Because Biomet had already ceased selling the M2a in Australia in 2011, the Australian government's recall of the M2a consisted of the "Hazard Alert" and mandated Biomet notify implanting surgeons in Australia of the recall and excessive revision rate.

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

112. Defendants failed to disclose to orthopedic surgeons or the public in the United States that they ceased selling the M2a in Australia in 2011, while continuing to sell the same devices in the United States until 2015.

T. Biomet Issued A "Safety Alert" For High M2a Revision Rates In Europe, But Failed To Inform American Citizens Of Danger

113. Similar to Australia, the National Joint Registry (hereafter, "NJR") of England, Wales, and Northern Ireland gathers information on orthopedic implants sold in those countries.

114. Biomet ceased selling M2a implants in Europe in 2012.

115. On April 12, 2016, Biomet issued a "Field Safety Corrective Action" in various European nations, including England, Wales, and Northern Ireland, for the M2a 38 system.

116. Biomet admitted to European Surgeons in this Safety Alert, much as it did in the Australian Hazard Alert, that registry data revealed the M2a 38 to have a "higher than expected revision rate."

117. Defendants have failed to disclose to orthopedic surgeons or the public in the United States the existence of the European Safety Alert or their admission of a "higher than expected revision rate" with the M2a 38.

118. Defendants failed to disclose to orthopedic surgeons or the public in the United States that they ceased selling the M2a in Europe in 2012, while continuing to sell the same devices in the United States until 2015.

U. The M2a Is A Silent Hazard Implanted In Tens Of Thousands Of United States Citizens' Bodies

119. The Biomet M2a is inherently defective and unreasonably dangerous.

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

121. 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.

122. 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 patients with ticking time-bombs in their hips.

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

V. Defendants Continue To Claim That The M2a Implants Are Safe And Successful

124. Unlike in the rest of the world, Defendants continued to sell M2a hip replacements for implantation into the bodies of United States patients until 2015.

125. Defendants ceased selling Biomet M2a metal on metal hip replacements in the United States in 2015.

126. 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 implants.

127. To this day, Defendants continue to claim to orthopedic surgeons and the public that the M2a implants are safe and successful.

W. The United States Is Facing A Public Health Disaster From Unmonitored M2a Implants

128. 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.

129. The United States is facing a public health disaster from unmonitored M2a metal on metal hip replacements.

X. Plaintiff Suffered Heavy Metal Poisoning From The Biomet M2a

130. Patricia Traffas was implanted with the M2a hip replacement in her left hip on March 2, 2009.

131. The left M2a hip replacement failed requiring Ms. Traffas to undergo an additional surgery to remove the M2a on September 27, 2017.

132. During the September 27, 2017 left hip revision procedure, Plaintiff's surgeon, Cameron Ledford, M.D. encountered significant metallosis surrounding the greater trochanter and proimal stem and that the adverse metal reaction was retro-acetabular in nature with multiple areas of necrotic metal-stained bone and tissue with large cavitary defects, particularly in the posterior wall, ischium, and medial wall.

133. Ms. Traffas then underwent a long and painful recovery and rehabilitation from the removal of the failed Biomet M2a hip replacement.

DAMAGES

134. As a direct and proximate result of the defective M2a hip replacement, Plaintiff 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.

135. Plaintiff expects to continue suffering such injuries in the future as a result of the injuries received from the M2a hip replacement.

136. As a direct and proximate result of the defective M2a hip replacement, Plaintiff incurred medical expenses and expects to incur additional medical expenses in the future.

137. As a direct and proximate result of the defective M2a hip replacement, Plaintiff incurred lost earning potential, income and wages and expects to incur lost earnings, income and wages in the future.

138. As a direct and proximate result of the defective M2a hip replacement, Plaintiff experienced emotional trauma and distress and is likely to experience emotional trauma and distress

in the future.

COUNT ONE – FRAUD BIOMET DEFENDANTS

139. Plaintiff incorporates by reference Paragraphs 1 through 133 as though set forth fully herein.

140. Prior to the implantation of the M2a products in Plaintiff's body, and continuing thereafter, Biomet Defendants knowingly and intentionally undertook an inadequate testing protocol and false marketing scheme which made misrepresentations and omissions in order to profit from the unproven promise of the theoretical advantages associated with metal on metal hip replacements; said misrepresentations are previously set forth in greater detail herein, including but not limited to ¶s38-64; ¶s75-78; ¶88, ¶94, ¶s95-99; ¶103-105, ¶111, ¶s117-118, ¶122, and ¶s126-127.

141. Prior to the implantation of the M2a products in Plaintiff's body, and continuing thereafter, Biomet Defendants knowingly and intentionally engaged in a false marketing scheme which made misrepresentations and omissions to alter the orthopedic community's understanding of the clinical history of failure with previous generations of metal on metal hip replacements; said misrepresentations are previously set forth in greater detail herein, including but not limited to ¶s38-64; ¶s75-78; ¶88, ¶94, ¶s95-99; ¶103-105, ¶111, ¶s117-118, ¶122, and ¶s126-127.

142. Following the release of Biomet's M2a system, and prior to implantation of the M2a products in Plaintiff's body, Biomet Defendants engaged in a knowing and intentional scheme to make misrepresentations and omissions to hide clinical information relating to heavy metal poisoning from its metal on metal hip replacements.

143. Further, in support of these Fraud allegations, the Plaintiff pleads, prior to the implantation of the M2a products in Plaintiff's body and continuing thereafter, as follows:

a. Biomet Defendants were warned in 1995 that their testing protocols ignored

known dangers of metal on metal implants, yet moved forward with insufficient testing, anyway.

b. Biomet Defendants conducted laboratory testing for plastic hip implants and knew such testing was not appropriate for metal on metal hip implants.

c. Biomet Defendants knew that metal ions and particles released from the M2a are smaller, higher in number, and more toxic than plastic particles released from plastic implants.

d. Biomet Defendants marketed the M2a as having less volumetric wear than plastic hip implants, knowing it would mislead the orthopedic community into incorrectly believing that the M2a was safer and more effective.

e. Biomet Defendants engaged in a deceptive scheme to train sales representatives to convince the medical community that concerns over clinical risks due to metal wear are fake.

f. Biomet Defendants knowingly and intentionally underreported product failures.

g. Biomet Defendants knowingly and intentionally failed to properly analyze clinical information in order to suppress concern about the M2a's track record.

h. Biomet Defendants knowingly marketed a "reported adverse event rate" it knew would be relied upon by the orthopedic community and which it knew to be false based on its own deceptive scheme to suppress such rate.

i. Biomet Defendants shirked the scientific method in clinical tests by either designing the tests in order to elicit an intended result or by altering the data or input criteria, or by simply disregarding damaging results under the arbitrary decision that such results are "outliers" not indicative of actual performance.

j. Biomet Defendants falsely claimed "clinically proven results" in M2a products upon launch, despite never conducting a single pre-market clinical test.

k. Biomet Defendants falsely claimed that the M2a system "offers optimal joint mechanic restoration and ultra-low-wear rates in vivo" despite citing to a 1996 article about previously abandoned types of metal on metal hip replacements.

l. Despite knowing that published medical literature explicitly discussed adverse physiologic effects related to heavy metal wear from metal on metal hip implants, Biomet Defendants falsely claimed in marketing that extensive experience with metal on metal implants "failed to prove any cause for

concern" with its M2a implants.

m. Biomet Defendants falsely claimed in its marketing that "Cobalt and Chromium may be beneficial to the body" despite knowing that Cobalt and Chromium released from M2a implants are toxic.

n. Biomet Defendants intentionally misrepresented the existence of concern over heavy metal wear in order to market and profit from the sale of M2a implants.

o. Biomet Defendants deceptively engaged in marketing the M2a through Dr. Cuckler by not revealing their financial relationship in marketing literature, such as "The Rationale for Metal-on-Metal Total Hip Arthroplasty."

p. Biomet Defendants failed to inform the orthopedic community in the United States regarding the Isala Clinic's finding of the need for advanced screening protocols in order to diagnose heavy metal poisoning in M2a patients; instead Biomet Defendants continued to heavily promote M2a products.

q. Biomet Defendants failed to inform the orthopedic community in the United States regarding Turku University's finding of heavy metal poisoning in over half of the patients who received an M2a and of Turku University's warning claiming that they "discourage use of this device."

r. Biomet Defendants failed to inform the public that the M2a posterchild, Mary Lou Retton, had both of her M2a implants fail due to heavy metal poisoning.

s. Biomet Defendants continued to falsely claim Mrs. Retton as a "patient success story."

t. Biomet Defendants failed to inform United States citizens and surgeons of the international recalls, hazard alerts, and safety notices related to its M2a.

144. Biomet Defendants made these misrepresentations and omissions with the specific intent that Plaintiff and Plaintiff's orthopedic surgeon rely on such representations and omissions with intent to deceive the orthopedic community and profit from deceitfully convincing them to use metal on metal hip replacements again, particularly the M2a.

145. The above representations and/or omissions were false or untrue, or were recklessly made without knowledge concerning them.

146. Biomet Defendants knew that these statements were false at the time they were made, in that they had information in their possession and control directly contradicting the misrepresentations, or alternatively Biomet Defendants made these representations without knowing whether they were true or false.

147. Biomet Defendants made these statements for the purpose of inducing Plaintiff, Plaintiff's orthopedic surgeon, the orthopedic community, and consumers in need of a hip replacement, to act in reliance thereon to purchase the M2a products.

148. Plaintiff, and Plaintiff's orthopedic surgeon agent, acted in reliance on the correctness of Biomet's representations which resulted in injury to Plaintiff as described above, by deciding to use, install and purchase the M2a products based on the misrepresentations.

149. The above referenced reliance was reasonable under the circumstances.

150. The representations and omissions were material to Plaintiff's orthopedic surgeon in selecting the M2a products installed in Plaintiff.

151. The representations and omissions were material to Plaintiff in selecting the M2a products.

152. As a direct and proximate result of the Biomet Defendants' fraudulent conduct, Plaintiff suffered pecuniary loss, injury and damage as described herein.

COUNT TWO – FRAUD CUCKLER DEFENDANTS

153. Plaintiff incorporates by reference Paragraphs 1 through 133 as though set forth fully herein.

154. Prior to the implantation of the M2a product in Plaintiff's body, and continuing thereafter, Cuckler Defendants knowingly and intentionally undertook an inadequate testing protocol and false marketing scheme which made misrepresentations and omissions in order to profit from the unproven promise of the theoretical advantages associated with metal on metal hip

replacements; said misrepresentations are previously set forth in greater detail herein, including but not limited to ¶s38-64; ¶s75-78; ¶88, ¶94, ¶s95-99; ¶103-105, ¶111, ¶s117-118, ¶122, and ¶s126-127.

155. Prior to the implantation of the M2a products in Plaintiff's body, and continuing thereafter, Cuckler Defendants knowingly and intentionally engaged in a false marketing scheme which made misrepresentations and omissions to alter the orthopedic community's understanding of the clinical history of failure with previous generations of metal on metal hip replacements. Cuckler Defendants intentionally minimized the risks of the toxic heavy metals released by metal on metal hip replacements; said misrepresentations are previously set forth in greater detail herein, including but not limited to ¶s38-64; ¶s75-78; ¶88, ¶94, ¶s95-99; ¶103-105, ¶111, ¶s117-118, ¶122, and ¶s126-127.

156. Cuckler Defendants engaged in this false marketing scheme with the specific intent that Plaintiff and Plaintiff's orthopedic surgeon rely on such representations and omissions and with intent to deceive the orthopedic community and profit from deceitfully convincing them to use metal on metal hip replacements and Biomet metal on metal hip replacements in particular.

157. Further, in support of these Fraud allegations, the Plaintiff pleads, prior to the implantation of the M2a products in Plaintiff's body and continuing thereafter, as follows:

a. Cuckler Defendants knew that laboratory testing conducted on the M2a was not appropriate for metal on metal hip implants.

b. Cuckler Defendants knew that metal ions and particles released from the M2a are smaller, higher in number, and more toxic than plastic particles released from plastic implants.

c. Cuckler Defendants marketed the M2a as having less volumetric wear than plastic hip implants, knowing it would mislead the orthopedic community into incorrectly believing that the M2a was safer and more effective.

d. Despite knowing that published medical literature explicitly discussed adverse physiologic effects related to heavy metal wear from metal on metal hip implants, Cuckler Defendants knowingly published literature falsely

claiming that extensive experience with metal on metal implants has shown "no adverse physiologic effects" related to metal on metal hip replacements.

e. Cuckler Defendants intentionally misrepresented the existence of concern over heavy metal wear in order to market and profit from the sale of M2a implants.

f. Cuckler Defendants deceptively engaged in marketing the M2a by not revealing its financial relationship with Biomet in marketing literature, such as "The Rationale for Metal-on-Metal Total Hip Arthroplasty."

158. The above referenced statements, representations and omissions were false, or untrue or were recklessly made without knowledge concerning them.

159. Cuckler Defendants knew that these statements were false at the time they were made, in that they had information in their possession and control directly contradicting the misrepresentation, or alternatively Cuckler Defendants made the representations without knowing whether they were true or false.

160. Cuckler Defendants made these statements for the purpose of inducing Plaintiff, Plaintiff's orthopedic surgeon, the orthopedic community, and consumers in need of a hip replacement, to act in reliance thereon to purchase the M2a products.

161. Plaintiff, and Plaintiff's orthopedic surgeon agent, acted in reliance on the correctness of Cuckler's representations which resulted in injury to Plaintiff as described above, by deciding to use, install and purchase the M2a products based on the misrepresentations.

162. The above referenced reliance was reasonably under the circumstances.

163. The representations and omissions were material to Plaintiff's orthopedic surgeon in selecting the M2a products installed in Plaintiff.

164. The representations and omissions were material to Plaintiff in selecting the M2a products.

165. As a direct and proximate result of the Cuckler Defendants' fraudulent conduct, Plaintiff suffered loss, injury and damage as described herein.

COUNT THREE – FRAUDULENT CONCEALMENT ALL DEFENDANTS

166. Plaintiff incorporates by reference Paragraphs 1 through 133 as though set forth fully herein.

167. Defendants had sole access to material facts concerning the dangers and unreasonable risks of the M2a.

168. Prior to implantation of the M2a Product in Plaintiff's body and continuing thereafter, Biomet Defendants knowingly and willfully concealed material information with respect to the M2A in a manner to distort its safety record and falsely portray the system to the orthopedic community and public as safe and effective, which is evidenced by the following:

a. Biomet Defendants were warned in 1995 that their testing protocols ignored known dangers of metal on metal implants, yet moved forward with insufficient testing, anyway.

b. Biomet Defendants conducted laboratory testing for plastic hip implants and knew the testing procedure used for plastic hips was not appropriate for metal on metal hip implants.

c. Biomet Defendants knew that metal ions and particles released from the M2a are smaller, higher in number, and more toxic than plastic particles released from plastic implants.

d. Biomet Defendants marketed the M2a as having less volumetric wear than plastic hip implants, knowing it would mislead the orthopedic community into incorrectly believing that the M2a was safer and more effective.

e. Biomet Defendants engaged in a deceptive scheme to train sales representatives to convince the medical community that concerns over clinical risks due to metal wear are fake.

f. Biomet Defendants knowingly and intentionally underreported product failures.

g. Biomet Defendants knowingly and intentionally failed to properly analyze clinical information in order to suppress concern about the M2a's track record.

h. Biomet Defendants knowingly marketed a "reported adverse event rate" it knew would be relied upon by the orthopedic community and which it knew to be false based on its own deceptive scheme to suppress such rate.

i. Biomet Defendants shirked the scientific method in clinical tests by either designing the tests in order to elicit an intended result or by altering the data or input criteria, or by simply disregarding damaging results under the arbitrary decision that such results are "outliers" not indicative of actual performance.

j. Biomet Defendants falsely claimed "clinically proven results" in M2a products upon launch, despite never conducting a single pre-market clinical test.

k. Biomet Defendants falsely claimed that the M2a system "offers optimal joint mechanic restoration and ultra-low-wear rates in vivo" despite citing to a 1996 article about previously abandoned types of metal on metal hip replacements.

l. Despite knowing that published medical literature explicitly discussed adverse physiologic effects related to heavy metal wear from metal on metal hip implants, Biomet Defendants falsely claimed in marketing that extensive experience with metal on metal implants "failed to prove any cause for concern" with its M2a implants.

m. Biomet Defendants falsely claimed in its marketing that "Cobalt and Chromium may be beneficial to the body" despite knowing that Cobalt and Chromium released from M2a implants are toxic.

n. Biomet Defendants intentionally misrepresented the existence of concern over heavy metal wear in order to market and profit from the sale of M2a implants.

o. Biomet Defendants deceptively engaged in marketing the M2a through Dr. Cuckler by not revealing their financial relationship in marketing literature, such as "The Rationale for Metal-on-Metal Total Hip Arthroplasty."

p. Biomet Defendants failed to inform the orthopedic community in the United States regarding the Isala Clinic's finding of the need for advanced screening protocols in order to diagnose heavy metal poisoning in M2a patients; instead Biomet Defendants continued to heavily promote M2a products.

q. Biomet Defendants failed to inform the orthopedic community in the United States regarding Turku University's finding of heavy metal poisoning in over half of the patients who received an M2a and of Turku University's warning claiming that they "discourage use of this device."

r. Biomet Defendants failed to inform the public that the M2a posterchild, Mary Lou Retton, had both of her M2a implants fail due to heavy metal poisoning.

s. Biomet Defendants continued to falsely claim Mrs. Retton as a "patient success story."

t. Biomet Defendants failed to inform United States citizens and surgeons of the international recalls, hazard alerts, and safety notices related to its M2a.

u. Biomet Defendants employed Cuckler Defendants to alter the orthopedic community's perception of the failures of past generations of metal on metal implants and to falsely market current metal on metal technology, including the M2a, as having no (or minimal) risk of wear-related pathological reaction.

169. Prior to implantation of the M2a Product in Plaintiff's body, and continuing thereafter, Cuckler Defendants knowingly and willfully concealed material information with respect to the M2A in a manner to distort its safety record and falsely portray the system to the orthopedic community and public as safe and effective, as evidenced by the following:

a. Cuckler Defendants knew that laboratory testing conducted on the M2a was not appropriate for metal on metal hip implants.

b. Cuckler Defendants knew that metal ions and particles released from the M2a are smaller, higher in number, and more toxic than plastic particles released from plastic implants.

c. Cuckler Defendants concealed the significance of heavy metal size, number, and toxicity, and instead marketed the M2a as having less volumetric wear than plastic hip implants. Cuckler Defendants did this knowing it would mislead the orthopedic community into incorrectly believing that the M2a was safer and more effective.

d. Despite knowing that published medical literature explicitly discussed adverse physiologic effects related to heavy metal wear from metal on metal hip implants, Cuckler Defendants knowingly published literature falsely claiming that extensive experience with metal on metal implants has shown "no adverse physiologic effects" related to metal on metal hip replacements.

e. Cuckler Defendants intentionally misrepresented the existence of concern over heavy metal wear in order to market and profit from the sale of M2a implants.

f. Cuckler Defendants deceptively engaged in marketing the M2a by not revealing its financial relationship with Biomet in marketing literature, such as "The Rationale for Metal-on-Metal Total Hip Arthroplasty."

170. Defendants concealed this information and provided its misrepresentations with the intent that Plaintiff and Plaintiff's orthopedic surgeon rely upon such misrepresentation and concealments, and with intent that the orthopedic community and Plaintiff, through Plaintiff's doctors, rely upon the misrepresented safety record of the M2a.

171. Defendants knew prior to the M2a being implant in Plaintiff, that cobalt chromium metal on metal hips were unreasonably dangerous and that the clinical history of the technology did not support its continued use. Despite this knowledge, Defendants knowingly and willfully concealed material information about the dangerous propensities of cobalt chromium metal on metal hips, including the M2a, in an effort to promote and financially benefit from the sales of the M2a.

172. Defendants were under an obligation to communicate the concealed information.

173. Plaintiff, through Plaintiff's physicians, did rely upon Defendants' concealed misrepresentations, both prior to implantation of the M2a Product in Plaintiff's body and subsequently thereafter.

174. The above referenced reliance by Plaintiff and Plaintiff's physicians was reasonable.

175. The fraudulent concealment from Plaintiff and Plaintiff's physicians was material to the use and installation by Plaintiff's physicians.

176. The fraudulent concealment from Plaintiff and Plaintiff's physicians was material to Plaintiff in the decision to have the M2a products installed in his body.

177. As a result of Defendants' fraudulent concealment, Plaintiff was injured as alleged herein.

COUNT FOUR – STRICT LIABILITY FAILURE TO WARN ALL DEFENDANTS

178. Plaintiff incorporates by reference Paragraphs 1 through 133 as though set forth fully herein.

179. 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.

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

181. At the time and on the occasion 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.

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

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

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

185. 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.

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

187. As a direct and proximate result of the lack of reasonable and adequate instructions or warnings regarding the defects in the M2a, Plaintiff suffered the injuries and damage as described herein.

COUNT FIVE – STRICT LIABILITY- DESIGN AND MANUFACTURING DEFECT ALL DEFENDANTS

188. Plaintiff incorporates by reference Paragraphs 1 through 133 as though set forth fully herein.

189. 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, including but not limited to the following defects:

a. The design of the M2a caused it to generate excessive cobalt and chromium metal debris into the body;

b. The surface roughness of the M2a was not within acceptable standards and specifications;

c. The thickness, porosity, tensile strength of the plasma porous spray coating was not within acceptable standards and/or specifications;

d. The plasma porous spray coating utilized was not designed to be utilized on the acetabular cup of the M2a;

e. The plasma porous spray coating contributed to generating excessive metal wear debris;

f. The design of the acetabular cup caused it to fail to obtain bone ingrowth;

g. The claimed advantages of the M2a did not justify the additional risks created by metal debris of the M2a as compared to non metal on metal hip replacements on the market;

h. The design of the M2a caused excessive corrosion as compared to other hip replacement products on the market;

i. The design of the M2a caused the taper adapter and stem to cold weld;

j. The design of the instrumentation, including the inserter tools, resulted in excessive failures.

190. The M2a reached Plaintiff without substantial change in the condition in which it was sold.

191. At the time and on the occasion 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.

192. The M2a, for the reasons previously set forth herein, was defective, unsafe and unreasonably dangerous in design and manufacture.

193. As a direct and proximate result of the defects in the M2a, Plaintiff suffered the injuries and damages described herein.

COUNT SIX – BREACH OF IMPLIED WARRANTY BIOMET DEFENDANTS

194. Plaintiff incorporates by reference Paragraphs 1 through 133 as though set forth fully herein.

195. 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.

196. Plaintiff was a foreseeable user of the products at issue in this Complaint.

197. Plaintiff's surgeon, as a purchasing agent, purchased the products at issue in this Complaint for Plaintiff from Biomet Defendants.

198. At all times relevant to this Complaint, Plaintiff was in privity with the Biomet Defendants.

199. Plaintiff used the products at issue in this Complaint for its ordinary and intended purpose.

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

201. As a direct and proximate result of Biomet Defendant's breach of implied warranty, Plaintiff suffered injuries and damages described herein.

COUNT SEVEN – BREACH OF EXPRESS WARRANTY BIOMET DEFENDANTS

202. Plaintiff incorporates by reference Paragraphs 1 through 133 as though set forth fully herein.

203. Biomet Defendants sold and Plaintiff purchased, through Plaintiff's purchasing agent surgeon, the products at issue in this Complaint.

204. At all times relevant to this Complaint, Plaintiff was in privity with Biomet Defendants.

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

206. Such representations by Biomet Defendants were meant to induce Plaintiff, through Plaintiff's physician, to purchase the products at issue in this Complaint.

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

208. Biomet Defendants breached the express warranties it provided with the products at issue in this Complaint.

209. As a direct and proximate result of Biomet Defendant's breach of express warranties, Plaintiff suffered injuries and damages described herein.

COUNT EIGHT – NEGLIGENT MISREPRESENTATION ALL DEFENDANTS

210. Plaintiff incorporates by reference Paragraphs 1 through 133 as though set forth fully herein.

211. 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 including the

statement and omission set forth in ¶s38-64; ¶s75-78; ¶88, ¶94, ¶s95-99; ¶s103-105, ¶111, ¶s117-118, ¶122, ¶s126-127, ¶143, ¶157, and ¶s168-169.

212. As stated above, Defendants, through sales literature, marketing materials, meetings, and verbal communications, medical publications, seminars and in the course of their business, made misrepresentations of material facts about the M2a and/or concealed information about the M2a from Plaintiff and her orthopedic surgeon prior to Plaintiff's surgery in 2009 including, but not limited to:

a. Misrepresenting the M2a is designed to reduce wear and provide higher function for all patients;

b. Misrepresenting the M2a is clinically proven to reduce wear;

c. Misrepresenting the M2a is based on a strong clinical history and reduces wear compared to the traditional hip replacement;

d. Misrepresenting the M2a is designed to be installed in younger and more active patients and will last longer than its competitors;

e. Misrepresenting the success rate of the M2a;

f. Failing to disclose that the metal used for the M2a was prone to increased wear and caused excessive metal debris;

g. Failing to disclose the M2a failed to obtain bony ingrowth and became loose;

h. Failing to disclose that they were aware of and/or witnessed revision surgeries in which the M2a had failed, including becoming loose, causing metalosis, excessive wear and corrosion on the neck stem, dislocations, fractures of hardware, loose acetabular components, pseudotumors, ALVAL, ARMD and infection; and

i. Failing to disclose that orthopedic surgeons were complaining about the M2a and were experiencing difficulty in installing the M2a.

213. Defendants made these misrepresentations of material fact and/or concealments of information about the M2a from Plaintiff and Plaintiff's orthopedic surgeon, prior to Plaintiff's surgery on March 2, 2009, and continued the misrepresentations and omissions thereafter.

214. Defendants were negligent in making such statements and/or concealing information

because they should have known the statements were false or omitted material information.

215. In making these statements and/or omissions, Defendants intended or expected that Plaintiff and others would rely on the statements and/or omissions.

216. Prior to Plaintiff's surgery, Plaintiff and her orthopedic surgeon were induced to act in reliance on Defendant's misrepresentations and/or omissions and in fact purchased the M2a and installed the M2a in Plaintiff's hips.

217. Defendants failed to exercise ordinary care in making the above representations and/or omissions and instead made the above representations and/or omissions knowing the representations were false or were ignorant of the truth of the assertion.

218. Plaintiff and her orthopedic surgeon relied on the truth of Defendant's representations and/or omissions about the M2a and had a right to rely on such.

219. Plaintiff and Plaintiff's orthopedic surgeon are persons or one of a group of person for whose benefit and guidance the false information was supplied.

220. Plaintiff was ignorant of Defendant's false information, misrepresentations and/or omissions.

221. As a direct and proximate result of the negligent misrepresentations and omissions regarding the M2a, Plaintiff suffered injuries and damages as described herein.

COUNT NINE – NEGLIGENCE ALL DEFENDANTS

222. Plaintiff incorporates by reference Paragraphs 1 through 133 as though set forth fully herein.

223. Defendants, as the designers, manufacturers, promoters, marketers, sellers, suppliers, distributors, and/or servicers of the Biomet M2a hip replacement system, owed a duty to use reasonable care in the design, manufacture, promotion, marketing, selling, supplying, distribution, and/or service of Plaintiff's hip replacement.

224. 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.

225. Further, Defendants owed Plaintiff 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.

226. Defendants had a duty to adequately warn Plaintiff of defects in the M2a which it knew or should have known about.

227. Defendants had a continuing, post-sale, duty to warn Plaintiff and others of unreasonable risks of harms associated with the M2a.

228. Defendants breached the above duties by failing to adequately warn Plaintiff, Plaintiff's orthopedic surgeon, and the orthopedic community regarding risks and dangers of the M2a.

229. Defendants, in breach of the duties described above, negligently and carelessly designed, manufactured, promoted, marketed, sold, supplied, distributed and serviced the M2a hip replacement components implanted in Plaintiff.

230. Defendants, in breach of the duties described above, negligently and carelessly failed to provide reasonable, complete, and accurate information to Plaintiff, his orthopedic surgeon, and the orthopedic community regarding Plaintiff's M2a.

231. As a direct and proximate result of Defendants' breaches of duty, Plaintiff needlessly suffered injuries and damages as described herein.

COUNT TEN – INFORMATION NEGLIGENTLY SUPPLIED FOR THE GUIDANCE OF OTHERS ALL DEFENDANTS

232. Plaintiff incorporates by reference Paragraphs 1 through 133 as though set forth fully herein.

233. Plaintiff's purchase of the M2a was a business transaction.

234. The Defendants all had a pecuniary interest in the design, development, promotion, and testing of the M2a.

235. The Defendants supplied false information for the guidance of others regarding the selection of the M2a as a safe and effective hip replacement option, as set forth in greater detail and alleged in ¶s38-64; ¶s75-78; ¶88, ¶94, ¶s95-99; ¶s103-105, ¶111, ¶s117-118, ¶122, ¶s126-127, ¶143, ¶157, ¶s168-169 and ¶212.

236. The Defendants failed to exercise reasonable care or competence in obtaining and communicating the information supplied for the guidance of others regarding the M2a.

237. Plaintiff, and Plaintiff's orthopedic surgeon agent, were within the limited group of persons for whose benefit and guidance the Defendants intended to supply the information.

238. The Defendants intended for their information to influence either the transaction in which Plaintiff, through Plaintiff's orthopedic surgeon agent, purchased the M2a or a substantially similar transaction.

239. Plaintiff's orthopedic surgeon is a person who is one of a group of orthopedic surgeons to whom Defendants supplied the false information in which Defendants knew would be communicated to Plaintiff and patients.

240. Plaintiff, individually and through Plaintiff's orthopedic surgeon agents, justifiably relied upon the information provided by Defendants.

241. As a direct and proximate result of the Defendants' false information, Plaintiff suffered pecuniary loss, injury and damages as described herein .

COUNT ELEVEN- VIOLATION OF KANSAS CONSUMER PROTECTION ACT, K.S.A. 50-623, *et. Seq*. ALL DEFENDANTS

242. Plaintiff incorporates by reference Paragraphs 1 through 135 as though set forth fully herein.

243. Defendants sold, promoted, marketed and advertised the M2a hip systems in violation of K.S.A. § 50-626, which states:

> 50-626. Deceptive acts and practices. (a) No supplier shall engage in any deceptive act or practice in connection with a consumer transaction. (b) Deceptive acts and practices include, but are not limited to, the following, each of which is hereby declared to be a violation of this act, whether or not any consumer has in fact been misled: (1) Representations made knowingly or with reason to know that: . . . (D) property or services are of particular standard, quality grade, style or model, if they are of another which differs materially from the representation; . . . (2) the willful use, in any oral or written representation, of exaggeration, falsehood, innuendo or ambiguity as to a material fact; (3) the willful failure to state a material fact, or the willful concealment, suppression or omission of a material fact

244. Defendants conduct set forth in paragraphs in ¶s 36-63; ¶s72-77; ¶87, ¶93, ¶s96-98; ¶102-104, ¶110, ¶111, ¶116, ¶117, ¶121, ¶125, ¶126, ¶145, ¶159, and ¶170-171 herein specifically violated K.S.A. § 50-626.

245. Plaintiff Patricia Traffas purchased the M2a hip systems for personal use.

246. As a direct result of the violation of K.S.A. 50-623, *et*. *Seq*, Plaintiff Patricia Traffas suffered an ascertainable loss of money.

247. Defendants conducted an improper act upon Plaintiff Patricia Traffas in that Defendants exhibited an unlawful practice as considered under K.S.A. 50-623, *et*. *Seq* by concealing from Plaintiff Patricia Traffas, and his orthopedic surgeon, that Defendants knew the defective M2a hip systems sold to Plaintiff Patricia Traffas were in fact not suitable for use as a hip prosthesis.

248. The Court should award an additional sum for punitive damages and attorney fees based on the amount of time reasonably expended as provided in K.S.A. § 50-634(e) which states:

> 50 -634(e). Except for services performed by the office of the attorney general or the office of a county or district attorney, the court may award to the prevailing party reasonable attorney fees, including those on appeal, limited to the work reasonably performed if: (1) The consumer complaining of the act or practice that violates this act has brought or maintained an action the consumer knew to be groundless and the prevailing party is the supplier; or a supplier has committed an act or practice that violates this act and the prevailing party is the consumer; and (2) an action under this section has been terminated by a judgment, or settled.

PUNITIVE DAMAGES

249. Plaintiff incorporates by reference each of the allegations set forth in this Complaint as though fully set forth herein.

250. The acts, conduct, and omissions of Defendants, as alleged throughout this Complaint were malicious, willful, wanton, intentionally, oppressive and fraudulent. Defendants committed these acts with a conscious disregard for the rights of Plaintiff and other M2a system users and for the primary purpose of increasing Defendants' profits from the sale and distribution of the M2a system. Defendants' outrageous and unconscionable conduct warrants an award of exemplary and punitive damages in an amount appropriate to punish and make an example deter such conduct of Defendants in the future.

251. Prior to the manufacturing, sale, and distribution of the M2a system, Defendants knew that said product was in a defective condition and users would experience and did experience severe injuries. Further, Defendants, through their officers, directors, managers, and agents, knew that the product presented a substantial and unreasonable risk of harm to the public, including Plaintiff and as such, Defendants unreasonably subjected consumers to risk of injury from using the M2a system

252. Despite their knowledge, Defendants, acting through their officers, directors and managing agents, for the purpose of enhancing Defendants' profits, knowingly and deliberately

failed to remedy the known defects in the M2a system and failed to warn the public, including Plaintiff, of the extreme risk of injury occasioned by said defects inherent in the M2a system. Defendants and their agents, officers, and directors intentionally proceeded with the manufacturing, sale, distribution and marketing of the M2a system, knowing that these actions would expose users to serious danger in order to advance Defendants' pecuniary interest and monetary profits.

DEMAND FOR JURY TRIAL

253. Plaintiff respectfully requests 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

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, prays for relief and judgment against Defendants as follows:

(a) For general damages in a sum in excess of the jurisdictional minimum of this Court;

(b) For medical, incidental, and hospital expenses; both past and future according to proof;

(c) For Past and future lost wages and loss of income:

(d) For pre-judgment and post-judgment interest as provided by law;

(e) For a full refund of all purchase costs Plaintiff paid for the M2a system;

(f) For compensatory damages in excess of the jurisdictional minimum of this Court;

(g) For consequential damages in excess of the jurisdictional minimum of this Court;

(h) For punitive damages in an amount sufficient to deter similar conduct in the future;

(i) For attorneys' fees, expenses, and costs of this action; and

(j) For such further relief as this Court deems necessary, just and proper.

Dated: February 28, 2019

/s/ Brian Franciskato

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Attorneys for Plaintiff

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF KANSAS

PATRICIA A. TRAFFAS, Plaintiff, v. BIOMET, INC.; BIOMET ORTHOPEDICS, LLC; BIOMET U.S. RECONSTRUCTION, LLC; BIOMET MANUFACTURING, LLC; ZIMMER BIOMET HOLDINGS, INC; JOHN CUCKLER, M.D.; and ALABAMA MEDICAL CONSULTANTS, INC., Defendants.	)	Case No. 2:19-cv-2115

PLAINTIFF'S DESIGNATION OF PLACE OF TRIAL

COMES NOW, the Plaintiff, by and through her counsel of record and hereby designate the place of trial as follows: **Kansas City, Kansas.**

Dated: February 28, 2019

/s/ Brian Franciskato

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JS 44 (Rev. 06/17)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS

PATRICIA A. TRAFFAS

(b) County of Residence of First Listed Plaintiff Johnson County, MO
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Nash & Franciskato Law Firm, 2300 Main Street, Suite 170
Kansas City, MO 64108; (816) 221-6600

DEFENDANTS

Biomet, Inc.; Biomet Orthopedics, LLC; Biomet U.S. Reconstruction, LLC; Biomet Manufacturing, LLC; Zimmer Biomet Holdings, Inc.; John Cuckler, M.D.; and Alabama Medical Consultants, Inc.

County of Residence of First Listed Defendant Kosciusko County, IN
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ☐ 1 U.S. Government Plaintiff
- ☐ 2 U.S. Government Defendant
- ☐ 3 Federal Question *(U.S. Government Not a Party)*
- ☒ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*

(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☒ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☒ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

Click here for: Nature of Suit Code Descriptions.

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Personal Injury - Medical Malpractice

PERSONAL INJURY
- ☐ 365 Personal Injury - Product Liability
- ☒ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

FORFEITURE/PENALTY
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 835 Patent - Abbreviated New Drug Application
- ☐ 840 Trademark

OTHER STATUTES
- ☐ 375 False Claims Act
- ☐ 376 Qui Tam (31 USC 3729(a))
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit
- ☐ 490 Cable/Sat TV
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 895 Freedom of Information Act
- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

CIVIL RIGHTS
- ☐ 440 Other Civil Rights
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 445 Amer. w/Disabilities - Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 448 Education

PRISONER PETITIONS

Habeas Corpus:
- ☐ 463 Alien Detainee
- ☐ 510 Motions to Vacate Sentence
- ☐ 530 General
- ☐ 535 Death Penalty

Other:
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition
- ☐ 560 Civil Detainee - Conditions of Confinement

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Management Relations
- ☐ 740 Railway Labor Act
- ☐ 751 Family and Medical Leave Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Employee Retirement Income Security Act

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 465 Other Immigration Actions

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

V. ORIGIN *(Place an "X" in One Box Only)*

☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from Another District *(specify)* ☐ 6 Multidistrict Litigation - Transfer ☐ 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing ***(Do not cite jurisdictional statutes unless diversity)***:
28 U.S.C. Sec 1332

Brief description of cause:
Products Liability

VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A **CLASS ACTION** UNDER RULE 23, F.R.Cv.P.

DEMAND $

CHECK YES only if demanded in complaint:

JURY DEMAND: ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY

(See instructions):

JUDGE _____ DOCKET NUMBER _____

DATE
02/28/2019

SIGNATURE OF ATTORNEY OF RECORD
s/ Brian S. Franciskato

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

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