3007-019

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF INDIANA

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In Re: Biomet M2a Magnum Hip
Implant Products Liability
Litigation (MDL 2391)

CAUSE NO. 3:12-md-2391

LORI NICHOLSON and
WILLIS WILLIAM NICHOLSON

3:13CV358

Plaintiffs,

CIVIL ACTION NO.

- against -

BIOMET, INC., BIOMET ORTHOPEDICS,LLC,
BIOMET MANUFACTURING CORP.,
BIOMET US RECONSTRUCTION, LLC

Defendants.

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1. Plaintiff Lori Nicholson ("Nicholson" or "Plaintiff") and Plaintiff Willis William Nicholson, by their attorneys, Schlesinger Law Offices, P.A., complain against Defendants Biomet, Inc., Biomet Orthopedics, LLC, Biomet Manufacturing Corp., and Biomet US Reconstruction, LLC (collectively "Biomet" or "Defendants") as follows:

NATURE OF THE CASE

2. Plaintiff brings this product liability action against Defendants to redress the injuries sustained due to Defendants' defective hip system implanted in Plaintiff, which required revision surgery to remove Defendants' defective hip system.

PARTIES

3. Plaintiffs are Iowa residents located at 620 1ST ST NW, Fort Dodge, Iowa 50501.

4. Upon information and belief, Defendant Biomet, Inc. is an Indiana corporation, with its principal place of business in Warsaw, Indiana. Defendant Biomet, Inc. designed, manufactured, marketed, promoted, and sold the M2a Magnum Hip System that is the subject of this lawsuit.

5. Upon information and belief, Defendant Biomet Orthopedics, LLC is an Indiana limited liability corporation, with its principal place of business in Warsaw, Indiana. Defendant Biomet Orthopedics, LLC designed, manufactured, marketed, promoted, and sold the M2a Magnum Hip System that is the subject of this lawsuit.

6. Upon information and belief, Defendant Biomet Manufacturing Corp. is an Indiana corporation with its principal place of business in Warsaw, Indiana. Defendant Biomet Manufacturing Corp. designed, manufactured, marketed, promoted, and sold the M2a Magnum Hip System that is the subject of this lawsuit.

7. Upon information and belief, Defendant Biomet US Reconstruction, LLC is an Indiana limited liability corporation, with its principal place of business in Warsaw, Indiana. Biomet US Reconstruction, LLC designed, manufactured, marketed, promoted, and sold the M2a Magnum Hip System that is the subject of this lawsuit.

8. Upon information and belief, at all relevant times, Defendants committed tortuous act(s) within the state of Iowa out of which act(s) these causes of action arise.

JURISDICTION AND VENUE

9. The Court has jurisdiction under 28 U.S.C. § 1332 because this lawsuit is between citizens of different states and the amount in controversy exceeds $75,000.00, exclusive of costs and interest. Plaintiffs are Iowa residents and domiciliaries; Defendants are all incorporated and/or have their principal place of business in Indiana.

10. Venue is proper in the Northern District Court in Iowa because Defendants committed tortuous act(s) within the state of Iowa out of which act(s) these causes of action arise. Plaintiffs will directly file their action in this Court pursuant to the Court's February 15, 2013 Order, which permits direct filing of complaints. Plaintiffs' case would be subject to transfer to MDL No. 2391 by the Judicial Panel on Multistate Litigation pursuant to its October 2, 2012 Transfer Order. Plaintiffs will file a separate Notice of Related Action pursuant to Northern District of Indiana Rule 40-1(d).

FACTUAL ALLEGATIONS

A. The M2a Magnum Hip System Is Defective And Was Not Adequately Tested

11. The hip joint is where the femur connects to the pelvis. The joint is made up of the femoral head (a ball-like structure at the very top of the femur) rotating within the acetabulum (a cup-like structure at the bottom of the pelvis). In a healthy hip, both the femur and the acetabulum are strong, and the rotation of the bones against each other is cushioned and lubricated by cartilage and fluids.

12. A total hip replacement replaces the body's natural joint with an artificial one, usually made out of metal and plastic. A typical hip replacement system consists of four separate components: (1) a femoral stem; (2) a femoral head; (3) a plastic (polyethylene) linear; and (4) an acetabular shell. After the surgeon hollows out a patient's femur bone, the femoral stem is implanted. The femoral head is a metal ball that is fixed on top of the femoral stem. The femoral head forms the hip joint when it is placed inside the polyethylene linear and acetabular shell.

13. While most hip replacements use a polyethylene plastic acetabular liner, Biomet's M2a Magnum Hip System has a critical difference: it is a monoblock system which does not

have an acetabular liner. Instead, the M2a Magnum Hip System forces metal to rub against metal with the full weight and pressure of the human body. Because of Biomet's defective design for the M2a Magnum Hip System, hundreds of patients – including Plaintiff – have been forced to undergo surgeries to replace the failed hip implants.

14. The M2a Magnum Hip System suffers from a design or manufacturing defect that causes excessive amounts of cobalt and chromium to wear and corrode from the surface of the acetabular cup, from the femoral head, and from the taper adapter. These cobalt and chromium fragments prompt the body to react by rejecting the hip implant. This rejection often manifests with symptoms of pain, looseness, dislocation, and squeaking and popping sounds. Inside the hip joint, the metal reaction often causes fluids to accumulate and soft tissues and bone to die. Additionally, reports were received that M2a Magnum Hip System generated metal debris from wear, which can spread throughout the bone and tissue and cause severe inflammation and damage.

15. Biomet failed to sufficiently test the design of the M2a Magnum Hip System, and the M2a Magnum Hip System was never approved by the FDA as being safe or effective for the products' intended purpose. Further, the M2a Magnum Hip System was not subject to the rigorous pre-market approval (PMA) testing and approval pursuant to 21 U.S.C. § 360(e). Instead, Defendants received FDA approval to market the M2a Magnum Hip System in the United States through the 510(k) pre-market notification process pursuant to 21 U.S.C. § 360(k), asserting that it was substantially equivalent to other metal-on-metal hip replacement systems already on the market. This approval process is generally reserved for Class II devices. Accordingly, the M2a Magnum Hip System is not subject to federal preemption because it was not approved as an FDA Class III device.

16. At the time the M2a Magnum Hip System was designed, tested, manufactured, marketed and introduced into the stream of commerce, safer more effective alternative designs of hip replacements existed and were available to patients.

17. On numerous occasions, Biomet met with orthopedic surgeons throughout the United States, and other cities, including, upon information and belief, with Plaintiff's orthopedic surgeon, to promote the M2a Magnum Hip System. At some or all of these meetings, a representative or representatives of Biomet were present. During these meetings, Biomet assured the orthopedic surgeons that the M2a Magnum Hip System was safe, was the best product on the market, had an excellent track record, and a low acceptable failure rate. Biomet continued to "defend" the M2a Magnum Hip System even after they became aware of numerous and serious complications with the M2a Magnum Hip System. Biomet did not reveal (and instead concealed) their knowledge of numerous complications and other "bad data" during their meetings with orthopedic surgeons.

B. Biomet Sold The M2a Magnum Hip Implant To Plaintiff After Biomet Knew It Was Defective, That It Had Injured Others, And That It Would Injure Plaintiff

18. Shortly after launching the M2a Magnum Hip System, reports of failures began flooding into Biomet. For example, in or about August 2004, Biomet received a complaint that a patient required and underwent surgery to remove and replace the M2a Magnum Hip System because it had become loose after only 3 years. Biomet closed its investigation of this complaint.

19. Biomet received hundreds of similar complaints reporting that M2a Magnum Hip System failed, that that failure forced patients to undergo painful and risky surgeries to remove and replace the failed hip component. To date, more than 350 reports of adverse events associate with the M2a Magnum Hip System have been filed with the FDA.

20. By the time Biomet sold the M2a Magnum Hip System to Plaintiff, numerous reports had been filed with the FDA reporting an adverse event associate with the M2a Magnum Hip System. Thus, Biomet was fully aware that the M2a Magnum Hip System was defective and that patients had been injured by that defect. Based on this information, Biomet should have recalled the M2a Magnum Hip System before it was sold to Plaintiff. Indeed, Biomet should have stopped selling the defective implant when Biomet became aware that the M2a Magnum Hip System had failed in several patients.

21. Despite knowing that the M2a Magnum Hip System had a defect, and that it failed hundreds of times, causing hundreds of patients to undergo complicated, expensive, and painful revision surgeries with a prolonged recovery time, Biomet continued to sell the defective M2a Magnum Hip System. Biomet actively concealed the known defects from doctors and patients – including Plaintiff and Plaintiff's doctor.

22. Ignoring the numerous reported M2a Magnum Hip System failures, Biomet continued to promote, market, and defend the defective M2a Magnum Hip System. For example, Biomet published marketing brochures touting the safety and durability of metal-on-metal implants and specifically, the M2a Magnum Hip System. Biomet gave these brochures to doctors around the world to encourage them to use the M2a Magnum Hip System.

23. Despite its knowledge that the M2a Magnum Hip System was defective, Biomet also made several false representations about specific design elements of the M2a Magnum Hip System that it claimed made the M2a Magnum Hip System superior to other more safe hip implants on the market. Biomet claimed:

(a) "The M2a-Magnum™ Large Metal Articulation System offers optimal joint mechanic restoration and ultra low-wear rates in vivo," and

(b) "Many studies conducted over the last several decades have shown no definitive correlation of negative health issues to ion levels exhibited from metal-on-metal implants;"

(c) "[S]et the standard for performance and design in hip systems;"

(d) "[A]n ultra-high performance metal-on-metal articulation;"

(e) "[D]esigned specifically to address the issue of wear debris;"

(f) "[T]he right choice for use in young, highly active patients."

Additionally, Biomet promoted the M2a Magnum Hip System as "offering improved range of motion and joint stability" and employed gymnast, Mary Lou Retton to deliver the message in April 2006 for direct-to-consumer print, TV and radio advertising.

24. Biomet's reason for concealing the defect in the M2a Magnum Hip System is clear. Hip implant sales are critically important to Biomet, and the M2a Magnum Hip System is one of Biomet's most profitable products. During the time period relevant to this Complaint, Biomet's management was trying to make Biomet appealing to investors, and in 2007, Biomet was purchased by a private equity firm for $10 billion.

25. Biomet chose corporate profits over patient safety. Rather than admit its M2a Magnum Hip System is defective, Biomet continued to promote, market, and sell the M2a Magnum Hip System. At present, Biomet continues to sell the defective M2a Magnum Hip System to unsuspecting patients without any warning about the risks or the failures reported to Biomet.

C. Plaintiff's Magnum Hip System Was Defective And Failed, Forcing Plaintiff To Undergo An Additional Painful and Risky Surgery

26. On or about July 10, 2007 Plaintiff underwent a surgical procedure to implant the M2a Magnum Hip System in her left hip. Dr. Emile Li performed the surgery at the Wright Medical Center in Clarion, Iowa.

27. By this time, numerous reports of adverse events associated with M2a Magnum Hip System had been filed with the FDA, and Biomet knew the M2a Magnum Hip System was defective. Nevertheless, Biomet refused to disclose that information to Plaintiff, her physicians, or the public. Instead, Biomet misrepresented to Plaintiff and her orthopedic surgeon that the M2a Magnum Hip System was safe and effective. Relying on Biomet's representations, Plaintiff's orthopedic surgeon decided to use the M2a Magnum Hip System. But for Biomet's misrepresentations, Plaintiff would not, and Plaintiff's orthopedic surgeon would not have used the M2a Magnum Hip System for Plaintiff's hip replacement surgery.

28. As a result of the defective design, manufacture and composition of the M2a Magnum Hip System, and its accompanying warnings and instructions (or lack thereof), Plaintiff's hip implant failed, causing her severe pain.

29. Plaintiff's M2a Magnum Hip System loosened, causing increased strain on the acetabulum consistent with increased ionic metal-on-metal wear contributing to a pseudo cyst. In addition Plaintiff's chromium levels were 6 times that of the normal rate.

30. Plaintiff underwent revision surgery on June 19, 2012, to remove the failed M2a Magnum Hip System from Plaintiff's body. Revision surgeries are generally more complex than the original hip replacement surgery, often because there is a reduced amount of bone in which to place the new hip implants. Revision surgeries also usually take longer than the hip replacement surgery and the revision surgery has a higher rate of complications.

31. Plaintiff's revision surgery was performed by Dr. Li at the Wright Medical Center in Clarion, Iowa. Dr. Li replaced the failed M2a Magnum Hip System with a metal-on-poly hip system.

32. Having to go through a revision surgery, has subjected Plaintiff to greater risks of future complications than she had before the revision surgery. Studies found that a revision surgery causes a much higher risk of dislocation compared with an original hip replacement surgery. A study by Charlotte Philips and her colleagues at Brigham and Women's Hospital in Boston showed that 14.4 percent of patients who had revision surgery suffered from a dislocation compared with 3.9 percent of patients who had an original hip replacement surgery. In other words, hip replacement patients who had a revision surgery are almost four times more likely to suffer from a hip dislocation than those who have not. (Phillips CB, et al. Incidence rates of dislocation, pulmonary embolism, and deep infection during the first six months after elective total hip replacement. American Journal of Bone and Joint Surgery 2003; 85:20-26).

33. As a direct and proximate result of the failure of her M2a Magnum Hip System and Biomet's wrongful conduct, Plaintiff sustained and continues to suffer economic damages (including medical and hospital expenses), severe and possibly permanent injuries, pain, suffering and emotional distress. As a result, Plaintiff has sustained and will continue to sustain damages in an amount to be proven at trial, but which will far exceed the $75,000.00 jurisdictional minimum of this Court.

FIRST CAUSE OF ACTION
STRICT PRODUCTS LIABILITY – MANUFACTURING DEFECT
AGAINST ALL DEFENDANTS

34. Plaintiff incorporates all of the preceding paragraphs of this Complaint as if fully set forth here and further alleges as follows:

35. Defendants are the manufacturers, designers, distributors, sellers, and/or suppliers of the M2a Magnum Hip System that was surgically implanted in Plaintiff.

36. The M2a Magnum Hip System manufactured, designed, sold, distributed, supplied and/or placed in the stream of commerce by Defendants was defective in its manufacture and construction when it left Defendants' hands because it deviated from product specifications and/or applicable federal requirements for these medical devices, posing a serious risk of injury and death.

37. As a direct and proximate result of Plaintiff's use of Defendants' M2a Magnum Hip System as manufactured, designed, sold, supplied and introduced into the stream of commerce by Defendants and/or the failure to comply with federal requirements, Plaintiff suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future. The M2a Magnum Hip System is not subject to federal preemption because it was not approved as an FDA Class III device.

38. Defendants' conduct as described above, was extreme and outrageous. Defendants risked the lives of recipients of their products, including Plaintiff's, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants knew or should have known of the serious health risks it created and/or the failure to comply with federal requirements. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting recipients of Defendants' M2a Magnum Hip System. Defendants' outrageous conduct warrants an award of punitive damages.

39. Plaintiff seeks actual and punitive damages from Defendants as alleged herein.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems just and proper.

SECOND CAUSE OF ACTION
STRICT PRODUCTS LIABILITY – DESIGN DEFECT

AGAINST ALL DEFENDANTS

40. Plaintiff incorporates all of the preceding paragraphs of this Complaint as if fully set forth here and further alleges as follows:

41. Defendants are the manufacturers, designers, distributors, sellers, and/or suppliers of the M2a Magnum Hip System that was surgically implanted in Plaintiff.

42. The M2a Magnum Hip System was in an unsafe, defective and inherently dangerous condition for users such as Plaintiff.

43. The M2a Magnum Hip System was in an unsafe, defective and inherently dangerous condition at the time it left Defendants' possession.

44. At all times relevant, the M2a Magnum Hip System was expected to and did reach the usual consumers, handlers, and persons coming into contact with the M2a Magnum Hip System without substantial change in the condition in which it was designed, produced, manufactured, sold, distributed and marketed by Defendants.

45. The M2a Magnum Hip System's unsafe, defective, and inherently dangerous condition injured Plaintiff.

46. The M2a Magnum Hip System failed to perform as safely as an ordinary consumer would expect when used in an intended or reasonably foreseeable manner.

47. Plaintiff's injuries resulted from use of the M2a Magnum Hip System that was both intended and reasonably foreseeable by Defendants.

48. At all times relevant, the M2a Magnum Hip System posed a foreseeable risk of danger inherent in the design, which greatly outweighed the benefits of that design.

49. At all time relevant, the M2a Magnum Hip System was defective and unsafe, and Defendants knew or had reason to now that said product was defective and unsafe, especially when used in the form and manner as provided by Defendants.

50. At all times relevant, Defendants knew, or should have known, that the M2a Magnum Hip System was in a defective condition and was and is inherently dangerous and unsafe.

51. When implanted into Plaintiff, the M2a Magnum Hip System was used for the purpose and in a manner normally intended, namely for use as a hip replacement device.

52. Defendants, with this knowledge, voluntarily designed their M2a Magnum Hip System in a dangerous condition for use by the public and, in particular, Plaintiff.

53. At all times relevant, the M2a Magnum Hip System lacked utility for any group of users, including Plaintiff.

54. The M2a Magnum Hip System provided no net benefit to any class of patients, including Plaintiff.

55. Defendants had a duty to create a product that was not unreasonably dangerous for its normal, intended use.

56. Defendants failed to complete adequate pre-market testing and post-market surveillance on the M2a Magnum Hip System.

57. Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed a defective product which, when used in its intended or reasonably foreseeable manner, created an unreasonable risk to the health of consumers and to Plaintiff in particular, and Defendants are therefore strictly liable for the injuries sustained by Plaintiff.

58. Defendants are strictly liable for Plaintiff's injuries in the following ways:

(a) the M2a Magnum Hip System as designed, manufactured, sold and supplied by Defendants, was defectively designed and placed into the stream of commerce by Defendants in a defective and unreasonably dangerous condition;

(b) Defendants failed to properly market, design, manufacture, distribute, supply and sell the M2a Magnum Hip System;

(c) Defendants failed to adequately test the M2a Magnum Hip System; and

(d) A feasible alternative design existed that was capable of preventing Plaintiff's injuries.

59. As a direct and proximate result of Defendants' placement of the defective M2a Magnum Hip System into the stream of commerce, Plaintiff suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future. The M2a Magnum Hip System is not subject to federal preemption because it was not approved as an FDA Class III device.

60. Defendants' conduct as described above, was extreme and outrageous. Defendants risked the lives of recipients of their products, including Plaintiff's, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants knew or should have known of the serious health risks it created and/or the failure to comply with federal requirements. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting recipients of Defendants' M2a Magnum Hip System. Defendants' outrageous conduct warrants an award of punitive damages.

61. Plaintiff seeks actual and punitive damages from Defendants as alleged herein.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems just and proper.

THIRD CAUSE OF ACTION
STRICT PRODUCTS LIABILITY – DEFECT DUE TO NONCONFORMANCE WITH REPRESENTATIONS AGAINST ALL DEFENDANTS

62. Plaintiff incorporates all of the preceding paragraphs of this Complaint as if fully set forth here and further alleges as follows:

63. Defendants are the manufacturers, designers, distributors, sellers, and/or suppliers of the M2a Magnum Hip System.

64. The M2a Magnum Hip System, manufactured and supplied by Defendants was defective in that, when it left Defendants' hands, the M2a Magnum Hip System did not conform to Defendants' representations concerning the product and/or with applicable federal requirements.

65. Defendants made representations to consumers regarding the character or quality of the M2a Magnum Hip System, including but not limited to statements that the M2a Magnum Hip System was a safe and durable replacement system. Defendants further asserted that the "Biomet metal-on-metal (MoM) M2a Magnum Large Metal articulation system offers optimal joint mechanic restoration and ultra low-wear rates in vivo. Many studies conducted over the last several decades have shown no definitive correlation of negative health issues to ion levels exhibited from metal-on-metal implants."

66. Plaintiff and/or her physicians justifiably relied upon Defendants' representations regarding the M2a Magnum Hip System when they selected Biomet orthopedic products to be used in surgery.

67. As a direct and proximate result of Plaintiff's use of the M2a Magnum Hip System, and Plaintiff's and/or Plaintiff's healthcare providers' reliance on Defendants' representations regarding the character and quality of the M2a Magnum Hip System and/or the failure to comply with federal requirements, Plaintiff suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future. The M2a Magnum Hip System is not subject to federal preemption because it was not approved as an FDA Class III device.

68. Defendants' conduct as described above, was extreme and outrageous. Defendants risked the lives of recipients of their products, including Plaintiff's, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants knew or should have known of the serious health risks it created and/or the failure to comply with federal requirements. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting recipients of Defendants' M2a Magnum Hip System. Defendants' outrageous conduct warrants an award of punitive damages.

69. Plaintiff seeks actual and punitive damages from Defendants as alleged herein.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems just and proper.

FOURTH CAUSE OF ACTION
STRICT PRODUCTS LIABILITY – FAILURE TO WARN
AGAINST ALL DEFENDANTS

70. Plaintiff incorporates all of the preceding paragraphs of this Complaint as if fully set forth here and further alleges as follows:

71. The M2a Magnum Hip System was defective and unreasonably dangerous when it left the possession of Defendants in that it contained warnings insufficient to alert consumers, including Plaintiff, of the dangerous risks and reactions associated with the M2a Magnum Hip System including but not limited to the risks of developing serious and dangerous side effects, including but not limited to component loosening, component mal-alignment, infections, fracture of the bone, dislocation, metal sensitivity and pain, irritation and discomfort, as well as the need for additional procedures to remove and replace the M2a Magnum Hip System, as well as other severe and permanent health consequences, notwithstanding Defendants' knowledge of an increased risk of these injuries and side effects over other hip arthroplasty devices.

72. At the time Plaintiff received and/or used the M2a Magnum Hip System, the M2a Magnum Hip System was being used for the purposes and in a manner normally intended, namely for hip arthroplasty.

73. Plaintiff could not, by the exercising reasonable care, have discovered the defects herein mentioned and perceived their danger.

74. Defendants, as manufacturers and/or distributors of the M2a Magnum Hip System, are held to the level of knowledge of an expert in the field.

75. Defendants' warnings were not accurate or clear, and/or were ambiguous.

76. Defendants' warnings failed to properly warn physicians of the increased risks, subjecting Plaintiff to risks that exceeded the benefits of the M2a Magnum Hip System, including but not limited to component loosening, component mal-alignment, infections, fracture of the bone, dislocation, metal sensitivity and pain irritation and discomfort, as well as the need for additional procedures to remove and replace the M2a Magnum Hip System, as well as other severe and permanent health consequences, notwithstanding Defendants' knowledge of an

increased risk of these injuries and side effects over other hip arthroplasty devices. Defendants also failed to provide timely and adequate post-marketing warnings and instructions after they knew of the risk of injury associated with the M2a Magnum Hip System.

77. Plaintiff, individually and through her physicians, reasonably relied upon Defendants' skill, superior knowledge and judgment.

78. Defendants had a continuing duty to warn Plaintiff of the dangers associated with the M2a Magnum Hip System.

79. Had Plaintiff received adequate warnings regarding the risks of the M2a Magnum Hip System, she would not have used it.

80. As a direct and proximate result of Plaintiff's use of the M2a Magnum Hip System, and Plaintiff's reliance on Defendants' representations regarding the character and quality of the M2a Magnum Hip System and/or the failure to comply with federal requirements, Plaintiff suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future. The M2a Magnum Hip System is not subject to federal preemption because it was not approved as an FDA Class III device.

81. Defendants' conduct as described above, was extreme and outrageous. Defendants risked the lives of recipients of their products, including Plaintiff's, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants knew or should have known of the serious health risks it created and/or the failure to comply with federal requirements. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting recipients of Defendants' M2a Magnum Hip System. Defendants' outrageous conduct warrants an award of punitive damages.

82. Plaintiff seeks actual and punitive damages from Defendants as alleged herein.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems just and proper.

FIFTH CAUSE OF ACTION
NEGLIGENCE
AGAINST ALL DEFENDANTS

83. Plaintiff incorporates all of the preceding paragraphs of this Complaint as if fully set forth here and further alleges as follows:

84. Defendants had a duty to exercise reasonable care in designing, researching, manufacturing, marketing, supplying, promoting, sale, testing, quality assurance, quality control, and/or distribution of the M2a Magnum Hip System into the stream of commerce, including a duty to assure that the device would not cause those who had it surgically implanted to suffer adverse harmful effects from it.

85. Defendants failed to exercise reasonable care in designing, researching, manufacturing, marketing, supplying promoting, sale, testing, quality assurance, quality control, and/or distribution of the M2a Magnum Hip System into interstate commerce in that Defendants knew or should have known that the M2a Magnum Hip System caused significant bodily harm, including but not limited to, partial or complete loss of mobility, loss of range of motion, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for a revision surgery to replace the device with the increased risks of complications and death from such further surgery. Defendants knew or should have known the M2a Magnum Hip System was unsafe and/or failed to comply with federal requirements.

86. Despite the fact that Defendants knew or should have known that the M2a Magnum Hip System posed a serious risk of bodily harm to consumers, Defendants continued to manufacture and market the M2a Magnum Hip System for use by consumer and/or continued to fail to comply with federal requirements.

87. Defendants knew or should have known that consumers such as Plaintiff would suffer foreseeable injury, and/or be at increased risk of suffering injury as a result of Defendants' failure to exercise ordinary care as described above, including the failure to comply with federal requirements.

88. As a direct and proximate result of Defendants' negligence, Plaintiff suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages, and economic loss in the future. The M2a Magnum Hip System is not subject to federal preemption because it was not approved as an FDA Class III device.

89. Defendants' conduct as described above, was extreme and outrageous. Defendants risked the lives of recipients of their products, including Plaintiff's, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants knew or should have known of the serious health risks it created and/or the failure to comply with federal requirements. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting recipients of Defendants' M2a Magnum Hip System. Defendants' outrageous conduct warrants an award of punitive damages.

90. Plaintiff seeks actual and punitive damages from Defendants as alleged herein.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems just and proper.

SIXTH CAUSE OF ACTION
BREACH OF EXPRESS WARRANTY
AGAINST ALL DEFENDANTS

91. Plaintiff incorporates all of the preceding paragraphs of this Complaint as if fully set forth here and further alleges as follows:

92. Defendants expressly warranted that the M2a Magnum Hip System was a safe and effective orthopedic device for those patients requiring a hip replacement.

93. The M2a Magnum Hip System manufactured and sold by Defendants did not conform to these express representations because it caused serious injury to Plaintiff when used as recommended and directed.

94. As a direct and proximate result of Defendants' breach of warranty, Plaintiff suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future. The M2a Magnum Hip System is not subject to federal preemption because it was not approved as an FDA Class III device.

95. Defendants' conduct as described above, was extreme and outrageous. Defendants risked the lives of recipients of their products, including Plaintiff's, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants knew or should have known of the serious health risks it created and/or the failure to comply with federal requirements. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting recipients of Defendants' M2a Magnum Hip System. Defendants' outrageous conduct warrants an award of punitive damages.

96. Plaintiff seeks actual and punitive damages from Defendants as alleged herein.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems just and proper.

SEVENTH CAUSE OF ACTION
BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY
AGAINST ALL DEFENDANTS

97. Plaintiff incorporates all of the preceding paragraphs of this Complaint as if fully set forth here and further alleges as follows:

98. At the time Defendants designed, manufactured, marketed, sold, and distributed the M2a Magnum Hip System for Plaintiff's use, Defendants knew of the use for which the M2a Magnum Hip System was intended and impliedly warranted the product to be of merchantable quality and safe for such use and that its design, manufacture, labeling and marketing complied with all applicable federal requirements.

99. Plaintiff and/or her physicians reasonably relied upon Defendants' skill and judgment as to whether the M2a Magnum Hip System was of merchantable quality and safe for its intended use and upon Defendants' implied warranty as to such matters, including that it was in compliance with federal requirements.

100. Contrary to Defendants' implied warranties, the M2a Magnum Hip System was not of merchantable quality or safe for the ordinary purposes for which the M2a Magnum Hip System was to be used, because the M2a Magnum Hip System was unreasonably dangerous and/or not reasonably fit for its intended, anticipated, or reasonably foreseeable use as described above.

101. As a direct and proximate result of Defendants' breach of warranty of merchantability, Plaintiff suffered serious physical injury, harm, damages and economic loss and

will continue to suffer such harm, damages and economic loss in the future. The M2a Magnum Hip System is not subject to federal preemption because it was not approved as an FDA Class III device.

102. Defendants' conduct as described above, was extreme and outrageous. Defendants risked the lives of recipients of their products, including Plaintiff's, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants knew or should have known of the serious health risks it created and/or the failure to comply with federal requirements. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting recipients of Defendants' M2a Magnum Hip System. Defendants' outrageous conduct warrants an award of punitive damages.

103. Plaintiff seeks actual and punitive damages from Defendants as alleged herein.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems just and proper.

EIGHTH CAUSE OF ACTION
BREACH OF IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE AGAINST ALL DEFENDANTS

104. Plaintiff incorporates all of the preceding paragraphs of this Complaint as if fully set forth here and further alleges as follows:

105. Defendants designed, manufactured, tested, marketed and distributed the M2a Magnum Hip System into the stream of commerce.

106. At the time Defendants designed, manufactured, tested, marketed and distributed the M2a Magnum Hip System into the stream of commerce, Defendants knew the particular use

for which the M2a Magnum Hip System was intended, and impliedly warranted the M2a Magnum Hip System to be safe for such use.

107. Plaintiff and/or her physicians reasonably relied upon Defendants' skill and judgment as to whether the M2a Magnum Hip System was safe for its intended use.

108. Contrary to Defendants' implied warranty of fitness for a particular purpose, the M2a Magnum Hip System was not safe for its intended use or fit for the particular purpose for which it was designed, manufactured, tested, distributed or sold – for use and implantation as a total hip replacement system, because the M2a Magnum Hip System was unreasonably dangerous and/or not reasonably fir for its intended, anticipated or reasonably foreseeable use as described above.

109. As a direct and proximate result of Defendants' breach of implied warranty of fitness for a particular purpose, Plaintiff suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future. The M2a Magnum Hip System is not subject to federal preemption because it was not approved as an FDA Class III device.

110. Defendants' conduct as described above, was extreme and outrageous. Defendants risked the lives of recipients of their products, including Plaintiff's, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants knew or should have known of the serious health risks it created and/or the failure to comply with federal requirements. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting recipients of Defendants' M2a Magnum Hip System. Defendants' outrageous conduct warrants an award of punitive damages.

111. Plaintiff seeks actual and punitive damages from Defendants as alleged herein.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems just and proper.

NINTH CAUSE OF ACTION
NEGLIGENT MISREPRESENTATION
AGAINST ALL DEFENDANTS

112. Plaintiff incorporates all of the preceding paragraphs of this Complaint as if fully set forth here and further alleges as follows:

113. Defendants supplied false information to the public, to Plaintiff and/or her physicians regarding the high-quality, safety and effectiveness of the M2a Magnum Hip System, including statements of low wear, excellent stability, optimal clearance, high survivorship rate, and low revision rate, and high superiority over other metal on metal hip implants. Defendants provided this false information to induce the public, Plaintiff and/or Plaintiff's physicians to purchase and/or use and implant the M2a Magnum Hip System. In the exercise of reasonable care, Defendants should have known that its M2a Magnum Hip System failed to comply with federal requirements for safe design and manufacture and or/ was in other ways out of specification.

114. Defendants knew or should have known that the information they supplied, as set forth above, would induce Plaintiff and/or Plaintiff's physicians to purchase and use the M2a Magnum Hip System was false and misleading.

115. Defendants were negligent in obtaining or communicating this false information. Defendants negligently misrepresented to Plaintiff and/or Plaintiff's physicians that the M2a Magnum Hip System was safe and met all applicable design and manufacturing requirements.

116. Plaintiff and/or Plaintiff's physicians reasonably relied on the false information and omissions supplied by Defendants, as set forth above, to Plaintiff's detriment by causing the M2a Magnum Hip System to be purchased and implanted in Plaintiff.

117. As a direct and proximate result of Defendants' negligent misrepresentations and omissions and/or Defendants' failure to disclose its violations of federal requirements applicable to the M2a Magnum Hip System, Plaintiff used Defendants' M2a Magnum Hip System and Plaintiff suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future. The M2a Magnum Hip System is not subject to federal preemption because it was not approved as an FDA Class III device.

118. Defendants' conduct as described above, was extreme and outrageous. Defendants risked the lives of recipients of their products, including Plaintiff's, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants knew or should have known of the serious health risks it created and/or the failure to comply with federal requirements. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting recipients of Defendants' M2a Magnum Hip System. Defendants' outrageous conduct warrants an award of punitive damages.

119. Plaintiff seeks actual and punitive damages from Defendants as alleged herein.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems just and proper.

TENTH CAUSE OF ACTION
FRAUDULENT MISREPRESENTATION
AGAINST ALL DEFENDANTS

120. Plaintiff incorporates all of the preceding paragraphs of this Complaint as if fully set forth here and further alleges as follows:

121. Defendants falsely and fraudulently represented to the medical and healthcare community and to Plaintiff, and/or the FDA, and the general public that the subject product had been tested and was found to be safe and/or effective for hip arthroplasty treatment.

122. Defendants' representations were false. When said representations were made, Defendants knew those representations were false and Defendants willfully, wantonly and recklessly disregarded whether the representations were true.

123. Defendants knowingly and intentionally made false representations of material fact to Plaintiff, including claims that the M2a Magnum Hip System was a safe and durable hip replacement system. Defendants further asserted that the "Biomet metal-on-metal (MoM) M2a Magnum Large Metal articulation system offers optimal joint mechanic restoration and ultra low-wear rates in vivo. Many studies conducted over the last several decades have shown no definitive correlation of negative health issues to ion levels exhibited from metal-on-metal implants."

124. Defendants made these representations with the intent of defrauding and deceiving Plaintiff, the public in general, and the medical and healthcare community in particular, and were made with the intent of inducing the public in general, and the medical and healthcare community in particular, to recommend, prescribe, dispense and/or purchase the M2a Magnum Hip System for hip arthroplasty treatment, all of which evinced a callous, reckless, willful, depraved indifference to the health, safety and welfare of Plaintiff and the public in general.

125. At the time the above representations were made by Defendants, and at the time Plaintiff was treated with the M2a Magnum Hip System, Plaintiff was unaware of their falsity and reasonably believed them to be true.

126. Relying upon Defendants' representations, Plaintiff was induced to, and did use the M2a Magnum Hip System, thereby sustaining severe and permanent personal injuries including but not limited to significant pain, irritation and discomfort, as well as other severe and permanent health consequences, notwithstanding Defendants' knowledge of an increased risk of these injuries and side effects over other hip arthroplasty devices.

127. Defendants knew and were aware or should have been aware that the M2a Magnum Hip System had not been sufficiently tested, was defective in nature, and/or that it lacked adequate and/or sufficient warnings.

128. Defendants knew or should have known that the M2a Magnum Hip System could, and would, cause severe and grievous injury to the M2a Magnum Hip System's users, and that it was inherently dangerous in a manner that exceeded any purported, inaccurate, and/or down-played warnings.

129. Defendants brought the M2a Magnum Hip System to the market, and acted fraudulently, wantonly and maliciously to Plaintiff's detriment.

130. As a direct and proximate result of Defendants' fraudulent misrepresentations and omissions and/or its failure to disclose their violations of federal requirements applicable to the M2a Magnum Hip System, Plaintiff used Defendants' M2a Magnum Hip System and Plaintiff suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future. The M2a Magnum Hip System is not subject to federal preemption because it was not approved as an FDA Class III device.

131. Defendants' conduct as described above, was extreme and outrageous. Defendants risked the lives of recipients of their products, including Plaintiff's, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants knew or should have known of the serious health risks it created and/or the failure to comply with federal requirements. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting recipients of Defendants' M2a Magnum Hip System. Defendants' outrageous conduct warrants an award of punitive damages.

132. Plaintiff seeks actual and punitive damages from Defendants as alleged herein.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems just and proper.

ELEVENTH CAUSE OF ACTION
FRAUDULENT CONCEALMENT
AGAINST ALL DEFENDANTS

133. Plaintiff incorporates all of the preceding paragraphs of this Complaint as if fully set forth here and further alleges as follows:

134. At all times during the course of dealing between Defendants and Plaintiff, Plaintiff's health care providers, and/or the FDA, Defendants misrepresented the safety of the M2a Magnum Hip System for its intended use.

135. Defendants knew or were reckless in not knowing that its representations were false.

136. In representations to Plaintiff, Plaintiff's health care providers, and/or the FDA, Defendants fraudulently concealed and intentionally omitted material information, including but not limited to:

a. the M2a Magnum Hip System was not as safe as other similar devices indicated from hip arthroplasty;

b. the M2a Magnum Hip System was defective, and that it caused dangerous side effects, including the risks of developing serious and dangerous side effects such as loosening, component mal-alignment, infections, fracture of the bone, dislocation, metal sensitivity and pain, irritation and discomfort, as well as the need for additional procedures to remove and replace the M2a Magnum Hip System, as well as other severe and permanent health consequences, notwithstanding Defendants' knowledge of an increased risk of these injuries and side effects over other hip arthroplasty devices;

c. the M2a Magnum Hip System was manufactured negligently;

d. the M2a Magnum Hip System was manufactured defectively;

e. the M2a Magnum Hip System was manufactured improperly;

f. the M2a Magnum Hip System was designed negligently;

g. the M2a Magnum Hip System was designed defectively;

h. the M2a Magnum Hip System was designed improperly.

137. Defendants were under a duty to disclose to Plaintiff, Plaintiff's healthcare providers, and/or the FDA the defective nature of the M2a Magnum Hip System, including the risk of developing elevated metal ion levels, device failure resulting in the need for revision surgery associated with the use of the M2a Magnum Hip System.

138. Defendants had sole access to material facts concerning the defective nature of the M2a Magnum Hip System and its propensity to cause serious and dangerous side effects, thereby causing damage to M2a Magnum Hip System users, including Plaintiff.

139. Defendants' concealment and omissions of material facts concerning, inter alia, the safety of the M2a Magnum Hip System was made purposefully, willfully, wantonly, and/or recklessly to mislead Plaintiff and Plaintiff's healthcare providers into reliance on the M2a Magnum Hip System, and to cause them to purchase, prescribe, dispense and/or use the M2a Magnum Hip System.

140. Defendants knew that Plaintiff, Plaintiff's healthcare providers, and/or the FDA had no way to determine the truth behind Defendants' concealment and omissions as set forth herein.

141. Plaintiff, as well as Plaintiff's healthcare providers, reasonably relied on facts revealed which negligently, fraudulently, and/or purposefully did not include facts that Defendants concealed and/or omitted.

142. As a direct and proximate result of Defendants' fraudulent misrepresentations and omissions and/or Defendants' failure to disclose its violations of federal requirements applicable to the M2a Magnum Hip System, Plaintiff used the M2a Magnum Hip System and Plaintiff suffered physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future. The M2a Magnum Hip System is not subject to federal preemption because it was not approved as an FDA Class III device.

143. Defendants' conduct as described above, was extreme and outrageous. Defendants risked the lives of recipients of their products, including Plaintiff's, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants knew or should have known of the serious health risks it created and/or the failure to comply with federal requirements. Defendants made conscious decisions not to redesign, re-

label, warn or inform the unsuspecting recipients of Defendants' M2a Magnum Hip System. Defendants' outrageous conduct warrants an award of punitive damages.

144. Plaintiff seeks actual and punitive damages from Defendants as alleged herein.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems just and proper.

TWELFTH CAUSE OF ACTION
PUNITIVE DAMAGES
AGAINST ALL DEFENDANTS

145. Plaintiff incorporates all of the preceding paragraphs of this Complaint as if fully set forth here and further alleges as follows:

146. At all times relevant, Defendants knew or should have known that their M2a Magnum Hip System was inherently more dangerous with respect to the risk of significant pain, irritation, discomfort and need for additional surgeries that the alternative hip arthroplasty systems on the market.

147. At all times relevant, Defendants attempted to misrepresent and did misrepresent facts concerning the safety of the M2a Magnum Hip System.

148. Defendants' misrepresentations included knowingly withholding material information from the medical community, the general public, and Plaintiff, concerning the safety and efficacy of the M2a Magnum Hip System.

149. At all times relevant, Defendants knew and recklessly disregarded the fact that the M2a Magnum Hip System was subject to an increased risk of causing significant pain, irritation, discomfort and need for additional surgeries in persons with M2a Magnum Hip System implants with far greater frequency than safer alternative hip arthroplasty systems.

150. Notwithstanding the foregoing, Defendants continued to aggressively market the M2a Magnum Hip System without disclosing the above-mentioned side effects when there were safer alternative methods.

151. Defendants knew the M2a Magnum Hip System was defective and unreasonably dangerous. Despite their knowledge, Defendants continued to design, develop, manufacture, market, distribute and sell the M2a Magnum Hip System to maximize sales and profits at the expense of the health and safety of the public, including Plaintiff, in conscious and/or negligent disregard of the foreseeable harm.

152. Defendants' intentional and/or reckless, fraudulent and malicious failure to disclose information deprived Plaintiff and her healthcare providers of necessary information to enable them to make an informed decision with regard to using the M2a Magnum Hip System.

153. As a direct and proximate result of Defendants' conscious and deliberate disregard for the rights and safety of consumers, Plaintiff suffered severe and permanent physical and emotional injuries. The M2a Magnum Hip System is not subject to federal preemption because it was not approved as an FDA Class III device.

154. Defendants' conduct, committed with a knowing, conscious and deliberate disregard for the rights and safety of consumers, including Plaintiff's, entitles Plaintiff to punitive damages in an amount appropriate to punish Defendants and deter them from similar conduct in the future.

155. Plaintiff seeks actual and punitive damages from Defendants as alleged herein.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems just and proper.

THIRTEENTH CAUSE OF ACTION
LOSS OF CONSORTIUM OF WILLIS WILLIAM NICHOLSON
AGAINST ALL DEFENDANTS

156. Plaintiffs incorporate all of the preceding paragraphs of this Complaint as if fully set forth here and further alleges as follows:

157. At all times relevant, Plaintiff Willis William Nicholson was and is the husband of Plaintiff Willis William Nicholson. As such, Plaintiff Willis William Nicholson was and is entitled to his wife's services, support, companionship, affection and consortium.

158. As a result of the injuries sustained by his wife as alleged in this Complaint, Plaintiff Willis William Nicholson has lost the services, support, companionship, affection and consortium of his wife, and will continue to lose said services, support, companionship, affection and consortium in the future.

159. Plaintiff Willis William Nicholson seeks actual and punitive damages from Defendants as alleged herein.

WHEREFORE, Plaintiff Willis William Nicholson demands judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems just and proper.

DEMAND FOR JURY TRIAL

160. Plaintiffs hereby demand a trial by jury on all counts as to all issues.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment against Defendants on each of the above-referenced claims and Causes of Action as follows:

1. Awarding compensatory damages to Plaintiff Lori Nicholson for past and future damages, including but not limited to pain and suffering for severe and permanent

personal injuries sustained by Plaintiff Lori Nicholson, health care costs, medical monitoring, together with interest and costs as provided by the law;

2. Awarding compensatory damages to Plaintiff Willis William Nicholson for past and future damages as a result of his loss of consortium;

3. Awarding punitive and/or exemplary damages, in an amount to be determined at trial;

4. Awarding Plaintiff's attorney's fees;

5. Awarding Plaintiff the costs of the proceedings; and

6. Awarding such other and further relief this Court deems just and proper.

Dated: April 24, 2013

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