IN THE CIRCUIT COURT OF THE TWENTIETH JUDICIAL CIRCUIT
IN AND FOR COLLIER COUNTY, FLORIDA

DEBRA WILLIAMS, Plaintiff, *v.* JOHN CUCKLER, M.D.; ALABAMA MEDICAL CONSULTANTS, INC.; GERALD R. CARTER; CARTER ORTHOPEDICS, INC.; BIOMET, INC; BIOMET ORTHOPEDICS, LLC; BIOMET U.S. RECONSTRUCTION, LLC; and BIOMET MANUFACTURING, LLC Defendants.	)	Civil Action No.:

AMENDED COMPLAINT

(Consent Addition of Demand for Punitive Damages)

Plaintiff, DEBRA WILLIAMS ("Plaintiff"), brings suit against Defendants JOHN CUCKLER, M.D. (hereafter "CUCKLER") and ALABAMA MEDICAL CONSULTANTS, INC. (hereafter "AMC")(CUCKLER and AMC collectively referred to as "Cuckler Defendants"), as designers, developers, and promoters of the Biomet M2a Metal-on-Metal Hip Replacement System, against Defendants GERALD R. CARTER (hereafter "CARTER") and CARTER ORTHOPEDICS, INC., (hereafter "COI")(CARTER and COI hereafter collectively, "Distributor Defendants" or "Distributors") as promoters, distributors, and servicers of the Biomet M2a Metal-on-Metal Hip Replacement System, and against Defendants BIOMET, INC., (hereafter "BMI"), BIOMET ORTHOPEDICS, LLC, (hereafter "BMO"), BIOMET U.S. RECONSTRUCTION, LLC (hereafter "BMR"), and BIOMET MANUFACTURING, LLC. (hereafter "BMM")(hereafter BMI, BMO, BMR, and BMM collectively referred to as "Biomet"

or "Biomet Defendants") as designers, developers, manufacturers, and promoters of the Biomet M2a Metal-on-Metal Hip Replacement System, and states as follows:

INTRODUCTION, PARTIES, VENUE AND JURISDICTION

1. This is a lawsuit regarding a defective metal-on-metal hip replacement designed, manufactured, marketed, and promoted by Biomet; designed, developed, and promoted by Cuckler Defendants, and marketed, distributed, sold, and serviced within Florida by Distributor Defendants.

2. The particular hip replacement at issue in this case is the "Biomet M2a Metal-on-Metal Hip Replacement System" (hereafter referred to as the "M2a").

3. At all times relevant to this Complaint, Defendant BMI was and is an Indiana corporation, with its principal place of business in Warsaw, Indiana. Further, at all times relevant to this Complaint, Defendants BMO, BMR, and BMM each are and have been wholly owned subsidiaries of Defendant BMI.

4. At all times relevant to this Complaint, Defendant CUCKLER was and is a Florida resident, residing at 12005 Collier's Reserve Drive, Naples, Florida, 34110 and as such is a citizen of the State of Florida.

5. At all times relevant to this Complaint, AMC was and is an Alabama corporation with its principal place of business at 12005 Collier's Reserve Drive, Naples, Florida, 34110 and as such is a citizen of the State of Florida.

6. Defendant CUCKLER, personally and through his company, AMC, received royalties and financially profited from his design, development, and promotion of the M2a metal-on-metal hip replacement system ("M2a").

7. At all times relevant to this Complaint, Defendant CARTER was and is a Florida resident, residing at 2633 Holly Point Road East, Orange Park, Florida, 32073, and as such is a citizen of the State of Florida.

8. At all times relevant to this Complaint, Defendant COI was and is a Florida corporation with its principal place of business at 2633 Holly Point Road East, Orange Park, Florida, 32073, and as such is a citizen of the State of Florida.

9. Jurisdiction is proper in the Courts of the State of Florida because Cuckler Defendants and Distributor Defendants are residents of the State of Florida.

10. Venue is proper in the Twentieth Judicial Circuit in and for Collier County in that at present and at all times relevant to this action, the following actions underlying this suit took place in Collier County:

a) Defendant CUCKLER resided in Collier County;
b) Defendant AMC had its principal place of business in Collier County;

TOTAL HIP ARTHROPLASTY

11. Total Hip Arthroplasty (hereafter "THA") is the term used to describe surgery wherein a patient's natural hip anatomy is replaced with synthetic components. THA is also commonly referred to as "hip replacement surgery." A patient may need a THA for a variety of medical reasons including degenerative bone disease and avascular necrosis.

12. THA involves invasive and traumatic surgery in which a surgeon saws and removes a considerable portion of bone, including the ball, from the top of the femur. In place of the removed bone, the surgeon places a metal shaft, called a "stem," down into what remains of the femoral bone. The portion of the stem which is housed inside the femur may be affixed to the bone via use of bone cement or by a porous coating on the synthetic surface of the stem into which the natural bone will grow. The top of the synthetic metal stem, referred to as the "neck,"

is not housed inside the femur and remains completely exposed inside the body. A component called a "taper," which can be roughly described as similar to a metal sleeve, fits on top of, and around, the exposed neck of the stem. A synthetic ball, whether made of metal, plastic, or ceramic, is then attached on top of, and around, the taper.

13. During THA, the surgeon also replaces the anatomical hip socket, the acetabulum, with an artificial "cup" against which the new, synthetic ball articulates. This cup is sometimes referred to as an "acetabular cup." To implant an acetabular cup, the surgeon removes bone from the natural acetabulum in an effort to create a new hip socket large enough to house the synthetic cup. The surgeon then places the synthetic cup into the newly formed hip socket. The cup affixes to the bone either through the use of screws, bone cement, a porous metal coating on the back of the synthetic cup into which the natural bone should grow, or by a combination of the three.

14. A successful THA results in a hip prosthesis that should last 20+ years in a patient.

15. If a hip prosthesis fails in a patient, the patient's surgeon may recommend a "revision" THA procedure in order to replace the failed hip component or components.

16. A revision THA is extremely traumatic to a patient, multitudes more so than a primary THA. The surgery is typically much longer, with greater blood loss, greater surgeon difficulty, and greater mortality rate. The rehabilitation period for a revision THA is typically much longer than after a THA.

17. Depending on the mode of failure for a hip prosthesis, the patient's natural anatomy may be so damaged that subsequent revision hip implants will be more likely to fail prematurely.

HIP IMPLANT DESIGN

18. Modern techniques for performing THA and for designing and manufacturing hip replacement components are based on a design introduced by Sir John Charnley in 1962. The design he created and used to perform THA consisted of three components: a one-piece stainless-steel femoral stem and head; an acetabular cup made of Ultra High Molecular Weight Polyethylene (a very hard type of plastic); and acrylic bone cement.

19. Long-term studies of patients undergoing a Charnley THA in the 1960s and early 1970s show excellent results. These studies found that between 85% and 96% of patients still had a well-functioning Charnley hip 25 years after implant. Another study found that 78% of patients still didn't need to have their original Charnley hip replaced even after 35 years.

20. The Charnley hip was not without its weaknesses. The one-piece design of the femoral stem and head did not allow surgeons to adjust the implant for any leg-length discrepancies due to surgery. Also, the design of the acetabular cup required the surgeon to apply bone cement to the back of the cup in order to affix it to the natural hip socket. These design elements contributed to a difficult and inflexible surgical procedure for surgeons. Further, the polyethylene plastic used for the cup could wear off as the stainless steel ball articulated inside and against it. As these plastic particles wore off, they damaged local tissue and bone in the patient and could serve to loosen the acetabular cup from the acetabular bone. However, these shortcomings did not occur often, as evidenced by the design's long term survivorship statistics.

21. Over time, varying designs and various compounds of plastic, ceramic, and metal have been implemented for the stem, femoral head (or ball) and the acetabular cup in an effort to improve upon the Charnley design.

22. Briefly, in the 1960s, the orthopedic device industry experimented with various metal-on-metal (hereafter "MoM") designs for hip implants. These designs call for a metal femoral head to articulate directly against the metal interior of an acetabular cup. The perceived benefit of MoM was the idea that metal was stronger than plastic and would hopefully last longer and wear less. Further, the strength of the metal would theoretically allow for designs that increased range of motion. However, by the mid-1970s, MoM hip implants were completely abandoned in favor of utilizing polyethylene components.

23. Factors that led to the complete abandonment of the MoM designs for hip implants related to:

a. High rates of early revision;
b. The early success of the Charnley prosthesis;
c. Frictional torque between the components;
d. Concerns over the unknown carcinogenic and toxic effects of metal wear;
e. Concerns over metal sensitivity in patients;
f. High rates of infection; and
g. Increased bone strain and fatigue fractures of the bones surrounding the MoM implant.

24. Due to the limited use and subsequent complete abandonment of MoM technology by the mid-1970s, there had been almost no medical or scientific advancement in decades relating to understanding the *actual*, *clinical* risks associated with using MoM technology for hip implants.

25. Despite the MoM hiccup in the evolution of THA surgery, various other improvements have been made to the Charnley design in recent decades.

26. Most modern acetabular cups now utilize some form of porous coating on the backside where the cup affixes to the hip socket. This coating should allow for bone to naturally grow into the pores so that the surgeon does not need to use screws or bone cement to seat the cup in the bone.

27. Typically, modern acetabular cups are "modular." This means the cups have multiple components. The components of a modular acetabular cup include the cup, which is implanted into the hip socket, and a "liner" which is placed on the inside of the cup and forms the surface against which the femoral head (or ball) articulates.

28. Another improvement was the use of Highly Cross-Linked Ultra High Molecular Weight ("HXUHMW") Polyethylene instead of Charnley's original Ultra High Molecular Weight Polyethylene. This improved polyethylene is stronger, harder, and reduces the amount of plastic wear produced during articulation of components.

29. HXUHMW Polyethylene Hip Implants were introduced years prior to the M2a metal-on-metal hip replacement.

30. Modern THA implants typically also have a separate femoral stem and femoral head, instead of Charnley's original one-piece design. These two pieces attach at the top of the stem, or "neck." The stem is nearly always made of metal (the particular metal alloy varies depending on manufacturer).

31. The femoral head can be made of HXUHMW Polyethylene or various forms of metal or ceramic.

32. These modern designs have resulted in highly successful implants intended to last and capable of lasting more than 20 years in a patient.

33. Further, these alternative modern designs, which may utilize a variety of articulation types including but not limited to metal on polyethylene, ceramic on ceramic, ceramic on polyethylene, ceramic on metal, and others, were available for use in Plaintiff at the time Plaintiff was originally implanted with the M2a.

M2A METAL-ON-METAL HIP REPLACEMENT

34. Despite the early failure of metal-on-metal technology and despite the near complete lack of a *clinical* safety record due to the previous abandonment of the technology, Defendants designed, developed, promoted, and (Biomet only) manufactured the M2a metal-on-metal hip replacement.

35. In 2004, as a result of Defendants' design, development, promotion, and manufacture (Biomet only), the M2a metal-on-metal hip replacement system was made available for sale in the United States.

36. Defendants did not perform clinical testing of the M2a metal-on-metal hip replacement system for safety prior to its sale.

37. Cuckler Defendants received a percentage of the sale price of M2a metal-on-metal hip replacement systems sold in the United States.

DEFECTIVE DESIGN OF THE M2A

38. Unfortunately for the patients implanted with Defendants' M2a metal-on-metal hip replacement system, the device was defective.

39. When implanted in a patient, the metal-on-metal articulation of the M2a generates cobalt and chromium metal debris that is released into the body.

40. Metal debris from the M2a results in elevated levels of cobalt and chromium in the blood, pseudotumors, tissue necrosis, osteolysis, muscle wasting, and other severe injuries.

41. The degenerative effects on a patient's anatomy can greatly decrease the chances of success for any replacement implant necessitated by the removal of the failed M2a components.

42. Despite Defendants' claims of the advantages of the M2a, the product is and always was unreasonably dangerous with an unreasonably high rate of complaints and revisions. Further, Defendants' claims regarding the risks of the M2a were inadequate.

43. The testing done on the M2a prior to launch was woefully inadequate and not representative of real-world, clinical situations.

DEFENDANTS' FALSE GUIDANCE TO THE MEDICAL COMMUNITY

44. Cuckler Defendants' role in the design of the M2a coupled with their status in the orthopedic community provided Cuckler Defendants with a powerful mouthpiece with which to affect the orthopedic community's actions regarding the M2a.

45. Further, Biomet utilized distributors, including Distributor Defendants, who were responsible for educating Plaintiff's orthopedic surgeon regarding the claimed advantages of the products at issue in this Complaint, answering any questions Plaintiff's orthopedic surgeon asked regarding the products, assisting Plaintiff's orthopedic surgeon at surgery regarding the products, and selling the products to Plaintiff through her orthopedic surgeon agent. These distributors, including Distributor Defendants, received education and training regarding, among other things, surgical technique, product design, product performance, patient selection, complaint and adverse event handling, marketing and promotion of the M2a.

46. Biomet also undertook national and regional advertising and marketing campaigns, including paying Mary Lou Retton to act as a spokesperson for the M2a.

47. Unfortunately, Defendants' statements in support of the M2a contained a number of statements which have been revealed to be false. These false statements were material to Plaintiff and the orthopedic community's understanding of the known and unknown risks and benefits with the M2a.

48. Defendant CUCKLER, personally and on behalf of his company, Defendant AMC, provided statements in support of the M2a to the orthopedic community through various promotional events, appearances, panels, speaking engagements, lavish surgeon retreats, surgical training sessions, etc. in which Defendant CUCKLER acted as event faculty, moderator, speaker, instructor, and promoter. This includes the "Current Concepts in Joint Replacement" conference which is held annually in Orlando, Florida and which Defendant CUCKLER regularly attends.

49. Cuckler Defendants were provided financial compensation for their actions by Biomet. In 2008, and as part of its responsibility to publicly identify and report payments to company consultants in order to satisfy a Deferred Prosecution Agreement, the manufacturer of the M2a, Biomet, reported that Cuckler Defendants received total compensation between $3.0 and $3.1 **million** dollars in just the previous year.[1] Exhibit A indicates that Cuckler Defendants, by a wide margin, received more compensation by Biomet than any other individual or entity in the country.

50. Cuckler Defendants claimed that there are no adverse effects attributable to metal articulations. This is clearly false. M2a MoM hips, and MoM hips in general, have a long history of adverse events, such as bone and tissue death, implant failure, and early revisions, due directly to metal wear and metal ions.

a. At the 19th Annual Current Concepts in Joint Replacement Winter 2002 Meeting, Defendant CUCKLER claimed: "[I]n spite of the metal ion release issue, there are no adverse effects that have ever been demonstrated."

[1] See "Exhibit A" – Defendants are identified at the second entry in the table.

b. In his 2005 article published in Clinical Orthopaedics and Related Research, entitled, *The Rationale for Metal-on-Metal Total Hip Arthroplasty*, Defendant CUCKLER states: "No adverse physiologic effects have been identified in the long-term followup of patients exposed to cobalt-chromium implants."
c. Biomet's M2a Magnum Design Rationale Brochure cites Defendant CUCKLER's Article, *The Rationale for Metal-on-Metal Total Hip Arthroplasty* to claim "No adverse physiologic effects."

51. Cuckler Defendants claimed that the M2a was appropriate for patients who were younger, heavier, or more active. This, however, was clearly false as higher stress and activity levels upon the M2a increase the levels of metal wear and ions released into the body, thereby increasing the risk of adverse events.

a. At the 19th Annual Current Concepts in Joint Replacement Winter 2002 Meeting, Defendant CUCKLER suggested that metal hips, such as the M2a, are more cost-effective because, even in younger and more active patients, they would last longer and not subject a patient to the medical cost of revision surgery: "The conventional poly-metal combination is admittedly cheaper, but for a younger, high-demand patient, the metal-metal is more cost effective."
b. As advertised on Biomet.com in the form of a patient testimonial under the website's "Patient Stories" section, for an active, 51-year old male patient, Defendant CUCKLER indicated that the M2a-38 Metal on Metal implant was the optimal implant "because it was designed to last longer than other conventional implant materials such as polyethylene."

52. Cuckler Defendants claimed that MoM implants have a long history of clinical success. This, however, is clearly false: MoM implants have a long history of clinical failure, as evidenced by the orthopedic implant industry's abandonment of the technology after the MoM's high failures decades ago.

a. At the 19th Annual Current Concepts in Joint Replacement Winter 2002 Meeting, Defendant CUCKLER Stated: "What would I want in myself? I'd want metal-metal … First, there is a long and successfully documented clinical history."
b. Biomet's M2a Magnum Design Rationale Brochure cites Defendant CUCKLER's Article, *The Rationale for Metal-on-Metal Total Hip Arthroplasty* to claim the "Long-term clinical results of MoM hips."

53. Cuckler Defendants claimed that there is a lesser histological response to the

smaller wear particles produced by MoM implants as compared with the larger particles produced by MoP hips. The exact opposite, however, is true. The smaller size of metal particles triggers a greater histological response and increased failure rates of metal on metal articulations, including the M2a.

a. In *The Rationale for Metal-on-Metal Total Hip Arthroplasty*, Defendant CUCKLER states: "It has been hypothesized that the small metal particulates may be below the critical size necessary to elicit a phagocytic response from tissue macrophages. Therefore, the histologic response to metallic wear debris does not show the intense histiocytic response common to metal-on-PE THAs."
b. In the same article, Defendant CUCKLER claimed that "larger-diameter metal-on-metal femoral heads have superior wear behavior in comparison with smaller diameter heads."
c. During the 72nd Annual Meeting of the American Academy of Orthopaedic Surgeons, Defendant CUCKLER was one of a number of surgeons who discussed MoM issues. Defendant CUCKLER stated: "Metal-metal particulates are much smaller than polyethylene particulates on the order of 1/10 of a micron or less." He continued, "This probably results in them being below the radar screen from detection of a macrophage or histocyte."

54. Cuckler Defendants claimed tissues surrounding MoM implants, like the M2a, rarely exhibit signs of metalosis. This, however, is untrue, given the large numbers of metalosis-related complaints reported regarding MoM implants, including the M2a.

a. In *The Rationale for Metal-on-Metal Total Hip Arthroplasty*, Defendant CUCKLER stated: "Examination of the periprosthetic tissues surrounding metal-on-metal THAs rarely shows metallosis."

55. Cuckler Defendants claimed that MoM hips, such as the M2a, are immune to third-body wear or subluxation because MoM hips are self-polishing, and further claimed that surfaces damaged as a result of these phenomena can "return to their pre-damage status." In essence, Cuckler Defendants claim that the metal hip implant can heal itself if it is damaged. This is simply not the case. Further, if third body wear or subluxation caused damage to the articulating surfaces, and if the hip implant is able to "self-polish," this necessarily means that the implant polishes material off of the implant surface and into the body, creating the very wear

the implant was purportedly designed to avoid.

a. During the 72nd Annual Meeting of the American Academy of Orthopaedic Surgeons, Defendant CUCKLER was one of a number of surgeons who discussed MoM issues. Defendant CUCKLER stated: "Metal-metal has a unique advantage relative to other wear couples in that it can self-polish in the event of damage caused by third-body wear or subluxation. The damaged surfaces can return to their pre-damage status."

56. Upon information and belief, further false statements by Defendants include, but are not limited to, the following:

a. Defendants claimed that the M2a was a safe and effective hip replacement system.
b. Defendants claimed that the M2a was clinically safe and effective based on laboratory tests.
c. Defendants claimed that the M2a was clinically safe and effective based on clinical tests.
d. Defendants attributed data regarding clinical failures of the M2a to improper patient selection by surgeons.
e. Defendants attributed data regarding clinical failures of the M2a to improper surgical technique by surgeons.
f. Defendants attributed data regarding clinical failures of the M2a to patient characteristics.
g. Defendants claimed the clinical existence of a run-in period for the M2a.
h. Defendants claimed that the metal wear clinically produced during the theoretical run-in period was within safe limits.
i. Defendants claimed that metal wear clinically released from the M2a is reduced after a theoretical run-in period of three years.
j. Defendants presented clinical research data from within the theoretical run-in period as being indicative of the long-term clinical safety and efficacy of the M2a.
k. Defendants claimed knowledge of clinically safe limits for metal wear.
l. Defendants attributed metal wear production to surgical technique and environmental contaminants to the exclusion of device related factors.
m. Defendants attributed clinical reactions to metal wear to patient hyper-sensitivity.
n. Defendants claimed the M2a was highly wear-resistant.
o. Defendants claimed the M2a exhibits less metal wear than other competing types of hip implants.
p. Defendants claimed they could not draw conclusions regarding the safety or efficacy of the M2a even after analyzing reports of revisions and explanted components.
q. Defendants claimed that the design differences between the M2a and other MoM hips made the M2a more safe and effective than other MoM hips.
r. Defendants claimed that the design differences between the M2a and other MoM

hips made the M2a a clinically safe and effective hip replacement system.

57. Defendants failed to adequately warn Plaintiff, Plaintiff's surgeon, and the orthopedic community of a number of material factors regarding the M2a, including, but not limited to:

a. The lack of evidence to support the clinical existence of fluid film lubrication during a large percentage of normal, everyday use of the M2a;
b. The clinical existence of greater histological reaction to the comparatively smaller wear particles produced by the M2a as compared to the larger particles produced by MoP hips that were available at the same time.
c. The likelihood of a smaller volume of metal particles from the M2a producing greater negative clinical effects than a larger volume of plastic particles from other MoP hips available at the same time;
d. A large number of M2a failures were assumed to not be device-related despite a lack of adequate investigation;
e. M2a design characteristics were a known potential cause of the complaints and revisions being reported;
f. Long-term clinical studies of the M2a were purposefully avoided or omitted when promoting the long-term outcome of the M2a;
g. "Hypersensitivity" to the M2a is defined solely by the occurrence of a negative outcome and not by a pre-disposition for a negative outcome;
h. Citations to data regarding the purported long-term success of past generations of MoM hips focused solely on the percentage of those devices not revised after a certain period of time, omitting data regarding those that failed and required revision;
i. Though metal ions can be excreted through the urine, the excretion can not be enough to offset the amount of metal ions and wear being released into the body;
j. The FDA's "clearance" for the M2a to be sold did not involve any extensive scrutiny for clinical safety and efficacy before sale and instead only required a showing of substantial equivalence to previously cleared devices (which also were not scrutinized for clinical safety before "clearance" for sale).

IMPLANTATION OF M2A INTO PLAINTIFF'S BODY

58. Plaintiff experienced a history of pain in Plaintiff's left hip that caused Plaintiff to be treated by orthopedic surgeon Michael Patney, M.D.

59. Dr. Patney determined Plaintiff needed surgery to replace Plaintiff's left hip with an artificial hip with the goal of providing Plaintiff with a well-functioning hip.

60. The surgery was conducted on October 5, 2005 with a M2a metal-on-metal hip

replacement being implanted in Plaintiff's hip.

61. The M2a was utilized as the orthopedic surgeon was convinced that the M2a, of all hip replacements, would best serve to replace Plaintiff's natural hip.

62. Unfortunately, that was far from the case.

INJURY TO PLAINTIFF BY M2A

63. The M2a metal-on-metal hip initially appeared to work well, however, after approximately one and a half years Plaintiff began to experience pain in her left hip.

64. Plaintiff's pain began to increase in severity and Plaintiff began experiencing decreased mobility and limitation on her daily activities.

65. On May 30, 2014, Plaintiff was seen at Southeast Orthopedic Specialists by orthopedic surgeon R. David Heekin, M.D.

66. Dr. Heekin reviewed lab results and imaging results of Plaintiff's left hip, and scheduled Plaintiff for surgery to remove the M2a metal-on-metal hip.

67. The revision surgery to remove components of the M2a metal-on-metal hip was performed on August 5, 2014.

68. Dr. Heekin's pre operative diagnosis was "1. Left hip metal on metal articulation with painful synovitis. 2. Painful exotosis lateral greater trochanteric femur."

69. Following the surgery to remove the M2a metal-on-metal hip, Plaintiff was forced to go through an extensive period of rehabilitation and recovery.

DAMAGES

70. As a direct and proximate result of the defective M2a metal-on-metal 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, lost wages and limitation of daily activities.

71. Plaintiff expects to continue suffering such injuries in the future as a result of the M2a System and component parts.

72. As a direct and proximate result of the defective M2a, Plaintiff was caused to incur medical expenses, and expects to incur additional medical expenses in the future.

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

COUNT ONE – ALL DEFENDANTS – NEGLIGENCE

74. Plaintiff re-alleges and incorporates by reference paragraphs 1-73 above as if fully stated herein.

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

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

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

78. As a direct and proximate result of Defendants' breaches of duty, Plaintiff needlessly suffered injuries as described in Paragraphs 70-73, above.

COUNT TWO – ALL DEFENDANTS –
NEGLIGENT FAILURE TO WARN

79. Plaintiff re-alleges and incorporates by reference paragraphs 1-73 above as if fully stated herein.

80. Defendants had a duty to give adequate and appropriate warnings to Plaintiff regarding particular risks about the products at issue in this Complaint.

81. Plaintiff's use of the products at issue in this Complaint was reasonably foreseeable by Defendants.

82. Defendants knew or should have known of particular risks involved in Plaintiff's reasonably foreseeable use of the products at issue in this Complaint.

83. Breaching their duty, Defendants failed to provide adequate or appropriate warnings to Plaintiff.

84. As a direct and proximate result of the conduct of Defendants, Plaintiff needlessly suffered injuries as described in Paragraphs 70-73, above.

COUNT THREE – CUCKLER DEFENDANTS –
INFORMATION NEGLIGENTLY SUPPLIED FOR THE GUIDANCE OF OTHERS

85. Plaintiff re-alleges and incorporates by reference paragraphs 1-69 above as if fully stated herein.

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

87. Cuckler Defendants had a pecuniary interest in the design, development, promotion, and testing of the M2a.

88. The design, development, promotion, and testing of the M2a was in the course of

Cuckler Defendants' business, profession, or employment as a designing orthopedic surgeon of the M2a.

89. Cuckler Defendants supplied false information for the guidance of others regarding the selection of the M2a as a safe and effective hip replacement option, as alleged in Paragraphs 44 through 57.

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

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

92. Alternatively, Cuckler Defendants knew that Plaintiff, through Plaintiff's orthopedic surgeon agent, is within the limited group of persons for whose benefit and guidance the recipient of Defendant's information intended to supply Cuckler Defendants' information.

93. Cuckler 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.

94. Alternatively, Cuckler Defendants knew the recipient of their information intended for the information to influence either the transaction in which Plaintiff, through Plaintiff's orthopedic surgeon agent, purchased the M2a or a substantially similar transaction.

95. Plaintiff, through Plaintiff's orthopedic surgeon agent, justifiably relied upon the information provided by Cuckler Defendants.

96. As a direct and proximate result of Cuckler Defendants' false information, Plaintiff suffered pecuniary loss, as described in Paragraph 72, above.

COUNT FOUR – ALL DEFENDANTS – MISREPRESENTATION

97. Plaintiff re-alleges and incorporates by reference paragraphs 1-73 above as if fully stated herein.

98. 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, as alleged in Paragraphs 44 through 57.

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

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

101. Plaintiff justifiably relied on the false statements.

102. As a direct and proximate result of the misrepresentations regarding the M2a, Plaintiff suffered injuries as described in Paragraphs 70-73, above.

COUNT FIVE – ALL DEFENDANTS – STRICT LIABILITY FAILURE TO WARN

103. Plaintiff re-alleges and incorporates by reference paragraphs 1-73 above as if fully stated herein.

104. 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.

105. The products at issue in this Complaint reached Plaintiff without substantial change in the condition in which they were sold.

106. At the time and on the occasions in question, the products at issue in this Complaint were being properly used for the purpose for which they were intended, and such components were in fact defective, unsafe and unreasonably dangerous.

107. The foreseeable risk of harm from the defects in the products at issue in this Complaint could have been reduced or avoided by providing adequate instructions or warnings.

108. Defendants failed to provide adequate instructions or warnings regarding the defects in the products at issue in this Complaint which were known by Defendants or should have been known by Defendants.

109. As a direct and proximate results of the lack of reasonable and adequate instructions or warnings regarding the defects in the products at issue in this Complaint, Plaintiff suffered injuries as described specifically in paragraphs 70-73.

COUNT SIX – ALL DEFENDANTS –
STRICT LIABILITY DESIGN AND MANUFACTURING DEFECT

110. Plaintiff re-alleges and incorporates by reference paragraphs 1-73 above as if fully stated herein.

111. 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.

112. The products at issue in this Complaint reached Plaintiff without substantial change in the condition in which they were sold.

113. At the time and on the occasions in question, the products at issue in this Complaint were being properly used for the purpose for which they were intended, and such components were in fact defective, unsafe and unreasonably dangerous.

114. The products at issue in this Complaint, for the reasons stated herein, were defective and unreasonably dangerous in design and manufacture.

115. As a direct and proximate result of the defects in the products at issue in this Complaint, Plaintiff suffered injuries described in paragraphs 70-73, above.

COUNT SEVEN – BIOMET DEFENDANTS – BREACH OF IMPLIED WARRANTY

116. Plaintiff re-alleges and incorporates by reference paragraphs 1-73 above as if fully stated herein.

117. 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.

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

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

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

121. Plaintiff used the product at issue in this Complaint for its ordinary and intended purpose.

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

123. As a direct and proximate result of Biomet Defendant's breach of implied warranty, Plaintiff suffered injuries as described specifically in paragraphs 70-73.

COUNT EIGHT – BIOMET DEFENDANTS – BREACH OF EXPRESS WARRANTY

124. Plaintiff re-alleges and incorporates by reference paragraphs 1-73 above as if fully stated herein.

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

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

127. 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.

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

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

130. Within a reasonable time after Plaintiff knew or should have known of the failure of the products at issue in this Complaint, Biomet was given notice of such failure.

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

132. As a direct and proximate result of Biomet Defendant's breach of express warranty, Plaintiff suffered injuries as described specifically in paragraphs 70-73.

DEMAND FOR PUNITIVE DAMAGES

133. Plaintiff states that the foregoing acts and omissions of the Defendants evidence intentional misconduct and/or gross negligence sufficient to fulfill the requisite reasonable basis for the recovery of punitive damages pursuant to F.S. §768.72 and that an award of punitive damages is demanded herein.

DEMAND FOR JURY TRIAL

~~133.~~134. 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.

WHEREFORE, Plaintiff respectfully demands judgment against Defendants for compensatory damages and punitive damages and any other relief the Court deems just and proper.

Dated this 8th ~~8th~~ day of ~~April~~, 2019~~16~~.

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