IN THE UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF GEORGIA
STATESBORO DIVISION

FILED
Scott L. Poff, Clerk
United States District Court
By wprescott at 2:42 pm, Jun 15, 2018

DOROTHY COEN and WILLIAM COEN,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	Civil Action No. CV618-66
	)	
ZIMMER BIOMET INC. f/k/a ZIMMER, INC. and ZIMMER BIOMET HOLDINGS, INC. f/k/a ZIMMER HOLDINGS, INC.	)	
	)	
Defendants.	)	

COMPLAINT

Plaintiffs DOROTHY COEN and WILLIAM COEN, her spouse, individually, and through their counsel, bring this action against Defendants ZIMMER BIOMET, INC. f/k/a ZIMMER, INC. and ZIMMER BIOMET HOLDINGS, INC. f/k/a ZIMMER HOLDINGS, INC., (collectively referred to as "Zimmer") and allege and state as follows:

NATURE OF THE ACTION

1. This is an action for strict products liability, failure to warn, defective design, manufacturing defect, negligence, breach of express and implied warranties, negligent misrepresentation, and punitive damages brought by Plaintiffs DOROTHY COEN and WILLIAM COEN, her spouse, for injuries arising out of the Zimmer Versys® Hip System.

2. Defendant Zimmer manufactured and supplied to doctors total hip arthroplasty systems known as the Zimmer Versys® Hip System, which was designed to be implanted with either (1) a cobalt-chromium femoral head or (2) a ceramic femoral head.

3. The Zimmer Versys® Hip System utilized with cobalt-chromium femoral heads

created unreasonable risks of harm to Plaintiff DOROTHY COEN.

4. The unreasonable risks of pain, swelling, metallosis, trunnionosis, adverse local tissue reaction, and/or the need for early revision surgical intervention, whether from corrosion, micromotion, fretting, or some other mechanism, renders the Zimmer Versys® Hip System with a metal cobalt-chromium femoral head a defective product.

5. The selection and implantation of the Zimmer Versys® Hip System by Plaintiff's surgeon was a result of the misinformation, marketing, sales, promotion and direction of Zimmer.

JURISDICTION & VENUE

6. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332, because the amount in controversy exceeds Seventy-Five Thousand Dollars ($75,000.00), exclusive of interest and costs, and because there is complete diversity of citizenship between the Plaintiffs and all Defendants.

7. Venue is proper in the United States District Court for the Southern District of Georgia Statesboro Division pursuant to 28 U.S.C. § 1391 because the Defendants promoted, advertised, marketed, distributed, and/or sold the Zimmer Versys® Hip System within this judicial district; because Plaintiff DOROTHY COEN was implanted with the defective Zimmer Versys® Hip System and was thereafter injured by the defective Zimmer Versys® Hip System in this judicial district (Tattnall County); and because Defendants are subject to personal jurisdiction within the State of Georgia.

PARTIES

8. Plaintiffs DOROTHY COEN and WILLIAM COEN were, at all times relevant to this cause of action, citizens and residents of Cleveland, Georgia.

9. Defendant ZIMMER BIOMET, INC., f/k/a ZIMMER INC. ("Zimmer Biomet, Inc.") is, and at all times material hereto was, a corporation organized under the laws of the State of Delaware, with its principal place of business in Indiana. At all times material hereto, Zimmer Biomet, Inc. tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold the Zimmer Hip System in interstate commerce and throughout the State of Georgia; engaged in business in Georgia; and derives substantial revenue from goods sold and used in the State of Georgia.

10. ZIMMER BIOMET HOLDINGS, INC., f/k/a ZIMMER HOLDINGS, INC. ("Zimmer Biomet Holdings, Inc.") is a corporation organized under the laws of the State of Delaware, with its principal place of business in Indiana. At all times material hereto, Zimmer Biomet Holdings, Inc. was the publicly traded holding company that wholly owned and controlled subsidiaries which tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold the Zimmer Versys® Hip System in interstate commerce and throughout the State of Georgia and generated substantial revenue as a result.

11. At all times relevant to this action, Zimmer Biomet, Inc. was a wholly owned subsidiary of Zimmer Biomet Holdings, Inc. On April 24, 2014, Zimmer Holdings, Inc. entered into an agreement to merge with LVB Acquisition, Inc., the parent company of Biomet, Inc. After the merger, Zimmer Holdings, Inc. was renamed Zimmer Biomet Holdings, Inc. and Zimmer, Inc. was renamed Zimmer Biomet, Inc.

12. Defendants Zimmer Biomet, Inc. and Zimmer Biomet Holdings, Inc., shall also hereinafter be collectively referred to as "Defendants," "Zimmer," and/or "Defendants Zimmer."

13. At all relevant times to this action, each of the Defendants and their directors and officers acted within the scope of their authority of each Defendant and on behalf of each other Defendant. At all times relevant to this action, Defendants possessed a unity of interest between themselves and Zimmer, and they exercised control over its subsidiaries and affiliates. As such, the Defendants are each individually, as well as jointly and severally, liable to Plaintiffs for Plaintiffs' injuries, losses, and damages as described herein.

GENERAL FACTUAL ALLEGATIONS

14. Zimmer were the designers, manufacturers, and suppliers of the Zimmer Versys® Hip System and related components and were in the business of putting medical devices on the market.

15. Zimmer warranted the Zimmer Versys® Hip System and placed the device into the United States stream of commerce.

16. Before it set out to design the Zimmer Versys® Hip System, Zimmer knew of the dangers to human beings if cobalt-chromium metal debris from its products were released into the body through corrosion, micromotion, and/or fretting.

17. Before placing the Zimmer Versys® Hip System on the market, Zimmer was required to mitigate risks of the product, including any element of the design that created toxic levels of corrosion and debris that could result in pain, swelling, pseudotumor formation, osteolysis, instability, dislocation, metallosis, trunnionosis, adverse tissue reaction and/or the need for early surgical revision in patients-consumers.

18. The Zimmer Versys® Hip System taper is a 12/14 size with threading on the taper. This threading can be described as shallow grooves on the portion of the taper that articulates with the head. This threading on the taper is used to comply with the requirements of the

manufacturer of ceramic head option, CeramTec.

19. The significance of the Zimmer Versys® Hip System taper threading is (1) it protects ceramic heads and (2) provides an interface at the junction with a metal head which is much more likely to produce wear and debris under fretting conditions. The threads were not designed to enhance the performance of metal heads.

20. The decision to allow the use of metals and CoCr heads (rather than ceramic heads) in the Zimmer Versys® Hip System created an unreasonable risk and made it defective.

21. The concept that that corrosion might occur at the head-neck taper junction of a total hip prosthesis was first described in the early 1980s. When Zimmer was designing the Zimmer Versys® Hip System this concept had to be a consideration.

ZIMMER VERSYS® HIP SYSTEM

22. The Zimmer Versys® Hip System implanted into Plaintiff DOROTHY COEN's left hip primarily consisted of four component parts: a) the Versys® Fiber Metal Midcoat Femoral Stem which was made of titanium alloy, b) the Versys® Hip System Femoral Head which was made of cobalt-chromium alloy which was affixed to the trunnion of the femoral stem, c) the Trabecular Metal Cluster Shell which was made of titanium alloy, and d) the Longevity Liner which was made of highly cross-linked polyethylene. Plaintiff's Zimmer Versys® Hip System is referred to as a "metal-on-polyethylene" bearing system.

23. In designing the Zimmer Versys® Hip System, Zimmer knew that the use of metal alloys as well as taper size and geometry, trunnion surface finish, and flexural rigidity contribute to causing fretting and corrosion at the femoral head-neck/stem taper interface.

24. Mechanically assisted crevice corrosion ("MACC") has been identified as a cause for symptomatic implant failure in metal-on-polyethylene hip devices. MACC produces cobalt

and chromium ions, fretting byproducts, and corrosive debris that can lead to adverse local tissue reaction.

25. Adverse local tissue reaction, also referred to as aseptic lymphocyte dominated vasculitis-associated lesions ("ALVAL"), represents a distinctive periprosthetic inflammatory reaction accompanied by extensive necrosis in the soft tissue-envelope of the hip. Early detection of adverse local tissue reaction is important because as time from onset of MACC to revision surgery increases, tissue damage may worsen.

FAILURE TO WARN PHYSICIANS OF THE DANGERS ASSOCIATED WITH THE ZIMMER VERSYS® HIP SYSTEM

26. Zimmer marketed its hip implants, including the Zimmer Versys® Hip System, to orthopedic surgeons and hospitals rather than end-user patients.

27. Zimmer had the ability to inform surgeons or hospitals of developing problems or defects in its devices through e-mail, letter, recalls, warnings in product inserts and/or through its product representative(s), who works directly with the surgeon.

28. The mechanical environment of the junction place the Zimmer Versys® Hip System at increased risk for failure from pain, swelling, pseudotumor formation, metallosis, adverse local tissue reaction, synovitis, osteolysis, and/or dislocation, resulting from excessive wear debris, fretting, corrosion, and recurrent repassivation.

29. The fretting process (mechanical micromotion) is strongly influenced by distribution of pressure and force at the junctions, rendering these junctions vulnerable to accelerated generation of metal wear debris and corrosion.

30. Each interface introduces a contributing source for metal wear particular and debris generation. These junctions exponentially compound and accelerate the wear debris

generation process.

31. Corrosion is time-sensitive and accelerated with mechanical stresses. This phenomenon was known to Zimmer, or should have been known by Zimmer, at all times relevant to the design, manufacture, marketing, and sale of the Zimmer Versys® Hip System.

32. At the time of design, manufacture, testing, and marketing, Zimmer knew or should have known, combinations of metal alloys at a junction, such as the metal CoCr heads and titanium neck/stem junctions of the Zimmer Versys® Hip System, generate excessive fretting, corrosion, and metal wear debris.

33. Zimmer did not inform or warn, and is still not informing or warning physicians or consumers, either through its sales representatives, correspondence, advertising, or package inserts that:

a. Selection of a metal CoCr head rather than a ceramic head to pair with the titanium neck/stem significantly increases the risk of toxic amounts of corrosion and metal debris which might cause pain, swelling, metallosis, trunnionosis, tissue necrosis, adverse local tissue reaction, osteolysis, dislocation, and/or the need for early revision;

b. Upon information and belief, Zimmer's pre-market corrosion testing, if any, was inadequate as it pertains to the Zimmer Versys® Hip System; and/or

c. Upon information and belief, Zimmer's Spectrum Accelerated Corrosion Fatigue ("SACF") Testing, if any, was inadequate as it pertains to the Zimmer Versys® Hip System.

34. Zimmer never performed any clinical trials and/or studies prior to marketing the Zimmer Versys® Hip System.

35. Zimmer did not fully and/or adequately test the configuration utilizing CoCr femoral heads and titanium neck/stem junctions that were implanted into Plaintiff.

36. Zimmer continues to market the CoCr heads for use with the titanium neck/stem in the Zimmer Versys® Hip System.

37. Reassurances of device safety were made through direct promotional contact by Defendants' sales representatives and distributors, through word-of-mouth from Zimmer's physician/technical consultants, and/or through industry targeted promotional materials.

38. Despite these reassurances, the defective design and manufacture of the Zimmer Versys® Hip System, with a CoCr femoral head, generates excessive fretting and corrosion occurring at the head-neck/stem taper junctions. The fretting and corrosion generates toxic metal debris, metal ions, and other chemical byproducts which are released into the surrounding tissues. These metal debris, metal ions, and byproducts destroy the surrounding tissue and bone, often causing pseudotumors and other metal related conditions. The release of metal debris and metal ions also causes systemic exposure to toxic metallic elements, often reflected in elevated blood serum and/or urine testing levels.

39. Defendants were aware of the problems at the time that they designed, manufactured, marketed, distributed, and/or sold the Zimmer Versys® Hip System. Nonetheless, Defendants employed the design in its Zimmer Versys® Hip System in reckless disregard for the safety of patients, including Plaintiff.

40. Moreover, despite direct knowledge of significant adverse events reported by patients and physicians, as well as awareness of failures that have been reported in the literature and published in national registries, Defendants have continued to market the Zimmer Versys® Hip System as being safe and effective with the CoCr femoral head.

41. From the time that Defendants first began selling the Zimmer Versys® Hip

System in the United States through today, its product labeling and product information failed to contain adequate information, instructions, and warnings concerning implantation of the product, specifically with the use of a CoCr femoral head, and its increased risks of fretting and corrosion.

42. The problems with the Zimmer Versys® Hip System are similar in nature to the issues that gave rise to Stryker Orthopedics' recent recall of the LFIT® Anatomic CoCr V40™ Femoral Heads on August 29, 2016. Both the LFIT® Anatomic CoCr V40™ Femoral Heads and the Versys Femoral Heads are made of cobalt-chromium and both are mated with metal alloy stems. Stryker's Urgent Medical Device Recall Notification states that the company initiated the worldwide recall after receiving higher than expected complaints of "taper lock failure" which could result in numerous potential hazards including but not limited to excessive metal debris, excessive wear debris, disassociation of the femoral head from the hip stem and fractured hip stem trunnion leading to adverse local tissue reaction, implant loosening, loss of mobility, and pain requiring revision surgery.

PLAINTIFF'S USE OF THE PRODUCT

43. On July 28, 2010, a defectively designed, manufactured and marketed Zimmer Versys® Hip System left the hands of Defendants in its defective condition, was delivered into the stream of commerce, and was implanted in Plaintiff DOROTHY COEN's left hip at The Doctors Hospital of Tattnall in Reidsville, Georgia. Plaintiff was implanted on the left hip with the following components:

a. Versys® 12/14 Tapered Cobalt-Chromium 36mm +0 femoral head,

b. Versys® Fiber Metal Midcoat Femoral Stem, Size 13,

c. Trabecular Metal Cluster® 50mm shell/standard, and,

d. Longevity® Poly Acetabular Liner.

44. Following Plaintiff's index surgery, Plaintiff experienced increasing pain and loss of function in her hip.

45. Diagnostic imaging revealed an enlarged soft tissue mass in the region of the Zimmer hip implant.

46. As a direct and proximate result of Defendants defective design, manufacture, marketing, distribution, and/or sale of the Zimmer Versys® Hip System and placement of the defective Device into the stream of commerce, Plaintiff DOROTHY COEN underwent revision surgery to her left hip at Emory University Hospital in Atlanta, Georgia on or around January 2, 2018 by Dr. Shervin Oskouei. Intraoperative findings included: "this was all necrotic muscle which involved her gluteus medius or minimus, a lot of her gluteus maximus and her vastus lateralis including her iliopsoas"; "this was 1 of the worst cases of muscular damage that I have seen intraoperatively" and "there was a tremendous amount of black corrosion around her neck morse taper." Further, Dr. Oskouei "used a ceramic head to avoid further metal corrosion issues at the neck taper."

47. Following her revision surgery, Plaintiff DOROTHY COEN suffered and continues to suffer from an ongoing infection requiring placement of an antibiotic spacer.

48. The mechanism of failure in Plaintiff's devices was exactly the same mechanism of failure that Defendants had marketed and warranted would not occur because of the Zimmer Versys® Hip System design and composition. It was also the same failure mechanism that the medical and scientific community had been studying and documenting in modular device designs since the 1990s,

49. Moreover, the symptoms and findings associated with modular device failures that have been reported in the literature are identical to those suffered by Plaintiff.

50. As a direct and proximate result of Defendants' defective design, manufacturing, marketing, distribution, sale, and warnings, of the defective Zimmer Versys® Hip System, Plaintiff has suffered and continues to suffer both injuries and damages, including, but not limited to: past, present and future physical and mental pain and suffering; physical disability, and past, present and future, medical, hospital, rehabilitative and pharmaceutical expenses, and other related damages.

THE FDA'S 510(k) CLEARANCE PROCESS

51. The 510(k) clearance process refers to Section 510(k) of the Medical Device Amendments of 1976 (hereafter "MDA") of the Federal Food, Drug and Cosmetic Act. Under this process, device manufacturers are only required to notify the FDA at least 90 days before they market a device claimed to be "substantially equivalent" to a device the FDA approved for sale prior to 1976, when the MDA was enacted.

52. No clinical testing is required under this process.

53. Subsequent amendments to the MDA allowed for 510(k) clearance for products deemed "substantially equivalent" to post-MDA, 510(k) cleared devices.

54. Through this domino effect, devices deemed "substantially equivalent" to devices previously deemed "substantially equivalent" to devices approved for sale by the FDA prior to 1976 could be sold to patients in a matter of 90 days without any clinical testing.

55. Clearance for sale under the 510(k) process does not equate to FDA approval of the cleared device.

56. In 2012, at the request of the FDA, the National Institute of Health (hereafter "NIH") conducted a thorough review of the 510(k) process, coming to the following major conclusions:

> **The 510(k) clearance process is not intended to evaluate the safety and effectiveness of medical devices with some exceptions. The 510(k) process cannot be transformed into a pre-market evaluation of safety and effectiveness so long as the standard for clearance is substantial equivalence to any previously cleared device.**

57. The NIH explained, "The assessment of substantial equivalence does not require an independent demonstration that the new device provides a 'reasonable assurance of safety and effectiveness.'" Further, the NIH even pointed out that the classification of predicate devices approved for sale prior to the 1976 MDA "did not include any evaluation of the safety and effectiveness of individual medical devices . . . Thus is common for devices to be cleared through the 510(k) program by being found substantially equivalent to devices that were never individually evaluated for safety and effectiveness, either through the original device classification program or through the 510(k) process."

58. Zimmer cleared the Versys® Hip System and its related components, under a process used by the United States Food and Drug Administration known as the 510(k) Premarket Notification. Under Section 510(k) of the Federal Food, Drug and Cosmetic Act, a medical device does not have to go through the rigors of a clinical study to gain approval by the FDA. Instead, the device is supposed to demonstrate substantial equivalence to a predicate medical device.

59. The first components of the Zimmer Versys® Hip System were cleared for sale in the United States according to Section 510(k) in November 2003.

CAUSES OF ACTION

FIRST CAUSE OF ACTION
(AGAINST ALL DEFENDANTS)

Strict Products Liability – Unreasonably Dangerous Design

60. Plaintiffs incorporate by reference paragraphs 1 through 59 of this Complaint, as if fully set forth herein and further allege as follows:

61. The Zimmer Defendants had a duty to design, manufacture, place into the stream of commerce, distribute, market, promote, and sell, the specific Zimmer Versys® Hip System so that it was neither defective nor unreasonably dangerous when put to the use for which it was designed, manufactured, distributed, marketed, and sold.

62. On and prior to July 2010, the Zimmer Defendants were engaged in the business of designing, manufacturing, marketing, distributing, and selling orthopedic hip implants and did design, manufacture, distribute, market, and sell the Zimmer Versys® Hip System.

63. The Zimmer Defendants did in fact design and manufacture, and engaged in selling, distributing, supplying and/or promoting the Zimmer Versys® Hip System to Plaintiff DOROTHY COEN and her implanting physician.

64. Defendants expected the Zimmer Versys® Hip System they were selling, distributing, supplying, manufacturing, and/or promoting to reach, and it did in fact reach, implanting physicians and consumers in the state of Georgia, including Plaintiff DOROTHY COEN and her implanting physician, without substantial change in condition.

65. Plaintiff is in the class of persons that Defendants should reasonably foresee as being subject to the harm caused by the defectively designed the Zimmer Versys® Hip System, insofar as Plaintiff was the type of person for whom the hip implants were intended to be used.

66. At the time the Zimmer Versys® Hip System left the Defendants' possession and at the time the Zimmer Versys® Hip System entered the stream of commerce in the state of Georgia, it was in an unreasonably dangerous or defective condition. These defects include, but

are not limited to, the following:

a. the Zimmer Versys® Hip System was not reasonably safe as intended to be used;

b. the Zimmer Versys® Hip System had an inadequate design for the purpose of hip replacement;

c. the Zimmer Versys® Hip System contained unreasonably dangerous design defects, including an inherently unstable and defective design paired with a Cobalt-Chromium femoral head, which resulted in unreasonably high metal wear debris, corrosion, fretting, and probability of early failure;

d. the Zimmer Versys® Hip System's unstable and defective design resulted in a hip prosthesis which had risks which exceeded the benefits of the medical device;

e. the Zimmer Versys® Hip System was not appropriately or adequately tested before its distribution; and

f. the Zimmer Versys® Hip System had an unreasonably high propensity for corrosion, fretting and fatigue under normal and expected use of the Zimmer Versys® Hip System.

67. At the time of the Zimmer Defendants' initial design, manufacture, and sale of the Zimmer Versys® Hip System, a feasible, alternative safer design for the Zimmer Versys® Hip System was known and available, including, but not limited to, a design that utilized a ceramic femoral head and monoblock design. A ceramic head would reduce and/or eliminate metal debris and particles.

68. At the time of and subsequent to the Zimmer Defendants' initial design, manufacture, marketing, and sale of the Zimmer Versys® Hip System, including prior to the time of Plaintiff DOROTHY COEN's hip implant surgery, Defendants had the ability to eliminate the unsafe character of the Zimmer Versys® Hip System without impairing its usefulness.

69. Had the Zimmer Defendants properly and adequately tested the Zimmer Versys® Hip System, they would have discovered that the components, paired with a cobalt-chromium

femoral head, generated excessive metal wear caused by the surface contact of the metal articulating components, resulting in pain, swelling, metallosis, tissue necrosis, bone necrosis, and a host of other maladies.

70. The Zimmer Versys® Hip System, manufactured, distributed, marketed, promoted, and sold by the Zimmer Defendants, was, therefore, defective in design or formulation in that, when it left the hands of Defendants, the foreseeable risk of harm from the product exceeded or outweighed the benefit or utility of the consumer would expect, and/or it failed to comply with federal requirements for such medical devices.

71. At all times relevant hereto, Plaintiff and Plaintiff's healthcare providers used the Zimmer Versys® Hip System for its intended or reasonably foreseeable purpose.

72. At all times relevant hereto, the Zimmer Versys® Hip System was dangerous, unsafe, and defective in design including but not limited to its tendency to: (a) create dangerous and harmful metal debris in the patient's body; (b) cause pain; (c) inhibit mobility; and (d) require revision surgery with predictable cascading complications.

73. Defendants knew or should have known of the unreasonably dangerous and serious risks associated with the design of the Zimmer Versys® Hip System.

74. Such risks were scientifically knowable to Defendants.

75. Defendants knew or should have known of the dangers.

76. Defendants either performed inadequate evaluation and testing, kept themselves willfully blind to the dangers, hid the dangers from physicians and patients, or some combination of the three.

77. As a direct, legal, and proximate result of Defendants' dangerous design, Plaintiff sustained injuries as set forth above.

78. Defendants' dangerous design and failure to adequately test contributed to cause the injuries suffered by Plaintiff.

79. As a direct and proximate result of Defendants' wrongful conduct, including the defective and dangerous design and inadequate warnings of the Zimmer Versys® Hip System, Plaintiff has sustained and will continue to sustain severe and debilitating injuries, economic loss, and other damages including, but not limited to, cost of medical care, rehabilitation, lost income, permanent instability, and loss of balance, immobility, and pain and suffering, for which he is entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

SECOND CAUSE OF ACTION
(AGAINST ALL DEFENDANTS)

Strict Products Liability – Failure to Warn

80. Plaintiffs incorporate by reference paragraphs 1 through 79 of this Complaint, as if fully set forth herein and further allege as follows:

81. Defendants researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and otherwise released into the stream of commerce the Zimmer Versys® Hip System, in the course of same, directly advertised or marketed the product to the FDA, health care professionals, and consumers, including the Plaintiff, or persons responsible for consumers, and therefore had a duty to warn of the risks associated with the use of the Zimmer Versys® Hip System.

82. Defendants distributed and sold the Zimmer Versys® Hip System in its original form of manufacture, which included the defects described herein.

83. The Zimmer Versys® Hip System was defective and unreasonably dangerous when it left the possession of Defendants because it contained an absence of warnings or limitations on when such device should be selected over safer alternatives.

84. The Zimmer Versys® Hip System was defective and unreasonably dangerous when it left the possession of Defendants because it contained an absence of warnings alerting the medical community and patients on the dangerous risks associated with the Zimmer Versys® Hip System when used for its intended and reasonably foreseeable purpose.

85. The risks associated with the Zimmer Versys® Hip System when used for its intended and reasonably foreseeable purpose, include but are not limited to: (a) the creation of dangerous and harmful metal debris in the patient's body, (b) pain, (c) mobility inhibition, and (d) likelihood of revision surgery with predictable cascading complications.

86. The Zimmer Versys® Hip System was expected to and did reach Plaintiff DOROTHY COEN and her implanting physician, in the state of Georgia, without substantial change or adjustment in its condition as manufactured and sold by Defendants.

87. The Zimmer Versys® Hip System designed, developed, tested, manufactured, distributed, promoted, marketed, and/or sold or otherwise placed into the stream of commerce by Defendants was in a dangerous and defective condition and posed a threat to any user or consumer of the Zimmer Versys® Hip System.

88. At all times relevant hereto, Plaintiff DOROTHY COEN was a person the Defendants should have considered to be subject to the harm caused by the defective nature of the Zimmer Versys® Hip System.

89. Defendants' Zimmer Versys® Hip System was implanted into Plaintiff DOROTHY COEN and used in the manner for which it was intended.

90. This use has resulted in severe physical, financial, emotional and other injuries to Plaintiff DOROTHY COEN.

91. Defendants failed to adequately warn health care professionals and the public, including Plaintiff and her prescribing physician, of the true risks of the Zimmer Versys® Hip System, including that the Zimmer Versys® Hip System was susceptible to micromotion, fretting, and corrosion at the junction, generating significant and toxic amounts of metal wear debris and corrosive byproducts in patients, causing severe pain and injury, and requiring further treatment, including revision surgeries and/or hip replacements.

92. Defendants failed to timely and reasonably warn of material facts regarding the safety and efficacy of the Zimmer Versys® Hip System. Had they done so, proper warnings would have been heeded and no health care professional, including Plaintiff's physician, would have used the Zimmer Versys® Hip System, or no consumer, including Plaintiff, would have purchased and/or used the Zimmer Versys® Hip System.

93. Defendants failed to timely and reasonably provide adequate instructions and training concerning safe and effective use of the Zimmer Versys® Hip System.

94. The Zimmer Versys® Hip System, which was researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and otherwise released into the stream of commerce by Defendants, was defective due to inadequate post-marketing warnings and/or instruction because, after Defendants knew or should have known there was reasonable evidence of an association between the Zimmer Versys® Hip System components and the development of corrosion, metal fatigue, failure, micromotion, and/or release of significant amounts of metal debris and/or ions, causing serious injury and pain, Defendants failed to provide adequate warnings to health care professionals and the consuming

public, including Plaintiff, and continued to aggressively promote the Zimmer Versys® Hip System.

95. The Zimmer Versys® Hip System, which was researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and otherwise released into the stream of commerce by Defendants, was defective due to inadequate post-marketing warnings and/or instruction regarding the increased risk of failure of the Zimmer Versys® Hip System resulting in revision surgery while knowing that a safer alternative design including, the use of a ceramic femoral head and monoblock stem components existed.

96. Defendants failed to perform or otherwise facilitate adequate testing, failed to reveal and/or concealed testing and research data, and selectively and misleadingly revealed and/or analyzed testing and research data.

97. Plaintiff DOROTHY COEN and her physician, used the Zimmer Versys® Hip System for its intended purpose, i.e., hip replacement.

98. Plaintiff DOROTHY COEN could not have discovered any defect in the Zimmer Versys® Hip System through the exercise of due care.

99. Defendants, as designers, manufacturers, distributors, promoters, marketers, and/or sellers of medical devices are held to the level of knowledge of experts in their field.

100. Neither Plaintiff DOROTHY COEN nor her implanting physician had substantially the same knowledge about the Zimmer Versys® Hip System as Defendants.

101. Defendants reasonably should have known the Zimmer Versys® Hip System was unsuited for active individuals such as Plaintiff DOROTHY COEN.

102. The warnings and instructions provided with the Zimmer Versys® Hip System and through Defendants and/or its representatives did not adequately educate and train medical

providers on the risk of side effects, or the cost-benefit analysis necessary for justified use of this product versus safer alternative designs.

103. Defendants had a continuing duty to warn the medical community and public, including Plaintiff and Plaintiff's healthcare providers, of the potential risks and increased failure rates or propensity for failure associated with the Zimmer Versys® Hip System.

104. As a direct and proximate result of Defendants' failure to adequately communicate a warning and/or failure to provide an adequate warning and other wrongful conduct as set forth herein, Plaintiff DOROTHY COEN has sustained and will continue to sustain severe physical injuries, severe emotional distress, mental anguish, economic losses and other damages, as set forth herein.

105. As a direct result of Defendants' failure to warn and/or inadequate warning and their other tortious conduct, Plaintiff DOROTHY COEN has suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

106. As a direct and proximate result of Defendants' failure to warn and/or inadequate warning and their other tortious conduct, as set forth herein, Plaintiff DOROTHY COEN has suffered and will continue to suffer injuries, damages and losses, and is entitled to compensatory damages in an amount to be determined by the trier of fact.

THIRD CAUSE OF ACTION
(AGAINST ALL DEFENDANTS)

Strict Products Liability – Manufacturing Defect

107. Plaintiffs incorporate by reference paragraphs 1 through 106 of this Complaint, as if fully set forth herein and further allege as follows:

108. Defendants designed, developed, manufactured, tested, packaged, advertised, promoted, marketed, distributed, labeled, and/or sold the Zimmer Versys® Hip System, in a condition which rendered it unreasonably dangerous due to its propensity to result in early failure of the device. The subject product was unreasonably dangerous in construction or composition.

109. The Zimmer Versys® Hip System manufactured and/or supplied by Defendants was defective in manufacture, construction, or composition in that, when it left the hands of Defendants, it deviated in a material way from Defendants' manufacturing performance standards and/or it differed from otherwise identical products manufactured to the same design formula. Defendants knew or should have known that the Zimmer Versys® Hip System could fail early in patients therefore causing pain and suffering, debilitation and the need for revision surgeries to replace the device with the attendant risks of complications and death from such further surgeries, Defendants continued to market the Zimmer Versys® Hip System as a safe and effective hip replacement system.

110. As a direct and proximate result of the use of the subject product as manufactured, designed, sold, supplied and introduced into the stream of commerce by Defendant, Plaintiff suffered harm, damages and economic loss as previously described and will continue to suffer such harm, damages and economic loss in the future.

FOURTH CAUSE OF ACTION
(AGAINST ALL DEFENDANTS)

Negligence

111. Plaintiffs incorporate by reference paragraphs 1 through 110 of this Complaint, as if fully set forth herein and further allege as follows:

112. While the focus of Plaintiff's strict liability claims (Counts I-III) is on the condition of the product, the focus of Plaintiff's negligence claim is instead on Defendants' conduct.

113. Zimmer Defendants had a duty to exercise reasonable care in the design, formulation, manufacture, testing, quality assurance, quality control, labeling, and/or warning of the Zimmer Versys® Hip System, including a duty to assure that their products did not pose a significantly increased risk of bodily harm and adverse events.

114. Zimmer Defendants failed to exercise ordinary care in the design, formulation, manufacture, testing, quality assurance, quality control, labeling, and warning of the Zimmer Versys® Hip System devices because they knew or should have known these products caused significant bodily harm and were not safe for use by consumers.

115. Zimmer Defendants failed to exercise ordinary care in the sale, marketing, promotion, and distribution of the Zimmer Versys® Hip System devices because they knew or should have known these products caused significant bodily harm and were not safe for use by consumers.

116. Zimmer Defendants failed to exercise ordinary care in testing the Zimmer Versys® Hip System prior to marketing, sale, and distribution of the Zimmer Versys® Hip System.

117. At all relevant times, Defendants had a duty to exercise reasonable care in the design, formulation, testing, manufacture, marketing, sale, and distribution of the Zimmer Versys® Hip System, including a duty to ensure that the Zimmer Versys® Hip System did not pose a significantly increased risk of bodily injury to its users.

118. Defendants had a duty to exercise reasonable care in the advertising and sale of

the Zimmer Versys® Hip System, including a duty to warn Plaintiff and other consumers, of the dangers associated with the Zimmer Versys® Hip System that were known or should have been known to Defendants at the time of the sale of the Zimmer Versys® Hip System to the Plaintiff.

119. Defendants failed to exercise reasonable care in the design, testing, manufacture, marketing, sale, and distribution of the Zimmer Versys® Hip System because Defendants knew or should have known that the Zimmer Versys® Hip System had a propensity to cause serious injury, including adverse local tissue reaction, pseudotumor formation, metal debris, corrosion, metal ions, excessive wear, tissue necrosis, pain, swelling, metal ion release, loosening of the implants, bone loss, decreased range of motion, diminished mobility, and revision surgeries.

120. Defendants failed to exercise ordinary care in the labeling of the Zimmer Versys® Hip System and failed to issue adequate pre-marketing or post-marketing warnings to doctors and the general public, including Plaintiff, regarding the risk of serious injury, including adverse local tissue reaction, pseudotumor formation, metal debris, corrosion, metal ions, excessive wear, tissue necrosis, pain, swelling, metal ion release, loosening of the implants, bone loss, decreased range of motion, diminished mobility, and revision surgeries.

121. Defendants knew or should have known that Plaintiff could foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care as described above.

122. Defendants breached their duty of reasonable care to Plaintiff by failing to exercise due care under the circumstances as follows:

a. Failing to use due care in the development, design, formulation, manufacturing, labeling, testing, assembly, marketing, advertising, promotion, inspection, sale, and/or distribution of the Zimmer Versys® Hip System, and/or to utilize and/or implement reasonably safe designs for them;

b. At all times relevant hereto, Defendants knew or should

have known that the design of the Zimmer Versys® Hip System was generating the potential for metal on metal problems, vulnerabilities, and injuries;

c. Defendants failed to perform sufficient clinical trials and other pre-marketing evaluations to determine risk and efficacy of the Zimmer Versys® Hip System;

d. Such testing would have revealed the increased risk of failure and tendency to cause significant corrosion, metal wear debris, metal byproduct release, resulting in necrosis, pain, swelling, adverse local tissue reaction, trunnionosis, and/or metallosis;

e. A reasonable manufacturer under the same or similar circumstances would have conducted additional testing and evaluation of the Zimmer Versys® Hip System before placing it into the stream of commerce;

f. A reasonable manufacturer under the same or similar circumstances would have conducted adequate testing of all junctions coupled with the cobalt-chromium femoral head and evaluation of the Zimmer Versys® Hip System before placing it into the stream of commerce;

g. A reasonable manufacturer under the same or similar circumstances would have required that significant information be provided to physicians regarding the risks associated with foreseeable metal on metal problems stemming from the design;

h. At all times relevant hereto, Defendants knew or should have known of the serious complications and high failure rate associated with the Zimmer Versys® Hip System;

i. Failing to provide adequate and proper warnings to the public and to Plaintiff of the dangerous propensities of the Zimmer Versys® Hip System when used in a reasonably foreseeable manner;

j. Failing to conduct adequate post marketing surveillance;

k. Failing to design, formulate, manufacture, and incorporate or to reformulate the Zimmer Versys® Hip System with reasonable safeguards and protections against the type of injury and damage suffered by Plaintiff when used in a reasonably foreseeable manner;

l. Failing to adequately prevent, identify, mitigate, and fix defective designs and hazards associated with the Zimmer Versys® Hip System in accordance with good design practices;

m. Failing to notify and warn the public including Plaintiff of reported incidents involving injury, etc., and the negative health effects attendant to the use of the Zimmer Versys® Hip System, thus misrepresenting the safety of the product;

n. Failing to make timely and adequate corrections to the manufacture, design, and formulation of the Zimmer Versys® Hip System so as to prevent and/or minimize the problems suffered by the Zimmer Versys® Hip System use;

o. Despite its knowledge of these risks, Defendants continued to promote and market the device; and,

p. Being otherwise careless, reckless, and negligent.

123. Despite knowing or having reason to know of the risks, Defendants did not (1) perform additional testing, (2) investigate the risks, (3) suspend sales or distribution, (4) warn physicians or patients of the propensity for the Zimmer Versys® Hip System to cause or create significant corrosion, metal wear debris, metal byproduct release, resulting in necrosis, pain, swelling, dislocation, osteolysis, pseudotumor formation, adverse local tissue reaction, trunnionosis, metallosis, and/or need for early surgical revisions.

124. As a direct and proximate result of Defendants' acts and omissions, including their failure to exercise ordinary care in the design, formulation, testing, manufacture, sale, labeling, warnings, and distribution of the Zimmer Versys® Hip System, Plaintiff was implanted with the Zimmer Versys® Hip System and suffered severe and debilitating injuries, economic loss, and other damages, including but not limited to, cost of medical care, rehabilitation, lost income, permanent instability and loss of balance, immobility, and pain and suffering, for which she is entitled to compensatory and equitable damages and declaratory relief in an amount to be

proven at trial.

FIFTH CAUSE OF ACTION
(AGAINST ALL DEFENDANTS)

Negligent Misrepresentation

125. Plaintiffs incorporate by reference paragraphs 1 through 124 of this Complaint, as if fully set forth herein and further allege as follows:

126. Prior to the Plaintiff receiving the Zimmer Versys® Hip System, Defendants misrepresented that the Zimmer Versys® Hip System was a safe and effective total hip replacement system.

127. In the exercise of reasonable care, Defendants should have known that the Zimmer Versys® Hip System failed to comply with federal requirements for safe design and manufacture and/or was in other ways out of specification, yet they negligently misrepresented to Plaintiff DOROTHY COEN and/or her physician that their device was safe and met all applicable design and manufacturing requirements.

128. Defendants failed to disclose material facts regarding the safety and efficacy of the Zimmer Versys® Hip System utilizing a CoCr femoral head, including information regarding increased risk of failure, harmful side-effects, increased risk of revision surgeries, and lack of adequate testing.

129. Defendants had a duty to provide Plaintiff, physicians, and other consumers with true and accurate information and warnings of any known risks and harmful side effects of the medical devices they marketed, distributed, and sold.

130. Defendants knew or should have known, based on prior experience, adverse event reports, studies, and knowledge of the efficacy and safety failures associated with the Zimmer

Versys® Hip System, that their representations regarding the Zimmer Versys® Hip System were false, and that they had a duty to disclose the dangers associated with the devices.

131. Plaintiff and her physician reasonably relied to Plaintiff's detriment upon Defendants' misrepresentations and material omissions in their marketing, advertisements, and promotions concerning the quality and safety of the Zimmer Versys® Hip System. Plaintiff and her physicians reasonably relied upon Defendants' representations that the Zimmer Versys® Hip System was of high quality and safe for implantation into her body.

132. Defendants made the representations and failed to disclose the material facts with the intent to induce consumers, including the Plaintiff, and the medical community, to act in reliance by purchasing the Zimmer Versys® Hip System with a CoCr femoral head.

133. Defendants' representations and nondisclosures regarding the safety and efficacy of the Zimmer Versys® Hip System was the direct and proximate cause of Plaintiff's injuries.

134. Defendants' conduct, as described above, was reckless. Defendants risked the lives of consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, re-label, warn, or inform the unsuspecting consuming public. Defendants' reckless conduct warrants an award of punitive damages.

135. Plaintiff DOROTHY COEN and/or her physician justifiably relied to their detriment upon Defendants' misrepresentations and omissions in their marketing, advertisements, promotions and labeling concerning these products.

136. Plaintiff DOROTHY COEN and/or her physician justifiably relied upon Defendants' representations that the Zimmer Versys® Hip System was safe for use in persons such as Plaintiff DOROTHY COEN.

137. As a direct and proximate result of Defendants' negligent misrepresentations and/or omissions regarding the Zimmer Versys® Hip System, Plaintiff DOROTHY COEN used the Zimmer Versys® Hip System and has suffered serious physical injury, harm, damages, and economic loss and will continue to suffer such harm, damages, and economic loss in the future.

138. As a direct and proximate result of Defendants' negligent misrepresentations, Plaintiff DOROTHY COEN has suffered and will continue to suffer injuries, damages and losses, and is entitled to compensatory damages in an amount to be determined by the trier of fact.

SIXTH CAUSE OF ACTION
(AGAINST ALL DEFENDANTS)

Breach of Express Warranty

139. Plaintiffs incorporate by reference paragraphs 1 through 138 of this Complaint, as if fully set forth herein and further allege as follows:

140. Defendants advertised, labeled, marketed, and promoted the Zimmer Versys® Hip System, representing the quality to health care professionals, the FDA, Plaintiff, and the public in such a way as to induce its purchase or use, thereby making an express warranty that the Zimmer Versys® Hip System would conform to the representations. More specifically, Defendants represented that the Zimmer Versys® Hip System was safe and effective, that it was safe and effective for use by individuals such as Plaintiff, and/or that it was safe and effective to treat Plaintiff's condition.

141. The representations, as set forth above, contained or constituted affirmations of fact or promises made by the seller to the buyer which related to the goods and became part of the basis of the bargain creating an express warranty that the goods shall conform to the

affirmations of fact or promises.

142. The Zimmer Versys® Hip System did not conform to the representations made by Defendants in that the Zimmer Versys® Hip System was not safe and effective, was not safe and effective for use by individuals such as Plaintiff, and/or was not safe and effective to treat in individuals, such as Plaintiff.

143. At all relevant times, Plaintiff used the Zimmer Versys® Hip System for the purpose and in the manner intended by Defendants.

144. Plaintiff and Plaintiff's physicians, by the use of reasonable care, could not have discovered the breached warranty and realized its danger.

145. The breach of the warranty was a substantial factor in bringing about Plaintiff's injuries.

146. Within a reasonable time after Plaintiff knew or should have known of the failure of her Zimmer Versys® Hip System components, Plaintiff gave notice to Zimmer of such failure.

147. Zimmer breached the express warranty it provided with the devices.

148. As a direct and proximate result of Defendants' acts and omissions, including their failure to exercise ordinary care in the design, formulation, testing, manufacture, sale, and distribution of the Zimmer Versys® Hip System, Plaintiff was implanted with the Zimmer Versys® Hip System and suffered severe and debilitating injuries, economic loss, and other damages, including but not limited to, cost of medical care, rehabilitation, lost income, permanent instability and loss of balance, immobility, and pain and suffering, for which she is entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

SEVENTH CAUSE OF ACTION
(AGAINST ALL DEFENDANTS)

Breach of Implied Warranty

149. Plaintiffs incorporate by reference paragraphs 1 through 148 of this Complaint, as if fully set forth herein and further allege as follows:

150. The Zimmer Versys® Hip System was not reasonably fit for the ordinary purposes for which such goods are used and did not meet the expectations for the performance of the product when used in the customary, usual, and reasonably foreseeable manner. Nor was the Zimmer Versys® Hip System minimally safe for its expected purpose.

151. At all relevant times, Plaintiff used the Zimmer Versys® Hip System for the purpose and in the manner intended by Defendants.

152. Plaintiff and Plaintiff's physicians, by the use of reasonable care, could not have discovered the breached warranty and realized its danger.

153. The breach of the warranty was a substantial factor in bringing about Plaintiff's injuries.

154. Zimmer impliedly warranted that the Zimmer Versys® Hip System and its components were merchantable and fit for the ordinary and intended purposes for which hip systems are used.

155. Plaintiff was a foreseeable user of the Zimmer Versys® Hip System.

156. Plaintiff's surgeon, as purchasing agent, purchased the Zimmer Versys® Hip System for Plaintiff from Zimmer.

157. At all times relevant to this Complaint, Plaintiff was and is in privity with Zimmer.

158. Plaintiff used the product for its ordinary and intended purpose.

159. The Zimmer Versys® Hip System failed while being used for its ordinary and intended purpose.

160. As a direct and proximate result of Zimmer's breach of implied warranty of merchantability, Plaintiff suffered injuries as described specifically above.

EIGHTH CAUSE OF ACTION
(AGAINST ALL DEFENDANTS)

Consumer Fraud and/or Unfair and Deceptive Trade Practice Under State Law

161. Plaintiffs incorporate by reference paragraphs 1 through 160 of this Complaint, as if fully set forth herein and further allege as follows:

162. Plaintiff purchased and used the Zimmer Versys® Hip System for personal use and thereby suffered ascertainable losses as a result of Defendants' actions in violation of the consumer protection laws of the State of Georgia.

163. Had Defendants not engaged in the deceptive conduct described herein, Plaintiff, her physicians, and hospitals and medical centers would not have purchased and/or paid for the Defective Device, and would not have incurred related medical costs and injuries.

164. Defendants engaged in wrongful conduct while at the same time obtaining, under false pretenses, moneys from Plaintiff, their physicians and hospitals for the Zimmer Versys® Hip System that would not have been paid had Defendants not engaged in unfair and deceptive conduct.

165. Unfair methods of competition or deceptive acts or practices that were proscribed by law, including the following: a. Representing that goods or services have characteristics, ingredients, uses, benefits, or quantities that they do not have; b. Advertising goods or services

with the intent not to sell them as advertised; and, c. Engaging in fraudulent or deceptive conduct that creates a likelihood of confusion or misunderstanding.

166. Plaintiff was injured by the cumulative and indivisible nature of Defendants' conduct. The cumulative effect of Defendants' conduct directed at patients, physicians, and consumers was to create demand for and sell the Zimmer Versys® Hip System . Each aspect of Defendants' conduct combined to artificially create sales of the Zimmer Versys® Hip System .

167. Defendants have a statutory duty to refrain from unfair or deceptive acts or trade practices in the design, development, manufacture, promotion, and sale of the Zimmer Versys® Hip System .

168. Had Defendants not engaged in the deceptive conduct described above, Plaintiff would not have purchased and/or paid for the Zimmer Versys® Hip System, and would not have incurred related medical costs.

169. Defendants' deceptive, unconscionable, or fraudulent representations and material omissions to patients, physicians and consumers, including Plaintiff, constituted unfair and deceptive acts and trade practices in violation of the state consumer protection statutes listed.

170. Defendants' actions, as complained of herein, constitute unfair competition or unfair, unconscionable, deceptive or fraudulent acts, or trade practices in violation of state consumer protection statutes, as listed below.

171. Defendants have engaged in unfair competition or unfair or deceptive acts or trade practices or have made false representations in violation of O.C.G.A. § 10-1-390, *et seq.*

172. Under the statutes listed above to protect consumers against unfair, deceptive, fraudulent, and unconscionable trade and business practices and false advertising, Defendants are the suppliers, manufacturers, advertisers, and sellers, who are subject to liability under such

legislation for unfair, deceptive, fraudulent and unconscionable consumer sales practices.

173. Defendants violated the statutes that were enacted in Georgia to protect consumers against unfair, deceptive, fraudulent, and unconscionable trade and business practices and false advertising, by knowingly and falsely representing that the Zimmer Versys® Hip System was fit to be used for the purpose for which they were intended, when in fact the Zimmer Versys® Hip System was defective and dangerous, and by other acts alleged herein. These representations were made in uniform promotional materials.

174. The actions and omissions of Defendants alleged herein are uncured or incurable deceptive acts under the statutes enacted in Georgia to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising.

175. Defendants had actual knowledge of the defective and dangerous condition of the Products and failed to take any action to cure such defective and dangerous conditions.

176. Plaintiff and the medical community relied upon Defendants' misrepresentations and omissions in determining which femoral head to use.

177. Defendants' deceptive, unconscionable, or fraudulent representations and material omissions to patients, physicians, and consumers, constituted unfair and deceptive acts and practices.

178. By reason of the unlawful acts engaged in by Defendants, and as a direct and proximate result thereof, Plaintiff has suffered ascertainable losses and damages.

179. As a direct and proximate result of Defendants' violations of the states' consumer protection laws, Plaintiff has sustained economic losses and other damages and is entitled to statutory and compensatory damages in an amount to be proven at trial.

NINTH CAUSE OF ACTION
(AGAINST ALL DEFENDANTS)

Punitive Damages

180. Plaintiffs incorporate by reference paragraphs 1 through 179 of this Complaint, as if fully set forth herein and further allege as follows:

181. At all times material hereto, Defendants knew or should have known that the Zimmer Versys® Hip System was inherently more dangerous than the alternative hip replacement stems on the market with respect to the risk of fretting and corrosion, shorter life span, and an increased need for additional surgeries.

182. At all times material hereto, Defendants attempted to misrepresent, and did misrepresent, facts concerning the safety of, the Zimmer Versys® Hip System.

183. Defendants' misrepresentations included knowingly withholding material information from the medical community and the public, including the Plaintiff, concerning the safety and efficacy of the subject Zimmer Versys® Hip System.

184. At all times material hereto, the Defendants knew and recklessly disregarded the fact that the Zimmer Versys® Hip System was subject to causing fretting and corrosion in persons implanted with the Zimmer Versys® Hip System with far greater frequency than alternative hip replacement stems.

185. Notwithstanding the foregoing, Defendants continued to aggressively market the Zimmer Versys® Hip System without disclosing the aforesaid side effects when there were safer alternative methods available.

186. The Defendants knew of the subject products' defective and unreasonably dangerous nature, as set forth herein, but continued to design, develop, manufacture, market,

distribute, and sell the Zimmer Versys® Hip System so as to maximize sales and profits at the expense of the health and safety of the public, including Plaintiff, in conscious and/or negligent disregard of the foreseeable harm.

187. The Defendants' intentional and/or reckless, fraudulent, and malicious failure to disclose information deprived the Plaintiff and her surgeon of necessary information to enable them to weigh the true risks of using the Zimmer Versys® Hip System against its benefits.

188. Defendants knew or ought to have known that this conduct would result in injury or damage, but continued to mislead both the medical community and the public at large, including Plaintiff, by making false representations about the safety and efficacy of the Zimmer Versys® Hip System .

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

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

191. Defendants' actions showed willful misconduct, malice, fraud, wantonness, oppression, or that the entire want of care which raises the presumption of conscious indifference to the consequences.

TENTH CAUSE OF ACTION
(AGAINST ALL DEFENDANTS)

Loss of Consortium

192. Plaintiff WILLIAM COEN hereby repeats, realleges and incorporates by reference all of the allegations and statements contained in Paragraphs 1 through 191, inclusive, as though fully set forth herein.

193. Plaintiff WILLIAM COEN was and is the lawful spouse of Plaintiff DOROTHY COEN and in such capacity, was and is entitled to the comfort, enjoyment, society and services of his spouse.

194. As a direct and proximate result of the foregoing allegations, Plaintiff WILLIAM COEN was deprived of the comfort, enjoyment, society and services of his spouse, has suffered and will continue to suffer economic loss, and otherwise has been emotionally and economically injured. Plaintiff WILLIAM COEN's injuries and damages are permanent and will continue into the future.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly and severally, and request:

1. Compensatory damages, both special and general damages, including but not limited to, past and future medical expenses, costs for past and future rehabilitation and/or home health care, permanent disability, pain and suffering, in excess of the amount required for federal diversity jurisdiction and in an amount to fully compensate Plaintiffs for all their injuries and damages, both past and present;
2. Loss of consortium;
3. Punitive damages as allowed by law;
4. All statutory damages and relief;

5. Attorneys' fees, expenses, and costs of this action;

6. Pre-judgment and post-judgment interest in the maximum amount allowed by law; and

7. Such further relief as this Court deems necessary, just, and proper.

DEMAND FOR JURY TRIAL

Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiffs demand a trial by jury of all claims in this Complaint so triable.

This 15th day of June, 2018.

/s/ R. Paul Hart, III
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JS 44 (Rev. 06/17)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS

DOROTHY COEN and WILLIAM COEN

(b) County of Residence of First Listed Plaintiff White County, GA
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Karsman, McKenzie & Hart
21 W. Park Avenue
Savannah, GA 31401 (912) 335-4977

DEFENDANTS

Zimmer Biomet Inc. f/k/a Zimmer, Inc. and Zimmer Biomet Holdings, Inc. f/k/a Zimmer Holdings, Inc.

County of Residence of First Listed Defendant Kosciusko County, IN
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ❒ 1 U.S. Government Plaintiff
- ❒ 3 Federal Question *(U.S. Government Not a Party)*
- ❒ 2 U.S. Government Defendant
- ☒ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☒ 1	❒ 1	Incorporated *or* Principal Place of Business In This State	❒ 4	❒ 4
Citizen of Another State	❒ 2	❒ 2	Incorporated *and* Principal Place of Business In Another State	❒ 5	☒ 5
Citizen or Subject of a Foreign Country	❒ 3	❒ 3	Foreign Nation	❒ 6	❒ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

Click here for: Nature of Suit Code Descriptions.

CONTRACT
- ❒ 110 Insurance
- ❒ 120 Marine
- ❒ 130 Miller Act
- ❒ 140 Negotiable Instrument
- ❒ 150 Recovery of Overpayment & Enforcement of Judgment
- ❒ 151 Medicare Act
- ❒ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ❒ 153 Recovery of Overpayment of Veteran's Benefits
- ❒ 160 Stockholders' Suits
- ❒ 190 Other Contract
- ❒ 195 Contract Product Liability
- ❒ 196 Franchise

REAL PROPERTY
- ❒ 210 Land Condemnation
- ❒ 220 Foreclosure
- ❒ 230 Rent Lease & Ejectment
- ❒ 240 Torts to Land
- ❒ 245 Tort Product Liability
- ❒ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ❒ 310 Airplane
- ❒ 315 Airplane Product Liability
- ❒ 320 Assault, Libel & Slander
- ❒ 330 Federal Employers' Liability
- ❒ 340 Marine
- ❒ 345 Marine Product Liability
- ❒ 350 Motor Vehicle
- ❒ 355 Motor Vehicle Product Liability
- ❒ 360 Other Personal Injury
- ❒ 362 Personal Injury - Medical Malpractice

PERSONAL INJURY
- ☒ 365 Personal Injury - Product Liability
- ❒ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ❒ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ❒ 370 Other Fraud
- ❒ 371 Truth in Lending
- ❒ 380 Other Personal Property Damage
- ❒ 385 Property Damage Product Liability

CIVIL RIGHTS
- ❒ 440 Other Civil Rights
- ❒ 441 Voting
- ❒ 442 Employment
- ❒ 443 Housing/ Accommodations
- ❒ 445 Amer. w/Disabilities - Employment
- ❒ 446 Amer. w/Disabilities - Other
- ❒ 448 Education

PRISONER PETITIONS

Habeas Corpus:
- ❒ 463 Alien Detainee
- ❒ 510 Motions to Vacate Sentence
- ❒ 530 General
- ❒ 535 Death Penalty

Other:
- ❒ 540 Mandamus & Other
- ❒ 550 Civil Rights
- ❒ 555 Prison Condition
- ❒ 560 Civil Detainee - Conditions of Confinement

FORFEITURE/PENALTY
- ❒ 625 Drug Related Seizure of Property 21 USC 881
- ❒ 690 Other

LABOR
- ❒ 710 Fair Labor Standards Act
- ❒ 720 Labor/Management Relations
- ❒ 740 Railway Labor Act
- ❒ 751 Family and Medical Leave Act
- ❒ 790 Other Labor Litigation
- ❒ 791 Employee Retirement Income Security Act

IMMIGRATION
- ❒ 462 Naturalization Application
- ❒ 465 Other Immigration Actions

BANKRUPTCY
- ❒ 422 Appeal 28 USC 158
- ❒ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ❒ 820 Copyrights
- ❒ 830 Patent
- ❒ 835 Patent - Abbreviated New Drug Application
- ❒ 840 Trademark

SOCIAL SECURITY
- ❒ 861 HIA (1395ff)
- ❒ 862 Black Lung (923)
- ❒ 863 DIWC/DIWW (405(g))
- ❒ 864 SSID Title XVI
- ❒ 865 RSI (405(g))

FEDERAL TAX SUITS
- ❒ 870 Taxes (U.S. Plaintiff or Defendant)
- ❒ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ❒ 375 False Claims Act
- ❒ 376 Qui Tam (31 USC 3729(a))
- ❒ 400 State Reapportionment
- ❒ 410 Antitrust
- ❒ 430 Banks and Banking
- ❒ 450 Commerce
- ❒ 460 Deportation
- ❒ 470 Racketeer Influenced and Corrupt Organizations
- ❒ 480 Consumer Credit
- ❒ 490 Cable/Sat TV
- ❒ 850 Securities/Commodities/ Exchange
- ❒ 890 Other Statutory Actions
- ❒ 891 Agricultural Acts
- ❒ 893 Environmental Matters
- ❒ 895 Freedom of Information Act
- ❒ 896 Arbitration
- ❒ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ❒ 950 Constitutionality of State Statutes

V. ORIGIN *(Place an "X" in One Box Only)*

☒ 1 Original Proceeding ❒ 2 Removed from State Court ❒ 3 Remanded from Appellate Court ❒ 4 Reinstated or Reopened ❒ 5 Transferred from Another District *(specify)* ❒ 6 Multidistrict Litigation - Transfer ❒ 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing ***(Do not cite jurisdictional statutes unless diversity)***:
28 USC 1332(a)

Brief description of cause:
Product Liability (Medical Device)

VII. REQUESTED IN COMPLAINT:

❒ CHECK IF THIS IS A **CLASS ACTION** UNDER RULE 23, F.R.Cv.P.

DEMAND $

CHECK YES only if demanded in complaint:
JURY DEMAND: ☒ Yes ❒ No

VIII. RELATED CASE(S) IF ANY

(See instructions):

JUDGE _____ DOCKET NUMBER _____

DATE
06/15/2018

SIGNATURE OF ATTORNEY OF RECORD
s/ R. Paul Hart, Esq.

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

I.(a) **Plaintiffs-Defendants.** Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.

(b) **County of Residence.** For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)

(c) **Attorneys.** Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".

II. **Jurisdiction.** The basis of jurisdiction is set forth under Rule 8(a), F.R.Cv.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.
United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.
United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.
Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.
Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below**; NOTE: federal question actions take precedence over diversity cases.**)

III. **Residence (citizenship) of Principal Parties.** This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.

IV. **Nature of Suit.** Place an "X" in the appropriate box. If there are multiple nature of suit codes associated with the case, pick the nature of suit code that is most applicable. Click here for: Nature of Suit Code Descriptions.

V. **Origin.** Place an "X" in one of the seven boxes.
Original Proceedings. (1) Cases which originate in the United States district courts.
Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441. When the petition for removal is granted, check this box.
Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.
Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.
Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.
Multidistrict Litigation – Transfer. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407.
Multidistrict Litigation – Direct File. (8) Check this box when a multidistrict case is filed in the same district as the Master MDL docket.
PLEASE NOTE THAT THERE IS NOT AN ORIGIN CODE 7. Origin Code 7 was used for historical records and is no longer relevant due to changes in statue.

VI. **Cause of Action.** Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity.** Example: U.S. Civil Statute: 47 USC 553 Brief Description: Unauthorized reception of cable service

VII. **Requested in Complaint.** Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.
Demand. In this space enter the actual dollar amount being demanded or indicate other demand, such as a preliminary injunction.
Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.

VIII. **Related Cases.** This section of the JS 44 is used to reference related pending cases, if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.

Date and Attorney Signature. Date and sign the civil cover sheet.