UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF INDIANA
SOUTH BEND DIVISION

GARY SANDEN AND SUSAN SANDEN, Plaintiffs, v. BIOMET, INC., BIOMET MANUFACTURING CORPORATION, BIOMET U.S. RECONSTRUCTION, LLC, and BIOMET ORTHOPEDICS, LLC, Defendants.	Civil Case. No.: Master Docket No.: 3:12-md-02391-RLM-CAN HON. ROBERT L. MILLER, JR.

COMPLAINT AND DEMAND FOR JURY TRIAL

COMES NOW Plaintiffs Gary Sanden and Susan Sanden, by and through their attorneys, and files this Complaint and Demand for Jury Trial against Defendants Biomet, Inc., Biomet Manufacturing Corporation, Biomet U.S. Reconstruction, LLC and Biomet Orthopedics, LLC, and respectfully shows the Court as follows:

NATURE OF THE CASE

1. This is an action for product liability case on behalf of Plaintiff Gary Sanden against Defendants Biomet, Inc., Biomet Manufacturing Corporation, Biomet U.S. Reconstruction, LLC and Biomet Orthopedics, LLC, who were responsible for the defective hip system implanted in Plaintiff Gary Sanden which caused him to undergo a revision surgery to remove the defective hip system.

VENUE STATEMENT

2. Venue of this case is appropriate in the United States District Court for the Eastern District of Arkansas. Plaintiff states that but for this Court's Order permitting direct filing into this Court (Master Docket No. 242), Plaintiff would have filed in the United States District Court for the Eastern District of Arkansas. Therefore, Plaintiff respectfully requests that at the time of transfer of this action back to the trial court for further proceedings that this case be transferred to the United States District Court for the Eastern District of Arkansas.

SUBJECT MATTER JURISDICTION

3. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332 because the amount in controversy as to the Plaintiffs exceed $75,000.00, exclusive of interest and costs, and because complete diversity exists between the parties.

PARTIES

4. Plaintiffs Gary and Susan Sanden are citizens of the United States of America and are residents of Jacksonville in the State of Arkansas.

5. Upon information and belief, Defendant Biomet, Inc. is, and at all times relevant to this Complaint was, a corporation organized and existing under the laws of the state of Indiana with its primary place of business at 56 East Bell Drive, Warsaw, Indiana 46582. Accordingly, the citizenship of Defendant Biomet, Inc. is Indiana. Defendant Biomet Inc. is and was at all times relevant herein doing business in and/or having direct activities in the State of Arkansas.

6. Defendant Biomet, Inc. 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 Manufacturing Corporation is, and at all times relevant to this Complaint was, a corporation organized and existing under the

laws of the state of Indiana with its primary place of business at 56 East Bell Drive, Warsaw, Indiana 46582. Accordingly, the citizenship of Defendant Biomet Manufacturing Corporation is Indiana. Defendant Biomet Manufacturing Corporation is and was at all times relevant herein doing business in and/or having direct activities in the State of Arkansas.

8. Defendant Biomet Manufacturing Corporation designed, manufactured, marketed, promoted, and sold the M2a Magnum™ Hip System that is the subject of this lawsuit.

9. Upon information and belief, Defendant Biomet U.S. Reconstruction, LLC is, and at all times relevant to this Complaint was, a wholly owned subsidiary of Defendant Biomet, Inc., an Indiana Corporation with its principal place of business 56 East Bell Drive, Warsaw, Indiana 46582. Accordingly, the citizenship of Defendant Biomet U.S. Reconstruction, LLC is Indiana. Defendant Biomet U.S. Reconstruction, LLC is and was at all times relevant herein doing business in and/or having direct activities in the State of Arkansas.

10. Defendant Biomet U.S. Reconstruction, LLC designed, manufactured, marketed, promoted, and sold the M2a Magnum™ Hip System that is the subject of this lawsuit.

11. On information and belief, Defendant Biomet Orthopedics LLC, is, and at all times relevant to this Complaint was, a wholly owned subsidiary of Defendant Biomet, Inc., an Indiana Corporation with its principal place of business 56 East Bell Drive, Warsaw, Indiana 46582. Accordingly, the citizenship of Defendant Biomet Orthopedics, LLC is Indiana. Defendant Biomet Inc. is and was at all times relevant herein doing business in and/or having direct activities in the State of Arkansas.

12. Defendant Biomet Orthopedics, LLC designed, manufactured, marketed, promoted, and sold the M2a Magnum™ Hip System that is the subject of this lawsuit.

13. Defendants Biomet, Inc., Biomet Manufacturing Corporation, Biomet U.S. Reconstruction, LLC, and Biomet Orthopedics, LLC are collectively referred to herein as "Biomet" or Defendants.

14. At all times mentioned, each of Biomet, Inc., Biomet Manufacturing Corporation, Biomet U.S. Reconstruction, LLC, and Biomet Orthopedics, LLC, was the representative, agent, employee, joint venturer, or alter ego of each of the other entities and in doing the things alleged herein was acting within the scope of its authority as such. Specifically, each Defendant was but an instrumentality or conduit of the other in the prosecution of a single venture, namely the design, promotion, and sale of the M2a Magnum™ Hip System. Therefore, it would be inequitable for any Defendant to escape liability for an obligation incurred as much for that Defendant's benefit as for the other.

FACTUAL ALLEGATIONS

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

15. 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.

16. A total hip replacement replaces the body's natural joint with an artificial one, usually made out of metal and plastic. A typical total hip replacement system consists of four separate components: (1) a femoral stem, (2) a femoral head, (3) a plastic (polyethylene) liner, 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 liner and acetabular shell.

17. 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.

18. The M2a Magnum™ Hip System suffers from a design or manufacturing defect that cause 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.

19. The design of the M2a Magnum™ Hip System was not sufficiently tested by Biomet.

20. On numerous occasions, Biomet met with orthopedic surgeons throughout the United States to promote the M2a Magnum™ Hip System. At some or all of these meetings, a representative or representatives of Biomet was present. During these meetings, Biomet assured the orthopedic surgeons that the M2a Magnum™ Hip System was safe, was the best product on the market, and had an excellent track record and a low and 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 and serious complications and other "bad data" during their meetings with orthopedic surgeons.

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

21. It wasn't long after Biomet launched the M2a Magnum™ Hip System that reports of failures began flooding into Biomet.

22. Biomet would go on to receive hundreds of similar complaints reporting that the M2a Magnum™ Hip System had failed and that the failure had 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 associated with the M2a Magnum™ Hip System have been filed with the FDA.

23. By the time Biomet sold the M2a Magnum™ Hip System to Plaintiff, numerous reports had been filed with the FDA reporting an adverse event associated with the M2a Magnum™ Hip System. Consequently, Biomet was fully aware that the M2a Magnum™ Hip System was defective and that dozens of patients already 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. At minimum, Biomet should have stopped selling the defective implant when it became aware that it had catastrophically failed in several patients.

24. Despite its knowledge that the M2a Magnum™ Hip System had a defect and that it had failed hundreds of times, causing hundreds of patients to undergo the agony of another surgery, Biomet continues to sell the defective M2a Magnum™ Hip System. In so doing, Biomet actively concealed the known defect from doctors and patients - including Plaintiff and

Plaintiff's doctor - and misrepresented that that the M2a Magnum™ Hip System was a safe and effective medical device.

25. As numerous failures of the M2a Magnum™ Hip Implant were reported to Biomet, it continued to actively promote, market and defend the defective products. For example, Biomet published marketing brochures touting the safety and durability of metal-on-metal implants and specifically, the M2a Magnum™ Hip System. These brochures were given to doctors around the world, including Plaintiff's orthopedic surgeon, to encourage them to use the M2a Magnum™ Hip System.

26. 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 they claimed made it superior to other more safe hip implants on the market. For example, Biomet said:

- "The 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."

27. Biomet's reason to conceal the defect in its M2a Magnum™ Hip System is clear. Hip implant sales are critically important to Biomet, and the M2a Magnum™ is one of its most profitable products. During the time period relevant to this Complaint, Biomet's management was trying to make Biomet look appealing to investors, and they ultimately were purchased by a private equity firm in 2007 for $10 billion. Biomet was faced with a critical defect in one of its most profitable hip implant systems. The last thing Biomet wanted to do was to admit that these popular products had a critical defect that could cause a premature failure, forcing patients to have to undergo another painful surgery. Focused on corporate profits, and at the expense of

patient safety, Biomet decided that it would continue to promote, market, and sell the M2a Magnum™ Hip System despite the fact that it knew the product was defective. To this day, Biomet continue to sell these defective implants to unsuspecting patients without any warning about the risks or the failures that have been reported to the company.

C. Plaintiff Was Implanted With A Defective M2a Magnum™ Hip System And As A Result Has Suffered Injuries

28. On or about September 11, 2008, Plaintiff Gary Sanden underwent a right total hip arthroplasty procedure performed by Dr. D. Gordon Newbern at Baptist Health Medical Center in North Little Rock. Biomet misrepresented to Mr. Sanden and his orthopedic surgeon that the M2a Magnum™ Hip System was safe and effective. In reliance on these representations, Mr. Sanden's orthopedic surgeon made the decision to use the M2a Magnum™ Hip System. If it were not for the misrepresentations made by Biomet, Mr. Sanden's orthopedic surgeon would not have used the M2a Magnum™ Hip System in Plaintiff's hip replacement surgery.

29. Over time, the known and common problem of corrosion and friction wear is believed to have caused amounts of toxic cobalt-chromium metal debris to be released into Plaintiff's tissue surrounding the M2a Magnum™ implant. Following his surgery to replace his right hip, Plaintiff began experiencing pain and difficulty in and around his implant. As a result of these injuries, Gary Sanden found himself in pain and his mobility was limited.

30. Elevated cobalt/chromium levels resulting from the metal on metal effects of the M2a magnum hip implant was suspected by his physician.

31. 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), Mr. Sanden's hip implant failed, causing him severe pain resulting in revision surgery, and significant economic loss.

32. On or about May 2, 2016, Plaintiff underwent a complex, risky and painful revision surgery performed by Dr. D. Gordon Newbern at St. Vincent Infirmary in Little Rock to remove the defective M2a Magnum™ device from his body. The previously suspected metal on metal disease was confirmed in surgery. 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 original hip replacement surgery and the revision surgery has a higher rate of complications.

33. Undergoing a revision surgery has subjected Mr. Sanden to greater risks of future complications than she had before the revision surgery. For example, several studies have found that a revision surgery causes a much higher risk of dislocation compared with an original hip replacement surgery. In one study conducted by Charlotte Phillips and her colleagues at Brigham and Women's Hospital in Boston, 14.4 percent of patients who underwent a revision surgery suffered from a dislocation compared with 3.9 percent of patients who underwent an original hip replacement surgery. In other words, hip replacement patients who have undergone 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.)

34. At the time of the facts set forth in the Plaintiffs' Complaint, the Plaintiffs were married and the Plaintiffs continue to be married.

35. That as a result of the wrongful and negligent acts of the Defendants, and each of them, the Plaintiffs were caused to suffer, and will continue to suffer in the future, loss of

consortium, loss of society, affection, assistance, and conjugal fellowship, all to the detriment of their marital relationship.

36. As a direct and proximate result of the failure of his defective M2a Magnum™ Hip System and Biomet's wrongful conduct, Plaintiff suffered and continues to suffer the following personal and economic damages:

a) Undergoing an additional surgical procedure that would not have been needed if the Magnum Device had performed satisfactorily during its expected usual life;

b) Permanent harm by metal poisoning and metallosis from the metal debris of the Magnum Device;

c) Loss of consortium, loss of society, affection, assistance, and conjugal fellowship, all to the detriment of their marital relationship;

d) Lost wages and future loss of earning capacity;

e) Medical expenses (past and future);

f) Physical scarring (past and future);

g) Disfigurement (past and future);

h) Impaired physical mobility (past and future);

i) Mental anguish and emotional distress (past and future);

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.

EQUITABLE TOLLING OF APPLICABLE STATUTES OF LIMITATIONS

37. The running of any statute of limitation has been tolled by reason of Defendants' conduct. Defendants, through their affirmative misrepresentations and omissions, actively concealed from Plaintiff and Plaintiff's prescribing physicians the true risks associated with Biomet.

38. As a result of Defendants actions, Mr. Sanden and his prescribing physician were unaware, and could not reasonably know or have learned through reasonable diligence that Mr. Sanden had been exposed to the risks alleged herein and that those risks were the direct and proximate result of the Defendants acts and omissions.

39. Furthermore, Defendants are stopped from relying on any statute of limitations because of their concealment of the truth, quality and nature of the M2a Magnum™ Hip Implant System. Defendants were under duty to disclose the true character, quality and nature of the M2a Magnum™ Hip Implant System because this was non-public information which the Defendants had and continue to have exclusive control, and because the Defendants knew that this information was not available to Plaintiff, his medical providers and/or to his health facilities.

40. Defendants had the ability to and did spend enormous amounts of money in furtherance of their purpose marketing and promoting a profitable medical device, notwithstanding the known or reasonably known risks. Mr. Sanden and medical professionals could not have afforded and could not have possibly conducted studies to determine the nature, extent and identity of health related risks, and were forced to rely on the Defendants' representations.

FIRST CAUSE OF ACTION
STRICT PRODUCTS LIABILITY - MANUFACTURING DEFECT
(Against All Defendants)

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

42. Defendants are the manufacturers, designers, distributors, sellers, and/or suppliers of orthopedic devices including the M2a Magnum™ Hip System.

43. 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 the hands of Defendants in that it deviated from product specifications and/or applicable federal requirements for these medical devices, posing a serious risk of injury and death.

44. As a direct and proximate result of the 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, emotional distress, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

45. Defendants' actions and omissions as alleged in this Complaint constitute a flagrant disregard for human life, so as to warrant the imposition of punitive damages.

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

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

SECOND CAUSE OF ACTION
STRICT PRODUCTS LIABILITY – DESIGN DEFECT
(Against All Defendants)

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

48. Defendants are the manufacturers, designers, distributors, sellers, and/or suppliers of orthopedic devices including the M2a Magnum™ Hip System.

49. The M2a Magnum™ Hip System, manufactured and supplied by Defendants was defective in design or formulation in that, when it left the hands of the Defendants, the foreseeable risks of the product exceeded the benefits associated with its design or formulation, or it was more dangerous than an ordinary consumer would expect, and/or it failed to comply with federal requirements for these medical devices.

50. The foreseeable risks associated with the design or formulation of the M2a Magnum™ Hip System, include, but are not limited to, the fact that the design or formulation of the M2a Magnum™ Hip System is more dangerous than a reasonably prudent consumer would expect when used in an intended or reasonably foreseeable manner, and/or it failed to comply with federal requirements.

51. As a direct and proximate result of the Plaintiff's use of the M2a Magnum™ Hip System, as manufactured, designed, sold, supplied, marketed and introduced into the stream of commerce by Defendants and/or its failure to comply with federal requirements, Plaintiff suffered serious physical injury, harm, emotional distress, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

52. Defendants' actions and omissions as alleged in this Complaint demonstrate a flagrant disregard for human life, which warrants the imposition of punitive damages.

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

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

THIRD CAUSE OF ACTION
STRICT PRODUCTS LIABILITY – DEFECT DUE TO NONCONFORMANCE WITH REPRESENTATIONS
(Against All Defendants)

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

55. Defendants are the manufacturers, designers, distributors, sellers, and/or suppliers of orthopedic devices including the M2a Magnum™ Hip System.

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

57. Defendants made representations to consumers regarding the character or quality of M2a Magnum Hip System, including but not limited to statements that the M2a Magnum™ Hip System was a safe and durable hip replacement system. They 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 decreased have shown no definitive correlation of negative health issues to ion levels exhibited from metal-on-metal implants."

58. The Plaintiff and/or his physicians justifiably relied upon Defendants' representations regarding the M2a Magnum™ Hip System, when they selected these Biomet orthopedic products to be used in surgery.

59. As a direct and proximate result of the 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, emotional distress, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

60. Defendants' actions and omissions as alleged in this Complaint demonstrate a flagrant disregard for human life, which warrants the imposition of punitive damages.

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

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

FOURTH CAUSE OF ACTION
STRICT PRODUCTS LIABILITY – FAILURE TO WARN
(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. The M2a Magnum™ Hip System was defective and unreasonably dangerous when it left the possession of the Defendants in that it contained warnings insufficient to alert consumers, including The Plaintiff herein, 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 malalignment, 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 the Defendants' knowledge of an increased risk of these injuries and side effects over other hip arthroplasty devices.

64. At the time of the Plaintiff's receipt and/or use of 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.

65. Plaintiff could not, by the exercise of reasonable care, have discovered the defects herein mentioned and perceived their danger.

66. 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.

67. The warnings that were given by the Defendants were not accurate, clear and/or were ambiguous.

68. The warnings that were given by the Defendants 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 malalignment, infections, fracture of the bone, dislocation, metal sensitivity, 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 the Defendants' knowledge of an increased risk of these injuries and side effects over other hip arthroplasty devices.

69. Plaintiff, individually and through his physicians, reasonably relied upon the skill, superior knowledge and judgment of the Defendants.

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

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

72. As a direct and proximate result of the 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, emotional distress, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

73. Defendants' actions and omissions as alleged in this Complaint demonstrate a flagrant disregard for human life, which warrants the imposition of punitive damages.

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

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

FIFTH CAUSE OF ACTION
NEGLIGENCE
(Against All Defendants)

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

76. Defendants had a duty to exercise reasonable care in the design, manufacture, sale and/or distribution of the M2a Magnum™ Hip System into the stream of commerce, including a duty to assure that its product did not pose a significantly increased risk of bodily harm and adverse events and/or a duty to comply with federal requirements.

77. Defendants failed to exercise ordinary care in the design, formulation, manufacture, sale, testing, quality assurance, quality control, labeling, marketing, promotions and distribution of the M2a Magnum™ Hip System into interstate commerce in that Defendants

knew or should have known that the product caused significant bodily harm and was not safe for use by consumers, and/or through failure to comply with federal requirements.

78. 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 consumers and/or continued to fail to comply with federal requirements.

79. Defendants knew or should have known that consumers such as Plaintiff would foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care as described above, including the failure to comply with federal requirements.

80. As a direct and proximate result of Defendants' negligence, Plaintiff suffered serious physical injury, harm, emotional distress, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

81. Defendants' conduct as described above, including but not limited to its failure to adequately design and manufacture, as well as its continued marketing and distribution of the M2a Magnum™ Hip System when it knew or should have known of the serious health risks it created and/or the failure to comply with federal requirements, evidences a flagrant disregard of human life so as to warrant the imposition of punitive damages.

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

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

SIXTH CAUSE OF ACTION
BREACH OF EXPRESS WARRANTY
(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 expressly warranted that the M2a Magnum™ Hip System was a safe and effective orthopedic device for those patients requiring a hip replacement.

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

86. As a direct and proximate result of Defendants' breach of warranty, Plaintiff suffered serious physical injury, harm, emotional distress, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

87. Defendants' conduct as described above, including but not limited to its failure to adequately design and manufacture, as well as its continued marketing and distribution of the M2a Magnum™ Hip System when it knew or should have known of the serious health risks it created and/or the failure to comply with federal requirements, evidences a flagrant disregard of human life so as to warrant the imposition of punitive damages.

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

89. Plaintiff has complied with notice requirements of Arkansas warranty law.

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

SEVENTH CAUSE OF ACTION
BREACH OF IMPLIED WARRANTY
(Against All Defendants)

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

91. At the time Defendants designed, manufactured, marketed, sold, and distributed the M2a Magnum™ Hip System for use by the Plaintiff, 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.

92. The Plaintiff and/or their physicians reasonably relied upon the skill and judgment of Defendants 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 all federal requirements.

93. Contrary to such implied warranty, Biomet's M2a Magnum™ Hip System was not of merchantable quality or safe for its intended use, because the product was defective as described above, and/or it failed to comply with federal requirements.

94. As a direct and proximate result of Defendants' breach of warranty, the Plaintiff suffered serious physical injury, harm, emotional distress, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

95. Defendants' conduct as described above, including but not limited to its failure to adequately design and manufacture, as well as its continued marketing and distribution of the M2a Magnum™ Hip System when it knew or should have known of the serious health risks it

created and/or the failure to comply with federal requirements, evidences a flagrant disregard of human life so as to warrant the imposition of punitive damages.

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

97. Plaintiff has complied with notice requirements of Arkansas warranty law.

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

EIGHTH CAUSE OF ACTION
NEGLIGENT MISREPRESENTATION
(Against All Defendants)

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

99. 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, yet Defendants negligently misrepresented the Plaintiff and/or her physicians that its device was safe and met all applicable design and manufacturing requirements.

100. The Plaintiff and/or her physicians reasonably relied to their detriment upon Defendants' misrepresentations and omissions in its labeling, advertisements, and promotions concerning the serious risks posed by these products. The Plaintiff and/or his physicians reasonably relied upon Defendants' representations that the M2a Magnum™ Hip System was safe for use.

101. As a direct and proximate result of Defendants' negligent misrepresentations and omissions and/or its failure to disclose its violations of federal requirements applicable to its 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.

102. Defendants' actions and omissions as alleged in this Complaint demonstrate a flagrant disregard for human life, so as to warrant the imposition of punitive damages.

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

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

NINTH CAUSE OF ACTION
FRAUDULENT MISREPRESENTATION
(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 falsely and fraudulently represented to the medical and healthcare community and to the Plaintiff, and/or the FDA, and the public in general, that the subject product had been tested and was found to be safe and/or effective for hip arthroplasty treatment.

106. The representations made by the Defendants were, in fact, false.

107. When said representations were made by the Defendants, they knew those representations to be false and it willfully, wantonly and recklessly disregarded whether the representations were true.

108. Defendants knowingly and intentionally made false representations of material fact to Plaintiff, including but not limited to claims that the M2a Magnum™ Hip System was a safe and durable hip replacement system. They 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 decreased have shown no definitive correlation of negative health issues to ion levels exhibited from metal-on-metal implants."

109. These representations were made by the Defendants with the intent of defrauding and deceiving the 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 subject product for hip arthroplasty treatment, all of which evinced a callous, reckless, willful, depraved indifference to the health, safety and welfare of the Plaintiff and the public in general.

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

111. In reliance upon said representations, Plaintiff was induced to, and did use the subject product, 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 the Defendants' knowledge of an increased risk of these injuries and side effects over other hip arthroplasty devices.

112. 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.

113. Defendants knew or should have known that the M2a Magnum™ Hip System had a potential to, could, and would cause severe and grievous injury to the users of said product, and

that it was inherently dangerous in a manner that exceeded any purported, inaccurate, and/or down-played warnings.

114. Defendants brought the subject product to the market, and acted fraudulently, wantonly and maliciously to the detriment of the Plaintiff.

115. As a direct and proximate result of Defendants' fraudulent misrepresentations and omissions and/or its failure to disclose its violations of federal requirements applicable to its M2a Magnum™ Hip System, the Plaintiff used Defendants' M2a Magnum™ Hip System and the Plaintiff suffered serious physical injury, harm, emotional distress, damages and economic loss and will continue to suffer such harm, damages.

116. Defendants' actions and omissions as alleged in this Complaint demonstrate a flagrant disregard for human life, so as to warrant the imposition of punitive damages.

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

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

TENTH CAUSE OF ACTION
FRAUDULENT CONCEALMENT
(Against All Defendants)

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

119. At all times during the course of dealing between the Defendants and Plaintiff, Plaintiff's healthcare providers, and/or the FDA, the Defendants misrepresented the safety of the subject product for its intended use.

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

121. In representations to Plaintiff, Plaintiff's healthcare providers, and/or the FDA, the Defendants fraudulently concealed and intentionally omitted material information, including but not limited to, the fact that:

a. the subject product was not as safe as other similar drugs and medications indicated for hip arthroplasty;

b. that the subject product was defective, and that it caused dangerous side effects, including but not limited to the risks of developing serious and dangerous side effects, 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 the Defendants' knowledge of an increased risk of these injuries and side effects over other hip arthroplasty devices.

c. that the subject product was manufactured negligently;

d. that the subject product was manufactured defectively;

e. that the subject product was manufactured improperly;

f. that the subject product was designed negligently;

g. that the subject product was designed defectively; and

h. that the subject product was designed improperly.

122. Defendants were under a duty to disclose to Plaintiff, Plaintiff's healthcare providers, and/or the FDA the defective nature of the subject product, including but not limited to 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.

123. Defendants had sole access to material facts concerning the defective nature of the subject product and its propensity to cause serious and dangerous side effects, and hence, cause damage to persons who used the M2a Magnum™ Hip System, including the Plaintiff, in particular.

124. 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 physicians, hospitals and healthcare providers into reliance on the use of the M2a Magnum™ Hip System, and to cause them to purchase, prescribe, dispense and/or use the subject product.

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

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

127. As a direct and proximate result of Defendants' fraudulent misrepresentations and omissions and/or its failure to disclose its violations of federal requirements applicable to its M2aMagnum™ Hip System, Plaintiff used Defendants' M2a Magnum™ Hip System and the Plaintiff suffered serious physical injury, harm, emotional distress, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

128. Defendants' actions and omissions as alleged in this Complaint demonstrate a flagrant disregard for human life, so as to warrant the imposition of punitive damages.

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

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

ELEVENTH CAUSE OF ACTION
CONSUMER PROTECTION - VIOLATION OF Ark. Code Ann. §§4-88-107 *et seq.*
(Against All Defendants)

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

131. The Defendants acted, used and employed unconscionable commercial practices, deception, fraud, false pretenses, false promises and misrepresentations, and knowingly concealed, suppressed and omitted material facts with the intent that consumers, including Plaintiff Gary Sanden herein and his physicians and medical providers, rely upon such concealment, suppression and omission, in connection with the sale, advertisement and promotion of the M2a Magnum™ Hip System, in violation of all applicable state consumer fraud statutes, for the purpose of influencing and inducing physicians and medical providers to prescribe the M2a Magnum™ Hip System for hip arthroplasty, to patients/consumers such as the Gary Sanden herein. By reason of the Defendants' unconscionable, deceptive and fraudulent acts and practices, and false pretenses, false promises and misrepresentations, reasonable patients/consumers acting reasonably, such as the Plaintiff Gary Sanden herein, were caused to suffer ascertainable loss of money and property and actual damages.

132. The Defendants engaged in consumer-oriented, commercial conduct by selling and advertising the subject product.

133. The Defendants misrepresented and omitted material information regarding the subject product by failing to disclose known risks.

134. The Defendants' misrepresentations and concealment of material facts constitute unconscionable commercial practices, deception, fraud, false pretenses, misrepresentation, and/or the knowing concealment, suppression, or omission of materials facts with the intent that others rely on such concealment, suppression, or omission in connection with the sale and advertisement of the subject product, in violation of Ark. Code Ann. §§4-88-107 *et seq.*

135. Arkansas has enacted statutes to protect consumers from deceptive, fraudulent, and unconscionable trade and business practices. The Defendants violated these statutes by knowingly and falsely representing that the subject product was fit to be used for the purpose for which it was intended, when the Defendants knew it was defective and dangerous, and by other acts alleged herein.

136. The Defendants engaged in the deceptive acts and practices alleged herein in order to sell the subject product to the public, including Plaintiff Gary Sanden.

137. As a direct and proximate result of the Defendants' violations of Ark. Code Ann. §§4-88-107 *et seq.*, the Plaintiff has suffered damages, for which he is entitled to compensatory damages, equitable and declaratory relief, punitive damages, costs and reasonable attorneys' fees.

138. As a direct and proximate result of Defendants' conduct, the Plaintiff used Defendants' M2a Magnum™ Hip System and the Plaintiff suffered serious physical injury, harm, emotional distress, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

139. Defendants' actions and omissions as alleged in this Complaint demonstrate a flagrant disregard for human life, so as to warrant the imposition of punitive damages.

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

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

TWELFTH CAUSE OF ACTION
PUNITIVE DAMAGES
(Against All Defendants)

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

142. At all times material hereto, the 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 than the alternative hip arthroplasty systems on the market.

143. At all times material hereto, the Defendants attempted to misrepresent and did misrepresent facts concerning the safety of the subject product.

144. Defendants' misrepresentations included knowingly withholding material information from the medical community and the public, including the Plaintiff in the instant matter, concerning the safety and efficacy of the subject product.

145. At all times material hereto, the 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 implanted with the device with far greater frequency than safer alternative hip arthroplasty systems.

146. Notwithstanding the foregoing, the Defendants continued to aggressively market the subject product without disclosing the aforesaid side effects when there were safer alternative methods.

147. The Defendants knew of the subject product's defective and unreasonably dangerous nature, as set forth herein, but continued to design, develop, manufacture, market, distribute and sell it so as to maximize sales and profits at the expense of the health and safety of the public, including the Plaintiff herein, in conscious and/or negligent disregard of the foreseeable harm.

148. The Defendants' intentional and/or reckless, fraudulent and malicious failure to disclose information deprived the Plaintiff and his surgeon of necessary information to enable them to weigh the true risks of using the subject product against its benefits.

149. As a direct and proximate result of the Defendants' conscious and deliberate disregard for the rights and safety of consumers such as the Plaintiff, the Plaintiff suffered severe and permanent physical injuries as set forth above.

150. The aforesaid conduct of Defendants was committed with knowing, conscious, and deliberate disregard for the rights and safety of consumers, including the Plaintiff herein thereby entitling the Plaintiff to punitive damages in an amount appropriate to punish the Defendants and deter them from similar conduct in the future.

151. The Plaintiff seeks actual and punitive damages from the Defendants as alleged herein.

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

PRAYER FOR RELIEF

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

a) That process issue according to law;

b) That Defendants be duly served and cited to appear and answer herein, and that after due proceedings are had, that there be judgment in favor of Plaintiff and against Defendants for the damages set forth below, along with court costs, pre-judgment and post-judgment interest;

1. pain and suffering (past and future);
2. wage loss (past and future);
3. loss of earnings and loss of earning capacity;
4. medical expenses (past and future);
5. loss of enjoyment of life (past and future);
6. mental anguish and distress (past and future);
7. disfigurement (past and future);
8. physical impairment (past and future);
9. attorney's fees;
10. costs and interest as provided by law;
11. punitive and/or exemplary damages for the wanton, willful, fraudulent, reckless acts of Defendants who demonstrated a complete disregard and reckless indifference for the safety and welfare of the general public and the Plaintiff in an amount sufficient to punish Defendants and deter future similar conduct;
12. loss of consortium; and
13. such other and further relief as this Court deems just and proper.

DEMAND FOR JURY TRIAL

The Plaintiff hereby demands a trial by jury on all counts and as to all issues.

DATED: June 3, 2016

Respectfully submitted,

GARY SANDEN AND SUSAN SANDEN, PLAINTIFFS

Paul J. James (Ark. Bar No. 83091)
JAMES & CARTER, PLC
500 Broadway, Suite 400
Little Rock, Arkansas 72201
Telephone: (501) 372-1414
Facsimile: (501) 372-1659
pjj@jamescarterlaw.com
Attorney for Plaintiff