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County of Los Angeles

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**SUPERIOR COURT OF THE STATE OF CALIFORNIA  
FOR THE COUNTY OF LOS ANGELES**

GARY LANGFORD and LAURA LANGFORD,	) CASE NO.: <b>19STCV13207</b>
Plaintiffs,	) JUDGE:
v.	) DEPT.:
BIOMET, INC.; BIOMET ORTHOPEDICS, LLC;	)
BIOMET U.S. RECONSTRUCTION, LLC;	) CIVIL COMPLAINT FOR
BIOMET MANUFACTURING, LLC; ZIMMER	) DAMAGES; DEMAND FOR JURY
BIOMET HOLDINGS, INC; CHRISTOPHER	) TRIAL.
ROBBINS; COMPREHENSIVE SURGICAL	)
SERVICES, INC.; ZIMMER BIOMET	) 1. FRAUD
SOUTHERN CALIFORNIA; JOHN CUCKLER,	) 2. STRICT LIABILITY - FAILURE TO
M.D.; and ALABAMA MEDICAL	) WARN

**COMPLAINT AND DEMAND FOR JURY TRIAL**

CONSULTANTS, INC.;;  
and DOES 1 THROUGH 25, inclusive;

Defendants.

) 3. STRICT LIABILITY – DESIGN  
) DEFECT AND/OR  
) MANUFACTURING DEFECT  
) 4. BREACH OF IMPLIED  
) WARRANTY  
) 5. BREACH OF EXPRESS  
) WARRANTY  
) 6. NEGLIGENCE  
) 7. MISREPRESENTATION  
) 8. LOSS OF CONSORTIUM  
) 9. PUNITIVE DAMAGES  
)

COME NOW Plaintiffs, GARY LANGFORD and LAURA LANGFORD;  
("Plaintiffs"), and bring suit against Defendants BIOMET, INC., BIOMET ORTHOPEDICS,  
LLC, BIOMET U.S. RECONSTRUCTION, LLC, BIOMET MANUFACTURING, LLC and  
ZIMMER BIOMET HOLDINGS, INC (hereafter collectively referred to as "Biomet" or  
"Biomet Defendants") and CHRISTOPHER ROBBINS, COMPREHENSIVE SURGICAL  
SERVICES, INC. and ZIMMER BIOMET SOUTHERN CALIFORNIA (hereafter collectively  
referred to as "Distributors" or "Distributor Defendants") and JOHN CUCKLER, M.D.  
(hereafter "Cuckler") and ALABAMA MEDICAL CONSULTANTS, INC. (hereafter  
collectively referred to as "Cuckler Defendants"), and DOES 1 through 25, inclusive, and state  
as follows:

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## **PARTIES, VENUE AND JURISDICTION**

1  
2 1. This is a lawsuit regarding a defective metal on metal hip replacement system  
3 implanted in Plaintiff GARY LANGFORD, which was designed, developed, distributed,  
4 manufactured, labelled, promoted, marketed, sold, and supplied by Defendants.  
5

6 2. The particular hip replacement system at issue in this case is the "Biomet M2a  
7 Magnum Metal on Metal Hip Replacement System" (hereafter referred to as the "Magnum").  
8 Biomet's M2a hip replacement system line consisted of several substantially similar metal on  
9 metal hip replacement systems, including the M2a "38", M2a "Magnum", and M2a "ReCap."  
10

11 3. Plaintiff GARY LANGFORD was implanted with the Biomet Magnum hip  
12 replacement system in the State of California and is a resident of the State of California.  
13

14 4. At all times relevant to this Complaint, Defendant BIOMET, INC. was and is an  
15 Indiana-based multinational corporation, with its corporate headquarters in Warsaw, Indiana,  
16 and facilities world-wide. Further, at all times relevant to this Complaint, Defendants BIOMET  
17 ORTHOPEDICS, LLC; BIOMET U.S. RECONSTRUCTION, LLC; and BIOMET  
18 MANUFACTURING, LLC each are and have been wholly owned subsidiaries of Defendant  
19 BIOMET, INC. In June of 2015, BIOMET, INC. was purchased by ZIMMER BIOMET  
20 HOLDINGS, INC, also having its world-wide corporate headquarters in Warsaw, Indiana.  
21 From June of 2015 to present, all activities of the subsidiary companies relating to the product  
22 at issue in this case were directed and controlled by ZIMMER BIOMET HOLDINGS, INC.  
23 Hereafter, these defendants are referred to collectively as the "Biomet Defendants" or simply  
24 "Biomet."  
25  
26  
27

28 5. At all times relevant to this Complaint, CHRISTOPHER ROBBINS was a  
29 citizen of the State of California, and currently resides at 228 McEwen Rd Waterford, CA  
30

1 95386.

2 6. At all times relevant to this Complaint, CHRISTOPHER ROBBINS, operated  
3 his distributorship through his corporation, COMPREHENSIVE SURGICAL SERVICES,  
4 INC.  
5

6 7. COMPREHENSIVE SURGICAL SERVICES, INC., is a registered Nevada  
7 corporation with its principal place of business located in the State of California at 1521 N.  
8 Carpenter, Modesto, CA 95351.  
9

10 8. Upon information and belief, from approximately 2005 to 2013,  
11 CHRISTOPHER ROBBINS, operating through his distributorship, had an agreement with the  
12 Biomet Defendants to serve as their exclusive distributor for hip replacement systems in large  
13 parts of California.  
14

15 9. Pursuant to industry practice and contractual agreement, the exclusive distributor  
16 for the Biomet Defendants was responsible for educating orthopedic surgeons about Biomet hip  
17 replacement systems and the advantages, benefits, indications, templating, surgical  
18 implantation, follow-up care, servicing, and addressing any post-surgical questions or concerns  
19 regarding those Biomet hip replacement systems.  
20

21 10. CHRISTOPHER ROBBINS, operating through his distributorship  
22 COMPREHENSIVE SURGICAL SERVICES, INC., was responsible for promoting the  
23 Magnum hip replacement to Plaintiff's surgeon, distributed the actual Magnum hip replacement  
24 system that was implanted in Plaintiff's body, had sales representatives present at the surgery to  
25 implant the Magnum hip replacement into Plaintiff's body, and serviced the Magnum hip  
26 replacement system implanted in Plaintiff's body.  
27  
28  
29  
30

1           11.     On information and belief, ZIMMER BIOMET SOUTHERN CALIFORNIA is  
2 a citizen of the State of California, with offices at 1647 Yeager Avenue La Verne, CA 91750  
3 and 1623 Mission Drive Suite 11 Solvang, CA 93463. ZIMMER BIOMET SOUTHERN  
4 CALIFORNIA is a subsidiary of Zimmer US, Inc., which is a subsidiary of ZIMMER  
5 BIOMET HOLDINGS, INC.  
6

7           12.     On information and belief, in June of 2015, ZIMMER BIOMET SOUTHERN  
8 CALIFORNIA, became responsible for servicing the surgeons responsible for implanting the  
9 Magnum hip replacement system in Plaintiff, the surgeons responsible for follow-up care of  
10 Plaintiff, and thus responsible for servicing the Magnum hip replacement system implanted in  
11 Plaintiff.  
12

13           13.     Hereafter, these defendants: CHRISTOPHER ROBBINS, COMPREHENSIVE  
14 SURGICAL SERVICES, INC. and ZIMMER BIOMET SOUTHERN CALIFORNIA, will be  
15 referred to collectively as "Distributors."  
16

17           14.     The information that Distributors provided to Plaintiffs, Plaintiffs' implanting  
18 surgeon and citizens of the State of California about Biomet hip replacement systems far  
19 exceeded the information provided on Magnum packaging or labeling.  
20

21           15.     Distributors' sales representatives selected the components and tools to have  
22 present in the operating room when GARY LANGFORD was surgically implanted with the  
23 Biomet Magnum.  
24

25           16.     At all times relevant to this Complaint, Plaintiff's surgeon relied upon  
26 information provided by Distributors' sales representatives in selecting the Magnum hip  
27 replacement for implantation into Plaintiff's body.  
28  
29  
30



1           17.     Distributors profited from the promotion, sale, and servicing of the Magnum hip  
2 replacement system at issue in the instant case at the time they were implanted in the body of  
3 GARY LANGFORD.

4           18.     Following the Magnum hip replacement being implanted in the body of GARY  
5 LANGFORD, Distributors continued to profit from the servicing of and the addressing of any  
6 questions or concerns regarding Biomet hip replacement systems.

7           19.     Defendant JOHN CUCKLER, M.D. is a citizen and resident of the State of  
8 Florida. Defendant JOHN CUCKLER, M.D. has ongoing contact with the State of California  
9 through years of presentations, including presentations related to the device and issues involved  
10 in this matter.

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

14           21.     Plaintiffs are ignorant of the true names and capacities of the Defendants sued  
15 herein as DOES 1 to 25, and therefore sue these Defendants by such fictitious names. Plaintiffs  
16 will amend this Complaint to allege the true names and capacities when that information is  
17 ascertained. Plaintiffs are informed and believe and, based on that information and belief, allege  
18 that each such fictitiously named Defendant is legally responsible in some manner for the  
19 occurrences alleged herein, and that the damages suffered from Plaintiffs' injuries were  
20 proximately caused by each such Defendant's actions.

21           22.     Plaintiff is informed and believes and, based on this information and belief,  
22 alleges that Defendants, and each of them, were the agents, servants and employees of their Co-  
23 Defendants, and in doing the things herein alleged were acting within the course, scope, purpose,  
24  
25  
26  
27  
28  
29  
30

1 and authority of such agency and employment with the full knowledge, permission and consent  
2 of each of their co-Defendants.

3 23. The Biomet Defendants and Distributors are severally and separately liable to the  
4 Plaintiffs.

5  
6 24. Plaintiff's ability to investigate and uncover Defendants' wrongful conduct such  
7 that Plaintiff could discover a potential cause of action against Defendants was delayed on  
8 account of Defendants' fraudulent concealment.

9  
10 25. Jurisdiction is proper in the courts of the State of California because  
11 CHRISTOPHER ROBBINS and ZIMMER BIOMET SOUTHERN CALIFORNIA are citizens  
12 of the State of California and Plaintiff's injury and implantation with the Biomet Magnum hip  
13 replacement system occurred in the State of California.

14  
15 26. Venue is proper in the Superior Court of California in and for Los Angeles  
16 County because ZIMMER BIOMET SOUTHERN CALIFORNIA resides in Los Angeles  
17 County California (1647 Yeager Avenue La Verne, CA 91750). (CCP section 395).

18  
19 27. Suit is brought on behalf of the Plaintiffs for damages in excess of the minimum  
20 jurisdictional amount for unlimited jurisdiction courts.

## 21 **STATEMENT OF FACTS**

### 22 **A. The Biomet Magnum is different than the typical hip replacement**

23  
24 28. A hip replacement surgery replaces the natural head and socket of the hip joint  
25 with artificial components.

26  
27 29. The majority of hip replacements implanted world-wide over the past several  
28 decades have utilized a replacement hip joint consisting of a metal head making contact with an  
29 ultra-heavy duty plastic cup inside a metal shell.



1           30.     This typical hip replacement consisting of a metal-plastic interface has been  
2 refined to the point that ultra-heavy duty plastic hip replacements have a greater than 99.5  
3 percent success rate per year.

4           31.     The Biomet Magnum instead uses a metal replacement head interfacing directly  
5 with a metal shell; there is no plastic liner in the Magnum. Accordingly, this type of hip system  
6 is commonly referred to as a metal on metal hip replacement.  
7

8  
9           **B. Metal on metal hip replacements were tried decades ago, failed, and abandoned**

10          32.     In the 1960s and early 1970s, hip replacement manufacturers first began to  
11 market metal on metal hip replacements to surgeons.

12          33.     Unfortunately, these early metal on metal hip replacements experienced a high  
13 rate of heavy metal poisoning and failure.  
14

15          34.     When the metal shell and metal head of these implants rubbed together, they  
16 released toxic cobalt and chromium debris into the body.  
17

18          35.     The release of cobalt and chromium debris resulted in patients suffering heavy  
19 metal poisoning, causing tissue death and bone destruction.

20          36.     As a result, the medical community abandoned metal on metal hip replacements  
21 in the 1970s.  
22

23           **C. Biomet and Cuckler revived abandoned metal on metal hip replacements with the**  
24 **Magnum**

25  
26          37.     Despite the known prior failure of metal on metal hip replacements to perform  
27 as intended, Biomet, John Cuckler M.D. and Alabama Medical Consultants, Inc. began  
28 designing metal on metal hip replacements in the 1990s.  
29  
30

38. The Magnum hip replacement implanted in Plaintiff was created by Biomet, John Cuckler M.D. and Alabama Medical Consultants, Inc., and began being sold in the United States in 2004.

**D. Biomet And Cuckler Employed Loopholes to Avoid Testing Magnum**

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

40. To avoid comprehensive testing of the Magnum hip replacement, Biomet and Cuckler claimed to United States regulators that the Magnum should be “grandfathered-in” because it was substantially similar to hip replacements sold prior to May 28, 1976.<sup>1</sup>

41. This loophole required no clinical testing nor any testing, whatsoever, for safety or efficacy.

42. Despite their knowledge that early metal on metal hip replacements were a failure and resulted in heavy metal poisoning, Biomet and Cuckler conducted extremely limited testing of the Magnum before selling it for implantation into the bodies of patients.

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

44. Despite the aforementioned knowledge, Biomet knowingly and intentionally failed to conduct any clinical or laboratory tests relating to the health risks associated with metal on metal hip replacement heavy metal poisoning prior to launching the Magnum.

<sup>1</sup> See, [https://www.accessdata.fda.gov/cdrh\\_docs/pdf4/K043037.pdf](https://www.accessdata.fda.gov/cdrh_docs/pdf4/K043037.pdf) containing Biomet Manufacturing Corp.’s 510(k) Summary of Safety and Effectiveness (Last accessed Mar. 28, 2019).

**E. Defendants Fraudulently Misrepresented to The Public by Marketing The Magnum As Having "Low Wear"**

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

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

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

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

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

50. Biomet and Cuckler were fully aware that the Magnum produced more toxic wear than polyethylene implants, regardless of total weight comparisons.

51. Despite the aforementioned knowledge, Biomet and Cuckler knowingly and intentionally marketed the Magnum by claiming that it produced less wear than polyethylene (plastic) hip replacements. Furthermore, Biomet and Cuckler knowingly and intentionally

1 marketed the Magnum by falsely associating its deceptively marketed “low wear” properties with  
2 safety and efficacy.<sup>2 3</sup>

3 52. Defendants provided this false information about the Magnum having lower wear  
4 to Plaintiff’s orthopedic surgeon, Dr. Jonathan Fow, prior to implant Plaintiff’s Magnum hip.

5 53. Dr. Fow foreseeably, and as intended by Defendants, relied on this false  
6 information in deciding to use the Magnum Hip installed in Plaintiff.

7  
8 **F. Defendants Suppressed Reports of Problems with The Magnum And Deceived**  
9 **Surgeons into Believing That Concerns About Heavy Metal Poisoning Were**  
10 **False**

11 54. Defendants knowingly and intentionally spread false information claiming that  
12 decades of experience with previous metal on metal implants purportedly resulted in zero  
13 instances of heavy metal poisoning.<sup>4</sup>

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

16 56. This scheme included explicit training to Biomet’s sales representatives including  
17 defendant Distributors CHRISTOPHER ROBBINS himself, COMPREHENSIVE SURGICAL  
18 SERVICES, INC. and ZIMMER BIOMET SOUTHERN CALIFORNIA, and sales  
19 representatives at CHRISTOPHER ROBBINS, COMPREHENSIVE SURGICAL SERVICES  
20 INC., and ZIMMER BIOMET SOUTHERN CALIFORNIA, on how to deceptively convince  
21 surgeons that reports of heavy metal poisoning were fake, merely a theoretical concern, and/or a  
22  
23  
24  
25  
26

27 <sup>2</sup> See, [http://www.biomet.com/wps/wcm/connect/internet/ach6d5c6-c3e9-42e2-b3e6-83fd38a5670/Y-BMT-735\\_021502\\_K.pdf?MOD=AJPERES](http://www.biomet.com/wps/wcm/connect/internet/ach6d5c6-c3e9-42e2-b3e6-83fd38a5670/Y-BMT-735_021502_K.pdf?MOD=AJPERES), (Last accessed Mar. 28, 2019).

28 <sup>3</sup> See, <http://www.biomet.com/campaign/truAlternativeBearings/BO103400MagnumDesignRationale.pdf> (Last  
29 accessed Mar. 28, 2019).

30 <sup>4</sup> See <http://www.grossortho.com/images/stories/pdf/currenttopics/MetallionWhitePaper.pdf>. (Last accessed Mar.  
28, 2019).



1 scheme by competitors who do not sell metal on metal hip replacements to steal business.

2 57. The Biomet Defendants, due to their sales representatives' role in the sale of  
3 particular implant components to orthopedic surgeons, had and have notice of every surgery in  
4 which Biomet components were and are implanted. This includes surgeries in which Biomet  
5 components are used to replace failed Magnum implants. As a result, the Biomet Defendants  
6 possess a unique set of clinical information through which the success or failure of their implants  
7 can be analyzed.  
8

9  
10 58. Unfortunately, Biomet Defendants engage in a corporate practice of under  
11 reporting and failing to properly analyze clinical information in their possession regarding  
12 implants which they sell.  
13

14 59. In 2016 and 2018 this practice resulted in multiple "483" observations by the FDA  
15 regarding the Biomet Defendants' failure to properly handle complaint reports and failure to  
16 properly analyze clinical information regarding product failures.  
17

18 60. The Biomet Defendants also marketed their metal on metal hip replacements  
19 based upon what it claimed was a low "reported adverse event rate" of ".056". However, the  
20 Biomet Defendants were intentionally and knowingly failing to include large numbers of adverse  
21 events, especially those relating to heavy metal poisoning. Biomet was fully aware that this  
22 scheme artificially suppressed the "reported adverse event rate." Regardless, Biomet consistently  
23 used the figure in its marketing. Biomet was aware that this figure would be heavily relied upon  
24 by the medical community.  
25  
26

27 **G. Defendants Claimed That the Magnum Was A "Lifetime Hip" And Suitable for**  
28 **Use in Younger, More Active Patients**  
29  
30

1           61. Defendants claimed that without the plastic liner to wear out, the Biomet Magnum  
2 should last for a patient's lifetime.

3           62. Defendants claimed that the Biomet Magnum was suitable for implantation in  
4 younger, more active patients, and would last longer than most other similar products, including  
5 implants with plastic components.  
6

7           63. Defendants promoted the Magnum as a "lifetime hip."

8           64. This information was false.  
9

10          65. Prior to October 31, 2011, Defendants represented to Plaintiff's implanting  
11 surgeon, Dr. Fow, that the Magnum was suitable for implantation in younger and more active  
12 patients and would last longer than similar plastic implants.  
13

14          66. Dr. Fow relied on this false information in deciding to use the Magnum hip  
15 installed in Plaintiff on October 31, 2011.

16          67. At no time prior to the implant of the Magnum in Plaintiff's body, or any time  
17 thereafter, did Defendants warn Plaintiff or his implanting surgeon, Dr. Fow, that the hip implant  
18 could cause metallosis, tissue necrosis, bone necrosis, excessive wear and/or corrosion on the  
19 neck stem, dislocations, fractures of hardware, loose acetabular components, pseudotumors,  
20 ALVAL, ARMD and infection.  
21

#### 22           **H. Biomet Falsely Claimed It Conducted Extensive Testing of Magnum**

23           68. Despite the fact that Biomet never conducted any pre-market clinical testing of  
24 the Magnum implants at issue, Biomet claimed that the implants had "clinically proven results"  
25 immediately upon marketing.<sup>5</sup>  
26  
27  
28

29 <sup>5</sup> See, [http://www.biomet.com/wps/wcm/connect/internet/acb6d5c6-c3e2-42e2-b3e6-83d38a5677/Y-BMT-735\\_021502\\_K.pdf?MOD=AJPERES](http://www.biomet.com/wps/wcm/connect/internet/acb6d5c6-c3e2-42e2-b3e6-83d38a5677/Y-BMT-735_021502_K.pdf?MOD=AJPERES), (Last accessed March 20, 2019).  
30



69. Further, Biomet claimed that its Magnum system “offers optimal joint mechanic restoration and ultra-low-wear rates in vivo” citing to a 1996 article about previously abandoned types of metal on metal hip replacements.<sup>6</sup>

70. In a 2004 publication titled “Metal Ions – A Scientific Review,” Biomet falsely concludes that: “Extensive research and years of clinical trials have failed to prove any cause for concern associated with the ion levels exhibited from metal-on-metal implants.”<sup>7</sup>

71. In fact, in a heading on page 7 of the publication, Biomet goes so far as to claim that: “Cobalt and Chromium may be beneficial to the body as established by research and listed by the US government.”<sup>8</sup>

#### **I. Biomet And Cuckler Misrepresented About the Existence of Adverse Reactions to Heavy Metal Wear**

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

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

74. Biomet and Cuckler affirmatively chose to ignore the existence of such literature because they simply did not agree with the conclusions of such literature.

75. In conjunction with the promotion of the Magnum hip replacements, Cuckler gave speeches and published articles such as “The Rationale for Metal-on-Metal Total Hip

<sup>6</sup> See, <http://www.biomet.com/campaign/trueAlternativeBearings/BOI63400MagnumDesignRationale.pdf> (Last accessed March 20, 2019).

<sup>7</sup> See <http://www.grossortho.com/images/stories/pdf/currenttopics/MetalIonWhitePaper.pdf>. (Last accessed March 20, 2019).

<sup>8</sup> *Id.*

1 Arthroplasty” published in 2005, claiming that there were “no adverse physiologic effects” to  
2 metal on metal hip replacements.

3 76. Biomet extensively cited Cuckler’s statement in marketing for its Magnum  
4 products.<sup>9</sup>

5  
6 77. Biomet trained and encouraged its sales representatives, including sales  
7 representative CHRISTOPHER ROBBINS, and sales representatives of COMPREHENSIVE  
8 SURGICAL SERVICES, INC. and ZIMMER BIOMET SOUTHERN CALIFORNIA, to utilize  
9 its marketing material with orthopedic surgeons to convince them the Magnum was a safe  
10 product.  
11

12 78. Defendants intentionally misrepresented the existence of literature regarding  
13 adverse reactions to heavy metal wear in order to market and profit from the sale of Magnum  
14 implants.  
15

16  
17 **J. Cuckler Conducted Secret Magnum Marketing Campaign in Exchange for**  
18 **Millions of Dollars**

19 79. At the time that Cuckler published “The Rationale for Metal-on-Metal Total Hip  
20 Arthroplasty”, Biomet was paying Cuckler a percentage (royalty) of the sale price of Magnum  
21 metal on metal hip replacement systems sold in the United States. Cuckler failed to mention this  
22 in the article promoting such hip replacements.  
23

24 80. In 2008, pursuant to a Deferred Prosecution Agreement with the United States  
25 Department of Justice, Biomet made public that Cuckler received payments from Biomet of  
26  
27

28  
29 <sup>9</sup> See e.g., <http://www.biomet.com/campaign/trueAlternativeBearings/BO103400MagnumDesignRationale.pdf>  
30 (Last accessed March 20, 2019).

1 between \$3.0 and \$3.1 million dollars in just the previous year. Extrapolating the one year that  
2 Biomet's payments to Cuckler are publicly available leads to the conclusion that Cuckler received  
3 tens of millions of dollars from Biomet.  
4

5 **K. Thousands of Biomet Magnum metal on metal hip replacement systems are**  
6 **presently implanted in the bodies of California citizens**

7 81. Defendants' promotion of the Magnum hip replacement was extremely  
8 successful.  
9

10 82. Upon information and belief, in the State of California alone, thousands of  
11 Biomet metal on metal hip replacements were sold by Defendants and remain surgically  
12 implanted in the bodies of patients.  
13

14 **L. Defendants continue to claim that the Magnum is safe and successful**  
15

16 83. Defendants sold the Magnum metal on metal hip replacement for implantation  
17 into the bodies of patients up to the year 2014.  
18

19 84. Defendants ceased selling Biomet Magnum metal on metal hip replacement in  
20 2014, claiming that the decision to cease selling was unrelated to reports of heavy metal  
21 poisoning and tissue death caused by the Magnum received by Defendants from around the  
22 world.  
23

24 85. However, Defendants have continued to reassure California physicians and the  
25 public that the heavy metal poisoning seen with other metal on metal hip replacements is not an  
26 issue with the Magnum.  
27

28 86. To this day, Defendants continue to claim to physicians and the public that the  
29 Magnum is a safe and successful product.  
30

1       **M. In 2010, Johnson & Johnson voluntarily recalled their version of the Magnum**

2           87.     At approximately the same time as Defendants began selling the Magnum,  
3 Johnson & Johnson began selling the DePuy ASR.  
4

5           88.     The Biomet Magnum was very similar to the ASR in its primary design features.

6           89.     Like the Magnum, the ASR was a monoblock metal on metal hip replacement  
7 system with its cobalt chromium alloy head articulating against its cobalt chromium alloy shell.  
8

9           90.     In the summer of 2010, in response to "higher than expected revision rates,"  
10 Johnson & Johnson conducted a world-wide recall of the ASR hip replacement.

11           91.     Johnson & Johnson advised physicians to conduct detailed testing and follow-up  
12 of patients with ASR hip replacements.  
13

14           92.     As a result of the testing and follow-up, dangerously high heavy metal levels  
15 were discovered in a significant percentage of patients necessitating surgery to remove the  
16 defective metal on metal hip replacements.  
17

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

20           94.     The Defendants were aware of the reports and studies discussing the injuries  
21 suffered by metal on metal patients as a result of this very similar product.  
22

23       **N. Defendants' response to the recall of the almost identical product: Sell more**  
24       **Magnums!**  
25

26           95.     In response to the 2010 voluntary world-wide recall of a nearly identical hip  
27 replacement, Defendants did not:  
28

29           a.     Recall Defendants' nearly identical Magnum hip replacement;  
30



- b. Suspend the sales of their very similar hip replacement pending a full investigation;
- c. Conduct comprehensive testing of the Magnum to ensure it was not prone to causing heavy metal poisoning; or
- d. Warn physicians of the design similarities and the need to inform and carefully follow-up their patients.

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

97. Defendants employed marketing tactics to differentiate the Magnum from the recalled ASR hip replacement and other metal on metal hip replacements.

98. Defendants promoted these marketing tactics to physicians and the public to reassure them that the Magnum did not cause heavy metal poisoning.

**O. In 2010, Netherlands hospital warns Biomet of high rate of pseudotumors with Magnum**

99. At the same time that Defendants were reassuring orthopedic surgeons and the public of the safety of the Magnum, Defendants were receiving reports of just the opposite.

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

101. From 2005 to 2007, Isala implanted patients with Biomet Magnum metal on metal hip replacements.

102. Prior to and during this time period, Isala was in fact a Biomet funded study site, paid by Biomet to conduct research on Biomet products.

103. In 2010, Isala reported to Biomet that when it performed CT scans of over 100 patients' hips, more than a third had pseudotumors adjacent to their Biomet metal on metal hip replacements.

**P. Biomet warned that CT/MRI scanning was necessary to see tissue death from  
Magnum heavy metal poisoning**

104. Isala reported to Biomet that the necessity for revision surgery was not identified until Isala conducted the CT scanning of their Biomet Magnum metal on metal hip replacement patients.

105. Isala warned that by the time that swelling, pain, and clicking indicating tissue death resulting from the heavy metal poisoning became apparent; the patient may have already suffered extensive injury.

106. In 2010, Isala informed Biomet that it had ceased implanting Biomet metal on metal hip replacements in its patients.

107. Isala encouraged Biomet to adopt a comprehensive screening protocol using CT scans and MRIs of all patients with Biomet metal on metal hip replacements implanted in their bodies and warned that without such an enhanced protocol, patients may be at risk.

108. Isala reported some of its findings regarding the Biomet metal on metal hip replacements in a British medical journal.<sup>10</sup>

109. Despite all of these critical warnings provided by the Isala Klinieken, Defendants failed to inform physicians or patients in the State of California of the study, ignored the need for follow-up screening, and instead continued to promote the Magnum for implantation into the bodies of unsuspecting patients by unsuspecting doctors.

**Q. Finland University reports severe adverse reactions from Biomet metal on metal  
hip replacements**

<sup>10</sup> Bosker B, Ettema H, Boomsma M, et al. High incidence of pseudotumour formation after large-diameter metal-on-metal total hip replacement: a prospective cohort study. *J Bone Joint Surg Br.* 2012 Jun;94(6):755-61.



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

3 111. Turku University was also a Biomet funded study site.

4  
5 112. From 2005 to 2012, Biomet metal on metal hip replacements were the most  
6 commonly implanted hip replacement at Turku University.

7 113. In 2013, Turku University reported to Biomet that when the University  
8 examined a sample of their patients implanted with Biomet Magnum metal on metal hip  
9 replacements, over half of the patients were experiencing ARMD or "Adverse Reaction to  
10 Metal Debris" from the devices.

11  
12 114. MRIs of the sample of Turku University Magnum patients revealed that over  
13 half had a psuedotumor or fluid collection in their hip.

14  
15 115. Despite its close relationship and funding from Biomet, in a 2013 publication of  
16 the Nordic Orthopedic Federation, Turku University stated that "ARMD is common after ...  
17 Magnum total hip arthroplasty, and we discourage the use of this device."<sup>11</sup>

18  
19 116. Defendants failed to inform physicians or patients in the State of California of  
20 this study, that Turku University had discouraged use of Biomet metal on metal hip  
21 replacements, the need for physicians to screen their patients for Adverse Reaction to Metal  
22 Debris, and instead continued to promote their metal on metal hip replacements for  
23 implantation into the bodies of patients.

24  
25 **R. Biomet used Olympic gymnast Mary Lou Retton as a Magnum spokesperson**  
26  
27  
28

29 <sup>11</sup> Mokka J, Junnila M, Seppänen M, et al. Adverse reaction to metal debris after ReCap-M2a-Magnum large-  
30 diameter-head metal-on-metal total hip arthroplasty. *Acta Orthopaedica*. 2013;84(6):549-554.

1 117. As part of the promotion of the Magnum hip replacement, Biomet hired  
2 Olympic gold-medal gymnast, Mary Lou Retton, as a spokesperson.

3 118. Mary Lou Retton had received a Biomet metal on metal hip replacement in  
4 2005.

5  
6 119. Biomet heavily promoted to surgeons and the public that the Magnum metal on  
7 metal hip allowed “younger, more active patients, like Mary Lou” to “return to her normal  
8 activities, including her workout schedule.”<sup>12</sup>

9  
10 120. Mary Lou Retton was used by Defendants to promote the Magnum in brochures,  
11 in newspapers, on radio and television, and in-person to orthopedic surgeons and the public.<sup>13</sup>

12 121. A heading on Biomet’s website proclaims, “Mary Lou lives pain-free, and so  
13 should you.”<sup>14</sup>

14  
15  
16 **S. Mary Lou Retton has sued Biomet over its defective Magnum hip replacements**

17 122. Unfortunately, Mary Lou Retton, like Plaintiff, is a Biomet metal on metal hip  
18 replacement victim.

19  
20 123. While initially “pain-free,” Mary Lou Retton suffered heavy-metal poisoning  
21 from her Magnum hip replacement necessitating the surgical removal and replacement of the  
22 metal on metal hip replacement.

23  
24  
25  
26  
27 <sup>12</sup> See, [http://www.biomet.com/fileLibrary/Patient\\_Education/PatientEdBrochures/Hip/English/Mary%20Lou%20Retton%20-%20Magnum%20Magnum.pdf](http://www.biomet.com/fileLibrary/Patient_Education/PatientEdBrochures/Hip/English/Mary%20Lou%20Retton%20-%20Magnum%20Magnum.pdf) (Last accessed Mar. 28, 2018).

28 <sup>13</sup> See, <http://www.biomet.com/news/getFile.cfm?id=113&rt=inline&type=pr> (Last accessed Mar. 28, 2018).

29 <sup>14</sup> See, [http://www.biomet.com/fileLibrary/Patient\\_Education/PatientEdBrochures/Hip/English/Mary%20Lou%20Retton%20-%20Magnum%20Magnum.pdf](http://www.biomet.com/fileLibrary/Patient_Education/PatientEdBrochures/Hip/English/Mary%20Lou%20Retton%20-%20Magnum%20Magnum.pdf) (Last accessed Mar. 28, 2018).

1           124. Mary Lou Retton was so severely injured by the Magnum metal on metal hip  
2 replacement, that despite her status as a celebrity spokesperson for the product, she too has sued  
3 the company.  
4

5           **T. Despite knowing of the failure of the Magnum in Mary Lou Retton for years,**  
6           **Biomet continues to claim her as a success story**

7           125. Biomet has failed to inform physicians and the public that Mary Lou Retton  
8 suffered heavy metal poisoning and had to have her Magnum surgically removed.  
9

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

11          127. Biomet has known of the failure of Mary Lou Retton's hip replacement for  
12 years, but has continued to promote to physicians and the public a false story.  
13

14           **U. Australian government required Biomet to recall Magnum**  
15

16          128. Australia has a world-leading implant registry which keeps track of every  
17 orthopedic hip replacement sold, implanted, and replaced in Australia.  
18

19          129. Biomet ceased selling the Biomet Magnum metal on metal hip replacements in  
20 Australia in 2011.  
21

22          130. In 2014, the Australian government communicated to Biomet that it was seeing  
23 excessive failure rates of the Magnum in Australian patients.

24          131. In 2015, the Australian government issued a "Hazard Alert" recalling the Biomet  
25 Magnum due to a "higher than expected revision rate."  
26

27          132. Because Biomet had already ceased selling the Magnum in Australia, the  
28 Australian government's recall of the Magnum consisted of the "Hazard Alert" and mandating  
29 Biomet notify implanting surgeons in Australia of the recall and excessive revision rate.  
30

133. Defendants have failed to disclose to orthopedic physicians or the public in the State of California that the Magnum hip replacement had been recalled in Australia and that the Australian government issued a "Hazard Alert" regarding the Magnum.

**V. Since 2012 Biomet has had false Magnum failure rate data posted on its website**

134. From 2012 until today, Biomet had posted on its website under the heading "Important information regarding metal-on-metal hips" data purporting to show the success of Biomet's metal on metal hip replacements at <http://www.biomet.com/wps/portal/internet/Biomet/Healthcare-Professionals/products/orthopedics/important-information-mom-hips> (Last accessed Mar. 28, 2018.)

135. The "Important information regarding metal-on-metal hips" is clearly intended to reassure patients and surgeons that Biomet's metal on metal hip replacements are safe and performing as intended.

136. The "Important information regarding metal-on-metal hips" states "Biomet has been closely monitoring the available data regarding its [metal on metal] hip devices."

137. The "Important information regarding metal-on-metal hips" claims that there is no statistically significant difference between survivorship of the Biomet Magnum and hip replacements generally in the Australian National Joint Registry and the England and Wales National Joint Registry.

138. By 2015, at the latest, Biomet was aware that the Biomet Magnum was failing at a statically significantly higher rate than hip replacements generally in the Australian National Joint Registry.



1           139. Likewise, for years Biomet has been aware that the Magnum was failing at a  
2 significantly significant higher rate in the England and Wales National Joint Registry than hip  
3 replacements generally.

4           140. Despite knowing that it would mislead orthopedic surgeons and the public  
5 concerning the safety of its metal on metal hip replacements, Biomet has continued to promote  
6 false information regarding the safety of its Magnum hip replacement.  
7

8  
9           **W. Biomet metal on metal hips are a ticking time-bomb implanted in thousands of**  
10           **California citizens' bodies**

11           141. The Biomet Magnum metal on metal hip replacement is inherently defective.

12           142. When implanted in patients, it is prone to release toxic levels of cobalt and  
13 chromium.  
14

15           143. Patients thus can suffer heavy metal poisoning, resulting in elevated levels of  
16 cobalt and chromium in the blood, pseudotumors, tissue necrosis, muscle wasting, bone loss,  
17 and other severe injuries.  
18

19           144. The Defendants' failure to warn physicians and patients that the Biomet  
20 Magnum metal on metal hip replacements that were surgically implanted in patients' bodies  
21 may be releasing toxic heavy metals has left thousands of California patients with ticking time-  
22 bombs in their hips.  
23

24           145. Based on the studies discussed above and others, hundreds, if not thousands, of  
25 California patients have already suffered undiagnosed pseudotumors, tissue death, bone death,  
26 etc. as a result of poisoning from the toxic heavy metals released from the Biomet Magnum.  
27  
28  
29  
30

1       **X. California is facing a public health disaster from unmonitored Magnums**

2  
3       146. As a result of Defendants' failure to warn physicians and patients of the  
4 necessity for immediate testing and radiographic screening of implanted Biomet Magnum hip  
5 replacements, the number of patients poisoned and severely injured by the Magnum will greatly  
6 increase.  
7

8       147. California is facing a public health disaster from unmonitored Biomet Magnum  
9 metal on metal hip replacements.  
10

11       **Y. Gary Langford suffered heavy metal poisoning from the Magnum**

12  
13       148. Gary Langford was implanted with the Biomet Magnum metal on metal hip  
14 replacement in his left hip on October 31, 2011, by Dr. Jonathon Fow, at Arroyo Grande  
15 Hospital, in Arroyo Grande, California.  
16

17       149. In preparation for the surgery, Dr. Fow, or someone at his direction, contacted  
18 defendants Biomet and/or distributor, to notify them of that need for the Magnum hip system  
19 components.  
20

21       150. Biomet and Distributor Defendants thereby selected and provided the specific  
22 Magnum components for use in Plaintiff's left hip surgery and delivered them to the operating  
23 room for surgery.  
24

25       151. Biomet utilized Distributor defendants' sales representatives, and DOES 1-25, to  
26 educate Plaintiff's orthopedic surgeon regarding the claimed advantages of the products used,  
27 answer any questions Plaintiff's orthopedic surgeon asked regarding the products, assist  
28  
29  
30



1 Plaintiff's orthopedic surgeon at surgery regarding the products, and to sell the products to  
2 Plaintiff through his orthopedic surgeon agent.

3 152. Biomet trained and educated Distributor defendants' sales representatives, and  
4 DOES 1-25's sales staff, regarding the Magnum, including orthopedic and surgical training,  
5 product design rationale, surgical technique tips, training in the use of implanting tools, training  
6 in selecting the hip replacement components to mate with the Magnum, and training on how to  
7 sell to orthopedic surgeon, including training on the advantages of the Magnum over its  
8 competitors.  
9  
10

11 153. Prior to Plaintiff's surgery, Defendants, including defendant Distributors and  
12 DOES 1-25, provided information to Plaintiff's orthopedic surgeon, including but not limited to,  
13 the advantages of the Magnum compared to its competitors, information regarding the design  
14 rationale for the Magnum, surgical techniques on how to implant the Magnum, and  
15 demonstrations on how to implant the Magnum and the components that could best be mated  
16 with the Magnum, including providing a variety of scenarios involving the various  
17 instrumentation used in implanting the Magnum.  
18  
19

20 154. Biomet and defendant Distributors' sales representatives and DOES 1-25, were  
21 responsible for answering any questions or concerns Plaintiff's orthopedic surgeon had regarding  
22 the Magnum.  
23

24 155. The above information was provided to Plaintiff's orthopedic surgeon with the  
25 intended purpose of convincing and inducing Plaintiff's orthopedic surgeon to use the Magnum  
26 instead of one of the competing hip replacements.  
27  
28  
29  
30

1           156. At all times relevant to this Petition, Plaintiff's orthopedic surgeon, nurses and  
2 hospital staff relied on information and assistance from Biomet and defendant Distributors' sales  
3 representatives and DOES 1-25's sales representative agents.

4           157. Defendant Distributors and DOES 1-25 were available to assist and provide  
5 information regarding the Magnum hip implants before, during and after plaintiff's surgery.  
6

7           158. Unknown to Mr. Langford and his physicians, during the ensuing years  
8 following implantation, the Biomet Magnum hip replacement continuously released toxic  
9 heavy metals into his body, gradually poisoning him.  
10

11           159. On May 22, 2017, a metal ion test reported elevated levels of Chromium and  
12 Cobalt metal ions in Plaintiff's body.  
13

14           **Z. The Magnum had to be surgically removed from Gary Langford's body**  
15

16           160. On December 5, 2017, Gary Langford underwent a revision surgery to remove  
17 his Biomet Magnum metal on metal hip replacement.

18           161. The preoperative diagnosis noted "metallosis and elevated metal ions."  
19

20           162. During the procedure, the operating surgeon noted "...evidence of metallosis  
21 with brownish discoloration of the soft tissue around the hip capsule and the bursa..."  
22

23           163. Gary Langford then underwent a long and painful recovery and rehabilitation  
24 from the removal of the failed Biomet M2a Magnum hip replacement.  
25

26           **DAMAGES AND CAUSES OF ACTION**

27           164. As a direct and proximate result of the defective Magnum hip replacement,  
28 Plaintiffs suffered injuries, including but not limited to significant pain, disability, tissue  
29  
30

1 destruction, bone destruction, metal wear, metal poisoning, loss of enjoyment of life, loss of  
2 consortium and limitation of daily activities and resulting in non-economic damages.

3 165. Plaintiffs expect to continue suffering such injuries and non-economic damages  
4 in the future as a result of the injuries received from the Magnum.

5  
6 166. As a direct and proximate result of the defective Magnum, Plaintiffs incurred  
7 medical expenses and other economic damages and expect to incur additional medical expenses  
8 and other economic damages in the future.

9  
10 167. As a direct and proximate result of the defective Magnum, Plaintiffs experienced  
11 emotional trauma and distress and will experience emotional trauma and distress in the future.

12 **FIRST CAUSE OF ACTION: FRAUD**  
13 **Against Biomet Defendants**

14 168. Plaintiffs incorporates by reference Paragraphs 1 through 167 as though set forth  
15 fully herein.

16  
17 169. Prior to the implantation of the Magnum products in Plaintiff's body, and  
18 continuing thereafter, Biomet Defendants knowingly and intentionally undertook an inadequate  
19 testing protocol and false marketing scheme which made misrepresentations and omissions in  
20 order to profit from the unproven promise of the theoretical advantages associated with metal on  
21 metal hip replacements; said misrepresentations are previously set forth in greater detail herein,  
22 including but not limited to ¶¶ 45-53; ¶¶ 61-67; ¶¶ 68-71; ¶¶ 72-78; ¶¶ 83-86; ¶¶ 95-116; ¶¶ 117-127  
23 and ¶¶ 134-140.

24  
25  
26 170. Prior to the implantation of the Magnum products in Plaintiff's body, and  
27 continuing thereafter, Biomet Defendants knowingly and intentionally engaged in a false  
28 marketing scheme which made misrepresentations and omissions to alter the orthopedic  
29  
30

community's understanding of the clinical history of failure with previous generations of metal on metal hip replacements; said misrepresentations are previously set forth in greater detail herein, including but not limited to ¶¶ 45-53; ¶¶61-67; ¶¶68-71; ¶¶72-78; ¶¶83-86; ¶¶95-116; ¶¶117-127 and ¶¶134-140.

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

172. Further, in support of these Fraud allegations, the Plaintiffs plead as follows:

- a. Biomet Defendants were warned in 1995 that their testing protocols ignored known dangers of metal on metal implants, yet moved forward with insufficient testing, anyway.
- b. Biomet Defendants conducted laboratory testing for plastic hip implants and knew such testing was not appropriate for metal on metal hip implants.
- c. Biomet Defendants knew that metal ions and particles released from the Magnum are smaller, higher in number, and more toxic than plastic particles released from plastic implants.
- d. Biomet Defendants marketed the Magnum as having less volumetric wear than plastic hip implants, knowing it would mislead the orthopedic community into incorrectly believing that the Magnum was safer and more effective.
- e. Biomet Defendants engaged in a deceptive scheme to train sales representatives to convince the medical community that concerns over clinical risks due to metal wear are fake.
- f. Biomet Defendants engaged in a corporate-wide abuse of legal privilege to hide internal documents regarding metal on metal data.

- 1
- 2 g. Biomet Defendants knowingly and intentionally underreported product
- 3 failures.
- 4 h. Biomet Defendants knowingly and intentionally failed to properly analyze
- 5 clinical information in order to suppress concern about the Magnum's
- 6 track record.
- 7 i. Biomet Defendants knowingly marketed a "reported adverse event rate" it
- 8 knew would be relied upon by the orthopedic community and which it
- 9 knew to be false based on its own deceptive scheme to suppress such rate.
- 10 j. Biomet Defendants shirked the scientific method in clinical tests by either
- 11 designing the tests in order to elicit an intended result or by altering the
- 12 data or input criteria, or by simply disregarding damaging results under
- 13 the arbitrary decision that such results are "outliers" not indicative of
- 14 actual performance.
- 15 k. Biomet Defendants falsely claimed "clinically proven results" in Magnum
- 16 products upon launch, despite never conducting a single pre-market
- 17 clinical test.
- 18 l. Biomet Defendants falsely claimed that the Magnum system "offers
- 19 optimal joint mechanic restoration and ultra-low-wear rates in vivo"
- 20 despite citing to a 1996 article about previously abandoned types of metal
- 21 on metal hip replacements.
- 22 m. Despite knowing that published medical literature explicitly discussed
- 23 adverse physiologic effects related to heavy metal wear from metal on
- 24 metal hip implants, Biomet Defendants falsely claimed in marketing that
- 25 extensive experience with metal on metal implants "failed to prove any
- 26 cause for concern" with its Magnum implants.
- 27 n. Biomet Defendants falsely claimed in its marketing that "Cobalt and
- 28 Chromium may be beneficial to the body" despite knowing that Cobalt
- 29 and Chrome released from Magnum implants are toxic.
- 30 o. Biomet Defendants intentionally misrepresented the existence of concern
- over heavy metal wear in order to market and profit from the sale of
- Magnum implants.

- 1
- 2 p. Biomet Defendants deceptively engaged in marketing the Magnum
- 3 through Dr. Cuckler by not revealing their financial relationship in
- 4 marketing literature, such as "The Rationale for Metal-on-Metal Total Hip
- 5 Arthroplasty."
- 6 q. Biomet Defendants failed to inform the orthopedic community in the
- 7 United States regarding the Isala Clinic's finding of the need for advanced
- 8 screening protocols in order to diagnose heavy metal poisoning in
- 9 Magnum patients; instead Biomet Defendants continued to heavily
- 10 promote Magnum products.
- 11 r. Biomet Defendants failed to inform the orthopedic community in the
- 12 United States regarding Turku University's finding of heavy metal
- 13 poisoning in over half of the patients who received an Magnum and of
- 14 Turku University's warning claiming that they "discourage use of this
- 15 device."
- 16 s. Biomet Defendants failed to inform the public that the Magnum
- 17 posterchild, Mary Lou Retton, had both of her Magnum implants fail due
- 18 to heavy metal poisoning.
- 19 t. Biomet Defendants continued to falsely claim Mrs. Retton as a "patient
- 20 success story."
- 21 u. Biomet Defendants failed to inform United States citizens and surgeons of
- 22 the international recalls, hazard alerts, and safety notices related to its
- 23 Magnum.

24 173. Biomet Defendants made these misrepresentations and omissions with the specific

25 intent that Plaintiffs and Plaintiff's orthopedic surgeon rely on such representations and

26 omissions with intent to deceive the orthopedic community and profit from deceitfully

27 convincing them to use metal on metal hip replacements again, particularly the Magnum.

28 174. The above representations and/or omissions were false and misleading.

29

30



1 175. Biomet Defendants knew that these statements were false at the time they were  
2 made, in that they had information in their possession and control directly contradicting the  
3 misrepresentations, or alternatively Biomet Defendants made these representations without  
4 knowing whether they were true or false.  
5

6 176. Biomet Defendants made these statements for the purpose of inducing Plaintiff,  
7 Plaintiff's orthopedic surgeon, the orthopedic community, and consumers in need of a hip  
8 replacement, to act in reliance thereon to purchase the Magnum products.  
9

10 177. These representations were made to Plaintiff's orthopedic surgeon prior to  
11 installing the Magnum in Plaintiff's body.  
12

13 178. Plaintiff, and Plaintiff's orthopedic surgeon agent, acted in foreseeable reliance  
14 on the correctness of Biomet's representations which resulted in injury to Plaintiff as described  
15 above, by deciding to use, install and purchase the Magnum products based on the  
16 misrepresentations.  
17

18 179. The above referenced reliance was reasonable under the circumstances.  
19

20 180. The representations and omissions were material to Plaintiff's orthopedic surgeon  
21 in selecting the Magnum products installed in Plaintiff.  
22

23 181. The representations and omissions were material to Plaintiffs in selecting the  
24 Magnum products.  
25

26 182. As a direct and proximate result of the Biomet Defendants' fraudulent conduct,  
27 Plaintiffs suffered pecuniary loss, injury and special and general damages as described herein.  
28

29 **SECOND CAUSE OF ACTION: FRAUD**  
30 **Against Cuckler Defendants**

1           183. Plaintiff incorporate by reference Paragraphs 1 through 167 as though set forth  
2 fully herein.

3           184. Prior to the implantation of the Magnum products in Plaintiff's body, and  
4 continuing thereafter, Cuckler Defendants knowingly and intentionally undertook an inadequate  
5 testing protocol and false marketing scheme which made misrepresentations and omissions in  
6 order to profit from the unproven promise of the theoretical advantages associated with metal on  
7 metal hip replacements; said misrepresentations are previously set forth in greater detail herein,  
8 including but not limited to ¶¶ 45-53; ¶¶61-67; ¶¶68-71; ¶¶72-78; ¶¶83-86; ¶¶95-116; ¶¶117-127  
9 and ¶¶134-140.

12           185. Prior to the implantation of the Magnum products in Plaintiff's body, and  
13 continuing thereafter, Cuckler Defendants knowingly and intentionally engaged in a false  
14 marketing scheme which made misrepresentations and omissions to alter the orthopedic  
15 community's understanding of the clinical history of failure with previous generations of metal  
16 on metal hip replacements. Cuckler Defendants intentionally minimized the risks of the toxic  
17 heavy metals released by metal on metal hip replacements; said misrepresentations are previously  
18 set forth in greater detail herein, including but not limited to ¶¶ 45-53; ¶¶61-67; ¶¶68-71; ¶¶72-  
19 78; ¶¶83-86; ¶¶95-116; ¶¶117-127 and ¶¶134-140.

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

28           187. Further, in support of these Fraud allegations, the Plaintiff pleads as follows:

29           a. Cuckler Defendants knew that laboratory testing conducted on the  
30

Magnum was not appropriate for metal on metal hip implants.

- b. Cuckler Defendants knew that metal ions and particles released from the Magnum are smaller, higher in number, and more toxic than plastic particles released from plastic implants.
- c. Cuckler Defendants marketed the Magnum as having less volumetric wear than plastic hip implants, knowing it would mislead the orthopedic community into incorrectly believing that the Magnum was safer and more effective.
- d. Despite knowing that published medical literature explicitly discussed adverse physiologic effects related to heavy metal wear from metal on metal hip implants, Cuckler Defendants knowingly published literature falsely claiming that extensive experience with metal on metal implants has shown "no adverse physiologic effects" related to metal on metal hip replacements.
- e. Cuckler Defendants intentionally misrepresented the existence of concern over heavy metal wear in order to market and profit from the sale of Magnum implants.
- f. Cuckler Defendants deceptively engaged in marketing the Magnum by not revealing its financial relationship with Biomet in marketing literature, such as "The Rationale for Metal-on-Metal Total Hip Arthroplasty."
- g. Cuckler Defendants promoted the Magnum and gave educational presentations to sales representatives including Select and McGinnis, misrepresenting the safety of the Magnum and providing false information to the sales representatives on how to answer questions and concerns of orthopedic surgeons.

188. The above referenced statements, representations and omissions were false and misleading.

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

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

4 191. The above representations and omission by Cuckler Defendants were made prior  
5 to the Magnum being implanted in Plaintiff's body.

6 192. Plaintiff, and Plaintiff's orthopedic surgeon agent, acted in foreseeable reliance  
7 on the correctness of Cuckler's representations which resulted in injury to Plaintiffs as described  
8 above, by deciding to use, install and purchase the Magnum products based on the  
9 misrepresentations.

10 193. The above referenced reliance was reasonable under the circumstances.

11 194. The representations and omissions were material to Plaintiff's orthopedic surgeon  
12 in selecting the Magnum products installed in Plaintiff.

13 195. The representations and omissions were material to Plaintiff in selecting the  
14 Magnum products.

15 196. As a direct and proximate result of the Cuckler Defendants' fraudulent conduct,  
16 Plaintiffs suffered loss, injury and damage as described herein.

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22 **THIRD CAUSE OF ACTION: FRAUDULENT CONCEALMENT**  
23 **Against Biomet Defendants And Cuckler Defendants**

24 197. Plaintiffs incorporate by reference Paragraphs 1 through 167 as though set forth  
25 fully herein.

26 198. Defendants had sole access to material facts concerning the dangers and  
27 unreasonable risks of the Magnum.  
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1           199. Biomet Defendants knowingly and willfully concealed material information with  
2 respect to the M2a Magnum in a manner to distort its safety record and falsely portray the system  
3 to the orthopedic community and public as safe and effective, which is evidenced by the  
4 following:  
5

- 6           a. Biomet Defendants were warned in 1995 that their testing protocols  
7 ignored known dangers of metal on metal implants, yet moved forward  
8 with insufficient testing, anyway.
- 9           b. Biomet Defendants conducted laboratory testing for plastic hip implants  
10 and knew the testing procedure used for plastic hips was not appropriate  
11 for metal on metal hip implants.
- 12           c. Biomet Defendants knew that metal ions and particles released from the  
13 Magnum are smaller, higher in number, and more toxic than plastic  
14 particles released from plastic implants.
- 15           d. Biomet Defendants marketed the Magnum as having less volumetric wear  
16 than plastic hip implants, knowing it would mislead the orthopedic  
17 community into incorrectly believing that the Magnum was safer and more  
18 effective.
- 19           e. Biomet Defendants engaged in a deceptive scheme to train sales  
20 representatives to convince the medical community that concerns over  
21 clinical risks due to metal wear are fake.
- 22           f. Biomet Defendants engaged in a corporate-wide abuse of legal privilege  
23 to hide internal documents regarding metal on metal data.
- 24           g. Biomet Defendants knowingly and intentionally underreported product  
25 failures.
- 26           h. Biomet Defendants knowingly and intentionally failed to properly analyze  
27 clinical information in order to suppress concern about the Magnum's  
28 track record.
- 29           i. Biomet Defendants knowingly marketed a "reported adverse event rate" it  
30 knew would be relied upon by the orthopedic community and which it



1 knew to be false based on its own deceptive scheme to suppress such rate.

- 2 j. Biomet Defendants shirked the scientific method in clinical tests by either  
3 designing the tests in order to elicit an intended result or by altering the  
4 data or input criteria, or by simply disregarding damaging results under  
5 the arbitrary decision that such results are "outliers" not indicative of  
6 actual performance.
- 7 k. Biomet Defendants falsely claimed "clinically proven results" in Magnum  
8 products upon launch, despite never conducting a single pre-market  
9 clinical test.
- 10 l. Biomet Defendants falsely claimed that the Magnum system "offers  
11 optimal joint mechanic restoration and ultra-low-wear rates in vivo"  
12 despite citing to a 1996 article about previously abandoned types of metal  
13 on metal hip replacements.
- 14 m. Despite knowing that published medical literature explicitly discussed  
15 adverse physiologic effects related to heavy metal wear from metal on  
16 metal hip implants, Biomet Defendants falsely claimed in marketing that  
17 extensive experience with metal on metal implants "failed to prove any  
18 cause for concern" with its Magnum implants.
- 19 n. Biomet Defendants falsely claimed in its marketing that "Cobalt and  
20 Chromium may be beneficial to the body" despite knowing that Cobalt  
21 and Chrome released from Magnum implants are toxic.
- 22 o. Biomet Defendants intentionally misrepresented the existence of concern  
23 over heavy metal wear in order to market and profit from the sale of  
24 Magnum implants.
- 25 p. Biomet Defendants deceptively engaged in marketing the Magnum  
26 through Dr. Cuckler by not revealing their financial relationship in  
27 marketing literature, such as "The Rationale for Metal-on-Metal Total Hip  
28 Arthroplasty."
- 29 q. Biomet Defendants failed to inform the orthopedic community in the  
30 United States regarding the Isala Clinic's finding of the need for advanced  
screening protocols in order to diagnose heavy metal poisoning in  
Magnum patients; instead Biomet Defendants continued to heavily  
promote Magnum products.

- r. Biomet Defendants failed to inform the orthopedic community in the United States regarding Turku University's finding of heavy metal poisoning in over half of the patients who received a Magnum and of Turku University's warning claiming that they "discourage use of this device."
- s. Biomet Defendants failed to inform the public that the Magnum posterchild, Mary Lou Retton, had both of her Magnum implants fail due to heavy metal poisoning.
- t. Biomet Defendants continued to falsely claim Mrs. Retton as a "patient success story."
- u. Biomet Defendants failed to inform United States citizens and surgeons of the international recalls, hazard alerts, and safety notices related to its Magnum.
- v. Biomet Defendants employed Cuckler Defendants to alter the orthopedic community's perception of the failures of past generations of metal on metal implants and to falsely market current metal on metal technology, including the Magnum, as having no (or minimal) risk of wear-related pathological reaction.

200. Cuckler Defendants knowingly and willfully concealed material information with respect to the M2a Magnum in a manner to distort its safety record and falsely portray the system to the orthopedic community and public as safe and effective, as evidenced by the following:

- a. Cuckler Defendants knew that laboratory testing conducted on the Magnum was not appropriate for metal on metal hip implants.
- b. Cuckler Defendants knew that metal ions and particles released from the Magnum are smaller, higher in number, and more toxic than plastic particles released from plastic implants.
- c. Cuckler Defendants concealed the significance of heavy metal size, number, and toxicity, and instead marketed the Magnum as having less volumetric wear than plastic hip implants. Cuckler Defendants did this knowing it would mislead the orthopedic community into incorrectly

believing that the Magnum was safer and more effective.

- d. Despite knowing that published medical literature explicitly discussed adverse physiologic effects related to heavy metal wear from metal on metal hip implants, Cuckler Defendants knowingly published literature falsely claiming that extensive experience with metal on metal implants has shown "no adverse physiologic effects" related to metal on metal hip replacements.
- e. Cuckler Defendants intentionally misrepresented the existence of concern over heavy metal wear in order to market and profit from the sale of Magnum implants.
- f. Cuckler Defendants deceptively engaged in marketing the Magnum by not revealing its financial relationship with Biomet in marketing literature, such as "The Rationale for Metal-on-Metal Total Hip Arthroplasty."

201. Defendants concealed this information both prior to and subsequent to the implantation of Plaintiff's Magnum.

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

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

204. Plaintiffs, through Plaintiff's physicians, did rely upon Defendants'

1 misrepresentations.

2 205. The above referenced reliance by Plaintiffs and Plaintiff's physicians was  
3 reasonable.

4 206. The fraudulent concealment from Plaintiffs and Plaintiff's physicians was  
5 material to the use and installation of the Magnum into Plaintiff's body by Plaintiff's physicians.  
6

7 207. The fraudulent concealment from Plaintiffs and Plaintiff's physicians was  
8 material to Plaintiff and Plaintiff's orthopedic surgeon in the decision to have the Magnum  
9 products installed in Plaintiff's body.  
10

11 208. As a result of Defendants' fraudulent concealment, Plaintiffs were injured as  
12 alleged herein.  
13

14 **FOURTH CAUSE OF ACTION: STRICT LIABILITY FAILURE TO WARN**  
15 **Against All Defendants**

16 209. Plaintiffs incorporate by reference Paragraphs 1 through 167 as though set forth  
17 fully herein.  
18

19 210. At the time Defendants designed, manufactured, promoted, marketed, sold,  
20 supplied, distributed and/or serviced the products at issue in this Complaint, such products  
21 contained defects that made them unreasonably dangerous beyond the expectations of the  
22 ordinary consumer, and were unfit for their intended use.  
23

24 211. The Magnum reached Plaintiff without substantial change in the condition in  
25 which it was designed, developed, promoted, manufactured, and sold.  
26

27 212. At the time and on the occasion in question, the Magnum was being properly used  
28 for the purpose for which it was intended, and such device was in fact defective, unsafe and  
29 unreasonably dangerous.  
30

1           213. The foreseeable risk of harm from the defects in the Magnum could have been  
2 reduced or avoided by providing adequate instructions or warnings.

3           214. Defendants had a continuing, post-sale duty to warn regarding the unreasonable  
4 risk of harm associated with the Magnum.

5           215. Defendants had sufficient notice about specific dangers associated with the  
6 Magnum.

7           216. Defendants failed to provide adequate instructions or warnings regarding the  
8 defects in the Magnum which were known by Defendants or should have been known by  
9 Defendants and could have been provided.

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

13           218. As a direct and proximate result of the lack of reasonable and adequate  
14 instructions or warnings regarding the defects in the Magnum, Plaintiffs suffered the injuries and  
15 damage as described herein.

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21           **FIFTH CAUSE OF ACTION: STRICT LIABILITY- DESIGN AND**  
22           **MANUFACTURING DEFECT**  
23           **Against All Defendants**

24           219. Plaintiffs incorporate by reference Paragraphs 1 through 167 as though set forth  
25 fully herein.

26           220. At the time that defendants designed, manufactured, promoted, marketed, sold,  
27 supplied, distributed and/or serviced the products at issue in this Complaint, such products  
28 contained defects that made them unreasonably dangerous beyond the expectations of the  
29



1 ordinary consumer, and were unfit for their intended use, including but not limited to the  
2 following defects:

- 3 a. The design of the Magnum caused it to generate excessive cobalt and chromium  
4 metal debris into the body;
- 5 b. The surface roughness of the Magnum was not within acceptable standards and  
6 specifications;
- 7 c. The thickness, porosity, tensile strength of the plasma porous spray coating was  
8 not within acceptable standards and/or specifications;
- 9 d. The plasma porous spray coating utilized was not designed to be utilized on the  
10 acetabular cup of the Magnum;
- 11 e. The plasma porous spray coating contributed to generating excessive metal wear  
12 debris;
- 13 f. The design of the acetabular cup caused it to fail to obtain bone ingrowth;
- 14 g. The claimed advantages of the Magnum did not justify the additional risks created  
15 by metal debris of the Magnum as compared to non-metal on metal hip  
16 replacements on the market;
- 17 h. The design of the Magnum caused excessive corrosion as compared to other hip  
18 replacement products on the market;
- 19 i. The design of the Magnum caused the taper adapter and stem to cold weld;
- 20 j. The design of the instrumentation, including the inserter tools, resulted in  
21 excessive failures.

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25 221. The Magnum reached Plaintiffs without substantial change in the condition in  
26 which it was sold.  
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1           222. At the time and on the occasion in question, the Magnum was being properly used  
2 for the purpose for which it was intended, and such device was in fact defective, unsafe and  
3 unreasonably dangerous.

4           223. The Magnum, for the reasons previously set forth herein, was defective, unsafe  
5 and unreasonably dangerous in design and manufacture.

6           224. As a direct and proximate result of the defects in the M2a Magnum, Plaintiffs  
7 suffered the injuries and damages described herein.  
8  
9

10                   **SIXTH CAUSE OF ACTION: BREACH OF IMPLIED WARRANTY**  
11                   **Against All Defendants**

12           225. Plaintiffs incorporate by reference Paragraphs 1 through 167 as though set forth  
13 fully herein.

14           226. Defendants impliedly warranted that the products at issue in this Complaint and  
15 its component parts were merchantable and fit for the ordinary and intended purposes for which  
16 hip systems are used.  
17

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

19           228. Plaintiff's surgeon, as a purchasing agent, purchased the products at issue in this  
20 Complaint for Plaintiff from Defendants.  
21

22           229. At all times relevant to this Complaint, Plaintiff was in privity with the Biomet  
23 and Distributor Defendants.  
24

25           230. The Cuckler Defendants received a royalty payment from the sale of the defective  
26 M2a Magnum that was implanted in Plaintiff's body by Plaintiff's orthopedic surgeon.

27           231. Plaintiff used the products at issue in this Complaint for its ordinary and intended  
28 purpose.  
29  
30

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

3           233. As a direct and proximate result of the Defendants' breach of implied warranty,  
4 Plaintiffs suffered injuries and damages described herein.  
5

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7           **SEVENTH CAUSE OF ACTION: BREACH OF EXPRESS WARRANTY**  
8           **Against All Defendants**

9           234. Plaintiffs incorporate by reference Paragraphs 1 through 167 as though set forth  
10 fully herein.

11           235. Defendants sold and Plaintiff purchased, through Plaintiff's purchasing agent  
12 surgeon, the Magnum products at issue in this Complaint.  
13

14           236. At all times relevant to this Complaint, Plaintiff was in privity with Biomet and  
15 Distributor Defendants.  
16

17           237. The Cuckler Defendants received a royalty payment from the sale of the defective  
18 M2a Magnum that was implanted in Plaintiff's body by Plaintiff's orthopedic surgeon.  
19

20           238. Defendants expressly warranted by affirmation, promise, description, and sample  
21 to Plaintiff and Plaintiff's physician that the products at issue in this Petition were of a quality  
22 and character suitable for implantation and extended safe use in Plaintiff.  
23

24           239. Such representations by Defendants were meant to induce Plaintiff, through  
25 Plaintiff's physician, to purchase the M2a Magnum products at issue in this Complaint.

26           240. The products at issue in this Complaint did not conform to the warranties and  
27 representations made by Defendants.  
28  
29  
30

1           241. Defendants breached the express warranties they provided with the M2a Magnum  
2 products at issue in this Complaint.

3           242. As a direct and proximate result of Biomet Defendant's breach of express  
4 warranties, Plaintiff suffered injuries and damages described herein.  
5

6  
7           **EIGHTH CAUSE OF ACTION: NEGLIGENT MISREPRESENTATION**  
8           **Against All Defendants**

9           243. Plaintiffs incorporate by reference Paragraphs 1 through 167 as though set forth  
10 fully herein.  
11

12           244. Defendants made statements concerning material facts which Defendants may  
13 have believed to be true but which in fact were false, or otherwise omitted material facts including  
14 the statement and omission set forth in ¶¶ 45-53; ¶¶61-67; ¶¶68-71; ¶¶72-78; ¶¶83-86; ¶¶95-116;  
15 ¶¶117-127 and ¶¶134-140  
16

17           245. As stated above, Defendants, through sales literature, marketing materials,  
18 meetings, verbal communications, medical publications, seminars and in the course of their  
19 business, made misrepresentations of material facts about the M2a Magnum and/or concealed  
20 information about the Magnum from Plaintiff and his orthopedic surgeon prior to Plaintiff's  
21 surgeries in 2011 including, but not limited to:  
22

- 23           a. Misrepresenting the Magnum is designed to reduce wear and provide  
24 higher function for all patients;  
25           b. Misrepresenting the Magnum is clinically proven to reduce wear;  
26           c. Misrepresenting the Magnum is based on a strong clinical history and  
27 reduces wear compared to the traditional hip replacement;  
28           d. Misrepresenting the Magnum is designed to be installed in younger and  
29 more active patients and will last longer than its competitors;  
30

- e. Misrepresenting the success rate of the Magnum;
- f. Failing to disclose that the metal used for the Magnum was prone to increased wear and caused excessive metal debris;
- g. Failing to disclose the Magnum failed to obtain bony ingrowth and became loose;
- h. Failing to disclose that they were aware of and/or witnessed revision surgeries in which the Magnum had failed, including becoming loose, causing metallosis, excessive wear and corrosion on the neck stem, dislocations, fractures of hardware, loose acetabular components, pseudotumors, ALVAL, ARMD and infection; and
- i. Failing to disclose that orthopedic surgeons were complaining about the Magnum and were experiencing difficulty in installing the Magnum.

246. Defendants made these misrepresentations of material fact and/or concealments of information about the Magnum from Plaintiff and Plaintiff's orthopedic surgeon, prior to Plaintiff's surgery, and continued the misrepresentations and omissions thereafter.

247. Defendants were negligent in making such statements and/or concealing information because they should have known the statements were false or omitted material information.

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

249. Prior to Plaintiff's surgery, Plaintiff and his orthopedic surgeon were induced to act in reliance on Defendants' misrepresentations and/or omissions and in fact purchased the Magnum and installed the Magnum in Plaintiff's hip.

250. Defendants failed to exercise ordinary care in making the above representations and/or omissions and instead made the above representations and/or omissions knowing the



1 representations were false or were ignorant of the truth of the assertion.

2 251. Plaintiff and his orthopedic surgeon relied on the truth of Defendants'  
3 representations and/or omissions about the Magnum and had a right to rely on such.

4 252. Plaintiff was ignorant of Defendants' misrepresentations and/or omissions.

5  
6 253. As a direct and proximate result of the negligent misrepresentations and omissions  
7 regarding the Magnum, Plaintiffs suffered injuries and damages as described herein.

8 **NINTH CAUSE OF ACTION: NEGLIGENCE**  
9 **Against All Defendants**

10  
11 254. Plaintiffs incorporate by reference Paragraphs 1 through 167 as though set forth  
12 fully herein.

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

17  
18 256. Defendants, in breach of the duties described above, negligently and carelessly  
19 designed, manufactured, promoted, marketed, sold, supplied, distributed and/or serviced the  
20 products at issue in this Complaint.

21  
22 257. Further, Defendants owed Plaintiffs a duty to provide reasonable complete and  
23 accurate information to Plaintiff, Plaintiff's orthopedic surgeon, and the orthopedic community  
24 regarding the products at issue in this Complaint.

25  
26 258. Defendants had a duty to adequately warn Plaintiffs of defects in the Magnum  
27 which it knew or should have known about.  
28  
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1           259. Defendants had a continuing, post-sale, duty to warn Plaintiffs and others of  
2 unreasonable risks of harms associated with the Magnum.

3           260. Defendants breached the above duties by failing to adequately warn Plaintiffs,  
4 Plaintiff's orthopedic surgeon, and the orthopedic community regarding risks and dangers of the  
5 Magnum.  
6

7           261. Defendants, in breach of the duties described above, negligently and carelessly  
8 designed, manufactured, promoted, marketed, sold, supplied, distributed and serviced the  
9 Magnum hip replacement components implanted in Plaintiff.  
10

11           262. Defendants, in breach of the duties described above, negligently and carelessly  
12 failed to provide reasonable, complete, and accurate information to Plaintiff, his orthopedic  
13 surgeon, and the orthopedic community regarding Plaintiff's Magnum.  
14

15           263. As a direct and proximate result of Defendants' breaches of duty, Plaintiffs  
16 needlessly suffered injuries and damages as described herein.  
17

18  
19           **TENTH CAUSE OF ACTION: INFORMATION NEGLIGENTLY**  
20           **SUPPLIED FOR THE GUIDANCE OF OTHERS**  
21           **Against All Defendants**

22           264. Plaintiffs incorporate by reference Paragraphs 1 through 167 as though set forth  
23 fully herein.

24           265. Plaintiffs' purchase of the Magnum was a business transaction.

25           266. The Defendants all had a pecuniary interest in the design, development, testing,  
26 promotion, marketing and sale of the Magnum.  
27

28           267. The Defendants supplied false information for the guidance of others regarding  
29 the selection of the Magnum as a safe and effective hip replacement option, as alleged above.  
30

1           268. The Defendants failed to exercise reasonable care and/or competence in obtaining  
2 and communicating the information supplied for the guidance of others regarding the Magnum.

3           269. Plaintiff, and Plaintiff's orthopedic surgeon agent, were within the limited group  
4 of persons for whose benefit and guidance the Defendants intended to supply the information.  
5

6           270. The Defendants intended for their information to influence either the transaction  
7 in which Plaintiff, through Plaintiff's orthopedic surgeon agent, purchased the Magnum or a  
8 substantially similar transaction.  
9

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

12          272. As a direct and proximate result of the Defendants' false information, Plaintiffs  
13 suffered pecuniary loss, injury and special and general damages as described herein.  
14

15                           **ELEVENTH CAUSE OF ACTION: NEGLIGENCE**  
16                           **Against Distributor Defendants**

17          273. Plaintiffs incorporate by reference Paragraphs 1 through 167 as though set forth  
18 fully herein.  
19

20          274. Distributor Defendants, as the promoters, marketers, sellers, distributor, and  
21 servicers of the Magnum, owed an independent duty to Plaintiffs to provide accurate and  
22 complete information to Plaintiffs, his orthopedic surgeon and the orthopedic community.  
23

24          275. Distributor Defendants, in breach of the duty described above, negligently and  
25 carelessly promoted, marketed, sold, distributed, and serviced the Magnum implanted in Plaintiff  
26 in that:  
27  
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- 1 a. Distributor Defendants knew or should have known that the M2a Magnum  
2 was failing at high rate and failed to disclose this information to Plaintiff  
3 and/or his orthopedic surgeon prior to installation of the Magnum;  
4  
5 b. Distributor Defendants knew or should have known that other patients  
6 experienced problems with the Magnum, including, but not limited to,  
7 loosening of the cup, a ratcheting or clunking sensation, metallosis,  
8 deterioration of the metal components, corrosion on the neck stem, and  
9 reports of significant groin pain, all prior to the installation of the Magnum  
10 in Plaintiff, and failed to disclose such information to Plaintiff and/or his  
11 orthopedic surgeon;  
12  
13 c. Distributor Defendants misrepresented to Plaintiff and/or his orthopedic  
14 surgeon prior to Plaintiff's surgery, that the Magnum's design will reduce  
15 wear and provide higher function for all patients;  
16  
17 d. Distributor Defendants misrepresented to Plaintiff and/or his orthopedic  
18 surgeon that the Magnum is clinically proven to reduce wear when, in fact,  
19 no clinical trials were submitted for approval by the FDA;  
20  
21 e. Distributor Defendants represented Magnum is based on a strong clinical  
22 history and reduces wear compared to traditional hip replacement  
23 components when, in fact, no clinical history was ever provided to the  
24 FDA for approval;  
25  
26 f. Distributor Defendants misrepresented prior to installation in Plaintiff,  
27 that the Magnum is designed to be installed in younger and more active  
28  
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1 patients and will last longer than similar products manufactured by  
2 competitors including plastic products;

3 g. Distributor Defendants failed to disclose to Plaintiff and his orthopedic  
4 surgeon, prior to Plaintiff's surgeries, that independent experts from  
5 around the world were warning the design of the Magnum was flawed;

6 h. Distributor Defendants failed to disclose to Plaintiff and his orthopedic  
7 surgeon that the design of the Magnum and metal used for the Magnum  
8 hip cup was prone to increase wear and caused excessive metal debris;

9 i. Distributor Defendants failed to disclose to Plaintiff and his orthopedic  
10 surgeon the Magnum hip cup failed to obtain bony ingrowth and became  
11 loose.

12 j. Distributor Defendants failed to disclose to Plaintiff and his orthopedic  
13 surgeon that the Magnum causes pseudotumors, adverse tissue reactions,  
14 tissue necrosis, metallosis, ALVAL, and bone necrosis.

15 276. As a direct and proximate result of Distributor Defendants' negligence, Plaintiffs  
16 needlessly suffered injuries and damages as described herein.  
17

18  
19 **TWELFTH CAUSE OF ACTION: MISREPRESENTATION**  
20 **Against All Defendants**  
21

22 277. Plaintiffs incorporate by reference Paragraphs 1 through 167 as though set forth  
23 fully herein.  
24

25 278. As stated above, Defendants, through sales literature, meetings, and verbal  
26 communications, and in the course of their business, made misrepresentations of material facts  
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1 about the Magnum and/or concealed information about the Magnum from Plaintiff and his  
2 orthopedic surgeon prior to Plaintiff's surgeries in 2011 and 2017 including, but not limited to:

- 3           a.     Misrepresenting the Magnum is designed to reduce wear and provide  
4                 higher function for all patients;
- 5           b.     Misrepresenting the Magnum is clinically proven to reduce wear;
- 6           c.     Misrepresenting the Magnum is based on a strong clinical history and  
7                 reduces wear compared to the traditional hip replacement;
- 8           d.     Misrepresenting the Magnum is designed to be installed in younger and  
9                 more active patients and will last longer than its competitors;
- 10          e.     Misrepresenting the success rate of the Magnum;
- 11          f.     Failing to disclose that the design of the Magnum and metal used for the  
12                 Magnum was prone to increased wear and caused excessive metal debris;
- 13          g.     Failing to disclose the Magnum failed to obtain bony ingrowth and became  
14                 loose;
- 15          h.     Failing to disclose that they were aware of and/or witnessed revision  
16                 surgeries in which the Magnum had failed, including becoming loose,  
17                 causing metallosis, pseudotumors, tissue necrosis, bone necrosis, adverse  
18                 tissue reactions, ALVAL and excessive wear and corrosion on the neck  
19                 stem, dislocations, fractures of hardware, loose acetabular components  
20                 and infection; and
- 21          i.     Failing to disclose that orthopedic surgeons were complaining about the  
22                 Magnum and were experiencing difficulty in installing the Magnum.
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1           279. The above representations and/or omissions were material and made with the  
2 intent that Plaintiff and Plaintiff's orthopedic surgeon rely on and were made to persuade and  
3 induce them to choose the Magnum to be surgically implanted in Plaintiff.

4           280. The same representations and/or omissions were made to Plaintiff's orthopedic  
5 surgeon prior to the Magnum being installed in Plaintiff's body.

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

9           282. Defendants made the above representations and/or omissions with the intention of  
10 inducing the Plaintiff and his orthopedic surgeon to purchase and continue to purchase the  
11 Magnum hip replacement components.

12           283. Prior to Plaintiff's surgeries, Plaintiff and his orthopedic surgeon were induced to  
13 act in reliance on Defendants' misrepresentations and/or omissions and in fact purchased the  
14 Magnum and installed the Magnum in the right hip of Plaintiff.

15           284. Upon information and belief, Defendants and/or their sales representative(s) were  
16 present during the surgeries and failed to disclose the falsity of the misrepresentation and/or  
17 omissions set forth herein, and knowingly let a defective product be installed in Plaintiff's body.

18           285. Plaintiff was ignorant of Defendants' misrepresentations and/or omissions.

19           286. Plaintiff and his orthopedic surgeon relied on the truth of Defendants'  
20 representations and/or omissions about the Magnum and had a right to rely on such.

21           287. As a direct and proximate result of Defendants' negligence, Plaintiffs needlessly  
22 suffered injuries and damages as described herein.

1                   **THIRTEENTH CAUSE OF ACTION: LOSS OF CONSORTIUM**  
2                   **Against All Defendants**

3           288. Plaintiff Laura Langford realleges and incorporates herein by reference each and  
4 every allegation contained in the previous paragraphs.

5           289. At all times mentioned, plaintiff Laura Langford was and is the wife of Plaintiff  
6 Gary Langford.

7  
8           290. That as a result of the negligent conduct of the Defendants and DOES 1-25, and  
9 each of them, Plaintiff Laura Langford suffered loss of marital services and consortium damages  
10 due to the injuries to Plaintiff Gary Langford, her husband. Plaintiff Laura Langford is entitled  
11 to recover consortium damages as a result of Defendants and DOES 1-25's negligent, and  
12 intentional and wrongful conduct.  
13

14  
15                   **FOURTEENTH CAUSE OF ACTION: PUNITIVE DAMAGES**  
16                   **Against Biomet Defendants And Cuckler Defendants**

17           291. Plaintiffs incorporate by reference each of the allegations set forth in this  
18 Complaint as though fully set forth herein.  
19

20           292. The acts, conduct, and omissions of Defendants and DOES 1-25, as alleged  
21 throughout this Complaint were malicious, willful, wanton, intentionally, oppressive and  
22 fraudulent. Defendants and DOES 1-25 committed these acts with a conscious disregard for the  
23 rights of Plaintiffs and other Magnum system users and for the primary purpose of increasing  
24 Defendants' profits from the sale and distribution of the Magnum system. Defendants and DOES  
25 1-25 outrageous and unconscionable conduct warrants an award of exemplary and punitive  
26 damages in an amount appropriate to punish and deter such conduct of Defendants and DOES 1-  
27 25 in the future.  
28  
29  
30

1           293. Prior to the manufacturing, sale, and distribution of the Magnum system implanted  
2 in Plaintiff's body, Defendants and DOES 1-25 knew that said product was in a defective  
3 condition and users would experience and did experience severe injuries. Further, Defendants  
4 and DOES 1-25, through their officers, directors, managers, and agents, knew that the product  
5 presented a substantial and unreasonable risk of harm to the public, including Plaintiffs and as  
6 such, Defendants and DOES 1-25 unreasonably subjected consumers to risk of injury from using  
7 the Magnum system  
8

9  
10           294. Despite their knowledge, Defendants and DOES 1-25, acting through their  
11 officers, directors and managing agents, for the purpose of enhancing Defendants' profits,  
12 knowingly and deliberately failed to remedy the known defects in the Magnum system and failed  
13 to warn the public, including Plaintiffs, of the extreme risk of injury occasioned by said defects  
14 inherent in the Magnum system. Defendants and DOES 1-25 and their agents, officers, and  
15 directors intentionally proceeded with the manufacturing, sale, distribution and marketing of the  
16 Magnum system, knowing that these actions would expose users to serious danger in order to  
17 advance Defendants and DOES 1-25's pecuniary interest and monetary profits.  
18

19  
20           295. As a direct and proximate result of Defendants and DOES 1-25's willful, wanton,  
21 careless, reckless, conscious, and deliberate disregard for the safety and rights of consumers  
22 including the Plaintiffs, the Plaintiffs have suffered and will continue to suffer severe and  
23 permanent physical and emotional injuries, as described with particularity, above. Plaintiffs have  
24 endured and will continue to endure pain, suffering, and loss of enjoyment of life; and have  
25 suffered and will continue to suffer economic loss, including incurring significant expenses for  
26 medical care and treatment.  
27  
28  
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30

1           296. Defendants and DOES 1-25's aforesaid conduct was committed with knowing,  
2 conscious, careless, reckless, willful, wanton, and deliberate disregard for the safety and rights  
3 of consumers including Plaintiffs, thereby entitling Plaintiffs to punitive damages in an amount  
4 appropriate to punish Defendants and DOES 1-25 and deter them from similar conduct in the  
5 future.  
6

7  
8                                   **DEMAND FOR JURY TRIAL**  
9

10           297. Plaintiffs demand that a jury be impaneled to hear this case and all causes of action  
11 stated herein and to award such damages as the jury finds to be fair and reasonable under the  
12 circumstances.  
13

14                                   **PRAYER FOR RELIEF**  
15

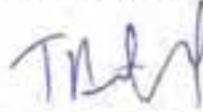
16           WHEREFORE, Plaintiffs, pray for relief and judgment against Defendants as follows:  
17

- 18           (a) For general damages in a sum in excess of the jurisdictional minimum of this  
19 Court;  
20           (b) For medical, incidental, and hospital expenses; both past and future according to  
21 proof;  
22           (c) For Past and future lost wages and loss of income;  
23           (d) For pre-judgment and post-judgment interest as provided by law;  
24           (e) For a full refund of all purchase costs Plaintiff paid for the Magnum system;  
25           (f) For compensatory damages in excess of the jurisdictional minimum of this Court;  
26           (g) For consequential damages in excess of the jurisdictional minimum of this Court;  
27  
28  
29  
30



- 1 (h) For punitive damages in an amount sufficient to deter similar conduct in the  
2 future;  
3 (i) For attorneys' fees, expenses, and costs of this action; and  
4 (j) For such further relief as this Court deems necessary, just and proper.  
5

6 Dated: April 16, 2019



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