IN THE CIRCUIT COURT OF THE 17TH JUDICIAL CIRCUIT, IN AND FOR BROWARD COUNTY, FLORIDA

MICHELLE HAGEN,

Plaintiff,

v.

BIOMET INC., BIOMET ORTHOPEDICS, LLC, BIOMET MANUFACTURING CORP., and BIOMET U.S. RECONSTRUCTION, LLC,

Defendants.

CASE NO:

COMPLAINT

Plaintiff, MICHELLE HAGEN, by and through undersigned counsel, hereby sues BIOMET, INC., BIOMET ORTHOPEDICS, LLC, BIOMET MANUFACTURING CORP., and BIOMET U.S. RECONSTRUCTION, LLC, and alleges as follows:

1. This is a product liability action for damages relating to Defendants' development, design, testing, assembling, manufacturing, packaging, labeling, preparing, distribution, marketing, supplying, and/or selling the defective product sold under the name "The M2a Magnum Hip System," components intended to function as a prosthetic hip replacement system.

JURISDICTION, PARTIES, AND VENUE

2. This is an action for damages in excess of the sum of Fifteen Thousand Dollars ($15,000.00), exclusive of interest and costs.
3. At all times material hereto, the Plaintiff MICHELLE HAGEN ("HAGEN") was and is a resident of Florida and Broward County.

4. The relevant injuries alleged herein occurred in Broward County, Florida, and therefore venue is proper in Broward County.
5. Defendant, BIOMET, INC. (hereinafter "BIOMET") is an Indiana Corporation with its principal place of business in Indiana. At all times material hereto, this Defendant was in the business of designing, manufacturing, promoting, marketing, developing, supplying, labeling, testing, selling and/or distributing of orthopedic implants including M2a Magnum hip implants and related components in the State of Florida and Broward County.
6. Defendant, BIOMET ORTHOPEDICS, LLC is a wholly owned subsidiary of Defendant, BIOMET, INC., and an Indiana Limited Liability Company with its principal place of business in Indiana. At all times material hereto, this Defendant was in the business of designing, manufacturing, promoting, marketing, developing, supplying, labeling, testing, selling and/or distributing of orthopedic implants including M2a Magnum hip implants and related components in the State of Florida and Broward County.
7. Defendant, BIOMET MANUFACTURING CORP. is a wholly owned subsidiary of Defendant, BIOMET, INC., and an Indiana Corporation with its principle place of business in Indiana. At all times material hereto, this Defendant was in the business of designing, manufacturing, promoting, marketing, developing, supplying, labeling, testing, selling and/or distributing of orthopedic implants including M2a Magnum hip implants and related components in the State of Florida and Broward County.
8. Defendant, BIOMET U.S. RECONSTRUCTION, LLC is a wholly owned subsidiary of Defendant, BIOMET, INC., and an Indiana Limited Liability Company with its principle place of business in Indiana. At all times material hereto, this Defendant was in the

business of designing, manufacturing, promoting, marketing, developing, supplying, labeling, testing, selling and/or distributing of orthopedic implants including M2a Magnum hip implants and related components in the State of Florida and Broward County.

9. Defendant BIOMET is subject to jurisdiction within the State of Florida where:
   a. BIOMET is engaged in substantial and not isolated business activity within the State of Florida and Broward County;
   b. BIOMET'S products, including the subject hip implants, which it designed and manufactured, were placed in the stream of commerce by BIOMET and were used within the State of Florida in the ordinary course of commerce, trade or use;
   c. The subject hip implants caused injury to persons, including Plaintiffs, within the State of Florida as a result of the tortious and wrongful acts and omissions of BIOMET as set for more fully herein; and
   d. Defendant BIOMET maintains an office or agency within the State of Florida.
10. At all times material hereto, Defendant BIOMET designed, developed, tested, assembled, manufactured, packaged, labeled, prepared, distributed, marketed, supplied, and/or sold the subject hip implant components under the name "The M2a Magnum Hip System," (hereinafter "the Device") either directly or indirectly, to members of the general public, including Plaintiff's physician and Plaintiff, within the State of Florida.
11. At all times material hereto Defendants BIOMET ORTHOPEDICS, LLC, BIOMET MANUFACTURING CORP., and BIOMET U.S. RECONSTRUCTION, LLC, were engaged in distributing, retailing, selling, reselling, marketing, detailing and supplying BIOMET Products, including the subject hip implants, in South Florida and Broward

County indirectly or directly to the public, including Plaintiff's physician and Plaintiff, MICHELLE HAGEN.

12. BIOMET, BIOMET ORTHOPEDICS, LLC, BIOMET MANUFACTURING CORP., and BIOMET U.S. RECONSTRUCTION, LLC, are collectively referred to herein as "Defendants."

THE BIOMET M2a MAGNUM HIP SYSTEM

13. The Device was developed by Defendants in order to reconstruct human hip joints due to conditions such as osteoarthritis, rheumatoid arthritis, avascular necrosis (AVN), functional deformity or femoral fracture. The hip joint connects the femur bone of a patient's leg to the patient's pelvis. The hip joint is a ball that fits in the socket. The socket portion of the hip is called the acetabulum. The femoral head at the top of the femur bone rotates within the curved surface of the acetabulum. In a healthy hip this is cushioned and lubricated by cartilage and fluids.

14. A total hip replacement implant device typically consists of four separate components: a femoral stem, a femoral head (or ball), a liner, and an acetabular shell (socket). Usually these components are made of metal and plastic. The metal-on-metal Device at issue includes a metal femoral head and a metal acetabular cup. Both these pieces of metal are made of a cobalt-chromium metal combination. Once implanted, these components are supposed to last for 15 or more years before requiring replacement.

15. The design of the Device was not sufficiently tested by Defendants, and it was never approved by the FDA as being safe or effective for the products' intended purpose. The Device was not subject to the rigorous premarket approval (PMA) testing and approval

pursuant to 21 U.S.C. § 360(e). Instead, Defendants obtained approval from the FDA to market the Device in the United States through the 510(k) premarket notification process pursuant to 21 U.S.C. § 360(k) based on Defendants' assertions that it was substantially equivalent to other metal-on-metal hip replacement systems already available on the market. The metal-on-metal Device that is the subject of this lawsuit is a Class III medical device; however, it received clearance through the 510(k) process which is generally reserved for Class II devices.

16. Defendants applied for the premarket clearance of the M2a Acetabular System on March 30, 2001 (K011110), introducing a one-piece cobalt chromium (CoCr) acetabular component with no liner. The substantial equivalence was based on earlier M2a systems, the Depuy Pinnacle Metal-on-Metal Acetabular System (currently the subject of similar ongoing litigation in the MDL in the Northern District of Texas), and the McKee Farrar, a device known for early failures due to acetabular loosening.

17. On July 28, 2004, Defendants applied for the market clearance of the M2a Magnum System (K042037), the Device that is the subject of the Complaint here. This system based its substantial equivalence on the earlier M2a Acetabular System as well as two Wright Medical Technology one-piece CoCr acetabular shells. The 510K states that mechanical testing was performed to establish substantial equivalence; however, no clinical testing was undertaken. Clearance was granted on October 1, 2004.

18. Defendants aggressively marketed the Device as part of a family of metal-on-metal hip systems, claiming that the device:

    a. had a low wear, long term, durable articulation, making it the right choice for active patients;

b. had a metal-on-metal bearing with low wear debris generation;

c. had solved and eliminated the defects and negative outcomes experienced with so-called first generation metal-on-metal implants, including aseptic loosening and metallosis (high metal levels in the blood);

d. was safe and efficacious because first generation metal-on-metal implants retrieved showed minimal wear and benign tissue reactions compared to polyethylene retrievals;

e. was safe and efficacious because technological advancements had led to second generation metal-on-metal designs that solved the problems previously associated with short-term failures of first generation metal-on-metal hip prosthetics;

f. was safe and efficacious because "Metal-on-Metal has Changed!," has "Minimal Wear!" and "Clinically Proven Results;"

g. was safe and efficacious because precise M2a tolerancing and 100% quality control enabled low wear rates and fluid film lubrication;

h. "The M2a-Magnum Large Metal Articulation System offers optimal joint mechanic restoration and ultra-low wear rates in vivo;" and

i. "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."

19. On numerous occasions, Defendants or their representatives met with orthopedic surgeons in cities around the nation, including Florida and Broward County. During these meetings, Defendants assured the orthopedic surgeons, including Plaintiff's surgeon, that the Device was safe, was the best product on the market, had an excellent track record,

and a low and acceptable failure rate. Even as complaints and complications with the Device cropped up, Defendants continued to market the Device during their meetings with orthopedic surgeons, declining to reveal the complications.

COMPLICATIONS AND PROBLEMS WITH THE DEVICE

20. It was not long after the launch of the Device that reports of problems and failures would flood into the Defendants. These failures necessitated painful and risky revision surgeries to remove and replace the failed components.

21. Defendants were well aware that the statements in their marketing literature were false, deceptive and misleading because, prior to the clearance of the Device by the FDA for sale in the United States, studies and articles published and available to Defendants established:

    a. that extensive necrosis of periprosthetic tissue due to metal toxicity associated with cobalt-chromium-alloy hip prostheses resulting in premature failure was a risk of such hip replacements;

    b. that excessive wear leading to bone and soft tissue discoloration resulting in premature failure was a risk of cobalt-chromium-alloy hip replacements;

    c. that cobalt-chromium-alloy hip replacements were associated with significant increases in particulate and ionic metal generation compared to polyethylene on metal bearings, that such debris led to significant increases in serum and urine metal concentrations and that measurement of such concentrations might be useful markers for the tribologic performance of metal-on-metal bearings;

d. that patients with cobalt-chromium-alloy metal-on-metal implants could have cobalt and chromium blood levels 50 to 100 times greater than controls, that metal wear debris causes inflammatory, toxic, or allergic local tissue reactions which may lead to implant loosening and that complications from metal wear products were the subject of concern; and

e. that metal particulate debris had enormous specific surface area available for electrochemical interaction with the surrounding tissue fluids.

22. The Device fits a metal femoral head directly into a one-piece metal acetabular cup, forcing metal-on-metal articulation with the full weight and pressure of the human body. This causes metal ion debris to shave off via mechanical wear, surface tension, or both. Inside the hip joint, these metals often cause fluids to accumulate and soft tissues and bone to die. If the metal fragments travel through the bloodstream, the patient can suffer symptoms such as: fatigue, blurred vision, headaches, dizziness, and other chronic ailments.

23. Long before the Plaintiff was implanted with the Device, Defendants were aware and on notice of the complications and issues surrounding usage of the Device. This is evidenced in available medical literature as well as Adverse Event Reports that are submitted to the FDA.

24. Despite the growing concerns over the Device, Defendants continued the aggressive marketing and sales campaign. Defendants have displayed callous indifference to the patients forced to suffer serious injury, metallosis, pseudotumors, biologic toxicity, and revision surgery as a result of the implantation of the Device.

25. On May 6, 2011, as a result of growing concern over the adverse effects of the metal-on-metal systems, and in particular the adverse effects associated with elevated levels of cobalt and chromium in the blood, the FDA ordered manufacturers of metal-on-metal hip implant systems to conduct post-market surveillance studies. Twenty-one manufacturers, including Defendants, have been ordered to submit research protocols to the FDA for studies relating to specific safety issues, such as loosening, adverse local tissue reactions and increased metal ions in the blood, related to the metal-on-metal devices and then provide the FDA with the study results for review and analysis.
26. In 2011, the Australian Orthopaedic Association published its annual report on data collected from the Australian National Joint Registry, which tracks surgical revisions of orthopedic devices in Australia (no such registry exists in the United States). The Report showed that the Device had a yearly cumulative revision rate of 7.2% after seven years, with a statistical range of 5.3% and 9.7%.
27. In a systematic review of clinical trials, observational studies, and registries conducted by the FDA and published in the British Medical Journal on November 29, 2011, it was found that metal-on-metal hip implants are no more effective than traditional polyethylene-lined implants, and increase the risk of revision surgery.
28. Despite the numerous problems and issues with the Device, Defendants continue to sell and market the Device. This is a clear choice of profitability over concern for patient safety. Even with the onset of these lawsuits, the Defendants continue to hold the Device out as a premium product with no serious complications.

PLAINTIFF'S USE OF THE PRODUCT

29. On May 4, 2009, HAGEN underwent both left and right total hip arthroplasty. This was performed by W. Vincent Burke, MD, at Broward General Medical Center.

30. She was implanted with the following products, all of which were manufactured, marketed, tested, and sold by the Defendants :

LEFT HIP	RIGHT HIP
M2a Magnum PF Cup Ref # US157846 Lot# 593740	M2a Magnum PF Cup Ref# US157846 Lot# 330100
Taperloc Microplasty Femoral Ref# 15-103201 Lot# 820290	Taperloc Microplasty Femoral Ref# 15-103201 Lot# 450930
Selex M2a Magnum Modular Head Ref# S001140 Lot# 693420	Selex M2a Magnum Modular Head Ref# S001140 Lot# 899220

31. After the implantation, HAGEN began a course of physical therapy which resulted in improvement for several months. She eventually returned to work and proceeded to resume a normal lifestyle.

32. However, in late 2012, HAGEN began to develop serious and aching pain in her right hip. After several months, this pain increased bilaterally. X-rays taken by Dr. Burke showed osteolysis (bone breakdown) bilaterally.

33. HAGEN'S symptoms continued to worsen as she developed nausea, weakness, lightheadedness, fatigue, queasiness, floaters in her vision, and tremors in her legs. A test for elevated cobalt and chromium levels came back positive.

34. On July 30, 2013, HAGEN underwent a revision surgery of her right hip with Michaela Schneider-Bauer, MD, at University of Miami Hospital. On September 23, 2013, she

underwent a revision surgery of her left hip with Dr. Schneider-Bauer at UMH. These risky and dangerous revision surgeries were necessitated by the damage and pain she suffered as a result of being implanted with the Defendants' Device.

35. Revision surgeries place Plaintiffs at a greater risk of future harm and hip dislocation compared with original hip arthroplasties. These surgeries are more difficult and take longer amounts of time to recover from.

COUNT I – STRICT LIABILITY – DEFECTIVE DESIGN

36. Plaintiff adopts and incorporates by reference the allegations in Paragraphs 1 through 35 as though fully set forth herein.
37. At all times material hereto, Defendants engaged in the business of designing, developing, manufacturing, testing, packaging, labeling, marketing, selling, and/or distributing the Device that is the subject of this Complaint.
38. At all times material hereto, the Device that was designed, developed, manufactured, tested, packaged, labeled, marketed, sold, and/or distributed into the stream of commerce by Defendants was expected to reach, and did reach, prescribing physicians and consumers, including HAGEN and her physician, without substantial change in the condition in which it was sold.
39. The Device implanted into Plaintiff is defective in design or formulation in that it is not reasonably fit, suitable, or safe for its intended purpose and/or its foreseeable risks exceed the benefits associated with its design. The Device is defective in design in that it lacks efficacy, poses a greater likelihood of injury, and is more dangerous than other available devices indicated for the same conditions and uses.

40. Plaintiff was unaware of the significant hazards and defects in the Device. The Device was unreasonably dangerous and/or not reasonably safe in that it was more dangerous than would be reasonably contemplated by the ordinary patient or physician. When the Device was implanted in Plaintiff, it was being utilized in a manner that was intended by Defendants. At the time Plaintiff had the Device implanted it was represented to be safe and free from latent defects.

41. Defendants knew or should have known of the danger associated with the use of the Device, as well as the defective nature of the Device, but has continued to design, manufacture, sell, distribute, market, promote and/or supply the Device so as to maximize sales and profits at the expense of the public health and safety, in conscious disregard of the foreseeable harm caused by the Device.

42. Defendants are strictly liable to Plaintiff for designing, developing, manufacturing, testing, packaging, labeling, marketing, selling, and/or distributing into the stream of commerce Devices, which were unreasonably dangerous for its foreseeable uses because of its design defects.

43. As a direct and proximate result of the defective design of the Device, the Plaintiff, MICHELLE HAGEN, suffered the failure of her hip replacements and needed additional revision surgeries, from which she now suffers further complications.

44. As a further proximate result of the defective design of the Device, Plaintiff suffered debilitating physical pain and mental suffering; incurred substantial hospital, surgical, medical, nursing, rehabilitative, pharmaceutical, and other expenses; suffered emotional distress, anxiety, depression, and disability; and loss of the enjoyment of life, injuries all of which are permanent or continuing in nature.

WHEREFORE, the Plaintiff, MICHELLE HAGEN, demands judgment against Defendants, BIOMET, INC., BIOMET ORTHOPEDICS, LLC, MANUFACTURING CORP., and BIOMET U.S. RECONSTRUCTION, LLC, for compensatory damages for an amount in excess of $15,000.00, together with costs.

COUNT II – STRICT LIABILITY – MANUFACTURING DEFECT

45. Plaintiff adopts and incorporates by reference the allegations in Paragraphs 1 through 35 as though fully set forth herein.
46. At all times material hereto, Defendants engaged in the business of designing, developing, manufacturing, testing, packaging, labeling, marketing, selling, and/or distributing the Device that is the subject of this Complaint.
47. The Device was intended for use in hip replacement procedures for consumers, and Plaintiff was a consumer who relied upon the manufacturing safety of the Device.
48. At all times material hereto, the Device that was designed, developed, manufactured, tested, packaged, labeled, marketed, sold, and/or distributed into the stream of commerce by Defendants was expected to reach, and did reach, prescribing physicians and consumers, including HAGEN and her physician, without substantial change in the condition in which it was sold.
49. The Device is defective in manufacture in that it deviated from product specifications, posing a serious risk that it could fail early in patients therefore giving rise to physical injury, pain and suffering.
50. Plaintiff was unaware of the significant hazards and manufacturing defects in the Device. The Device was unreasonably dangerous and/or not reasonably safe in that it was more

dangerous than would be reasonably contemplated by the ordinary patient or physician. When the Device was implanted in Plaintiff, it was being utilized in a manner that was intended by Defendants. At the time Plaintiff had the Device implanted it was represented to be safe and free from manufacturing defects. Had the Plaintiff known of such manufacturing defects, she would not have consented to the implantation.

51. As a direct and proximate result of the manufacturing defect of the Device, the Plaintiff, MICHELLE HAGEN, suffered the failure of her hip replacements and needed additional revision surgeries, from which she now suffers further complications.

52. As a further proximate result of the manufacturing defect of the Device, Plaintiff suffered debilitating physical pain and mental suffering; incurred substantial hospital, surgical, medical, nursing, rehabilitative, pharmaceutical, and other expenses; suffered emotional distress, anxiety, depression, and disability; and loss of the enjoyment of life, injuries all of which are permanent or continuing in nature.

WHEREFORE, the Plaintiff, MICHELLE HAGEN, demands judgment against Defendants, BIOMET, INC., BIOMET ORTHOPEDICS, LLC, MANUFACTURING CORP., and BIOMET U.S. RECONSTRUCTION, LLC, for compensatory damages for an amount in excess of $15,000.00, together with costs.

COUNT III – STRICT LIABILITY – FAILURE TO WARN

53. Plaintiff adopts and incorporates by reference the allegations in Paragraphs 1 through 35 as though fully set forth herein.

54. At all times material hereto, Defendants engaged in the business of designing, developing, manufacturing, testing, packaging, labeling, marketing, selling, and/or

distributing the Device that is the subject of this Complaint, and therefore had a duty to warn of risks associated with the Device.

55. The Device implanted in Plaintiff is defective because Defendants failed to adequately warn health care professionals and the public, including Plaintiff and her physician, of the true risks of the Device, including that the Device was prone to excessive metal wear, that the metal wear particles could cause inflammation and tissue and bone damage and that the acetabular cup could loosen and separate from the hip socket, causing severe pain and injury, and requiring further treatment, including revision surgery and/or replacement, and that the Device has not been tested clinically.

56. The Device implanted in Plaintiff is defective because Defendants failed to provide timely and reasonable warnings regarding the safety and efficacy of the Device. Had they done so, proper warnings would have been heeded and no health care professional, including Plaintiff's physician, would have used the Device.

57. The Defendants, as manufacturers of the Device, are held to the level of knowledge of experts in the field of that type of prosthetic device, and had a duty to warn their consumers and prescribing physicians of the dangers associated with the device and failed to do so.

58. The Device was defective because Defendants' misleading marketing campaign and materials contradicted and down-played any warnings that did accompany the Device.

59. Defendants failed to provide timely and reasonable instructions and training concerning safe and effective use of the Biomet device to either Plaintiff or her physician. At the time Plaintiff was implanted with the Device, neither she nor her physician had

substantially the same knowledge as the Defendants about the high risks of failure of the Device because the Defendants failed to provide adequate warnings to Plaintiff.

60. As a direct and proximate result of the Defendant's failure to warn of the dangers inherent to the Device, the Plaintiff, MICHELLE HAGEN, suffered the failure of her hip replacements and needed additional revision surgeries, from which she now suffers further complications.

61. As a further proximate result of the failure to warn of the danger the Device posed, Plaintiff suffered debilitating physical pain and mental suffering; incurred substantial hospital, surgical, medical, nursing, rehabilitative, pharmaceutical, and other expenses; suffered emotional distress, anxiety, depression, and disability; and loss of the enjoyment of life, injuries all of which are permanent or continuing in nature.

WHEREFORE, the Plaintiff, MICHELLE HAGEN, demands judgment against Defendants, BIOMET, INC., BIOMET ORTHOPEDICS, LLC, MANUFACTURING CORP., and BIOMET U.S. RECONSTRUCTION, LLC, for compensatory damages for an amount in excess of $15,000.00, together with costs.

DEMAND FOR JURY TRIAL

The Plaintiff, MICHELLE HAGEN, demands trial by jury on all issues so triable by jury as a matter of law.

DATED this 11th day of April, 2014.

FREEDLAND HARWIN VALORI, P.L.
110 SE 6th Street, Suite 2300
Fort Lauderdale, FL 33301
Tel: (954) 467-6400
Fax: (954) 670-2530

By: /s/ Raymond Valori

RAYMOND VALORI
Fla. Bar #: 33200
Ray@westonlawyers.com
AARON ROTHENBERG
Fla. Bar #: 99634
Aaron@westonlawyers.com