UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

JUDITH HARMS and
SAMUEL HARMS,

Plaintiffs,

V.

ZIMMER, INC., and
ZIMMER HOLDINGS, INC.,
N/K/A ZIMMER BIOMET HOLDINGS, INC.,

Defendants.

Case No. 0:18-cv-1378

COMPLAINT
AND JURY TRIAL DEMAND

Plaintiffs Judith Harms and Samuel Harms, by their attorneys, [redacted] complaining of Defendants Zimmer Inc. and Zimmer Holdings, Inc., n/k/a Zimmer Biomet Holdings, Inc. (collectively referred to as "Zimmer") upon information and belief, and at all times hereinafter mentioned, allege:

NATURE OF THE CASE

1. This is an action for strict products liability, breach of express warranty, breach of implied warranty, negligence, and negligent misrepresentation brought by Judith Harms and Samuel Harms (Plaintiffs) for injuries arising out of the Zimmer M/L taper Prosthesis with Kinectiv® Modular Neck Technology (hereafter "Kinectiv® Hip System").
2. Defendant Zimmer manufactured and supplied to doctors a dual modular, total hip arthroplasty system known as the Zimmer M/L Taper with Kinectiv® Technology Hip Implant System, which was designed to be implanted with either (1) a cobalt-chromium femoral head or (2) a ceramic femoral head.
3. The Zimmer M/L Taper with Kinectiv® Technology Hip Implant System, utilized with a cobalt-chromium femoral head, created an unreasonable risk of harm to Plaintiff.

4. The unreasonable risk 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 M/L Taper with Kinectiv® Technology Hip Implant System with a metal cobalt-chromium femoral head a defective product.
5. The selection and implantation of the Zimmer Versys CoCr head and Kinectiv® Hip System by Plaintiff's surgeon was a result of the misinformation, marketing, sales, promotion, and direction by Zimmer.

PARTIES

6. Plaintiff Judith Harms currently resides, and did at all relevant times reside, in the City of Sauk Rapids, County of Benton, and State of Minnesota. Plaintiff Judith Harms underwent a left total hip replacement on September 2, 2008, where she was implanted with the Zimmer Kinectiv® Hip System, manufactured, designed, distributed, and warranted by Defendants.
7. Plaintiff Samuel Harms currently resides, and did at all relevant times reside, in the City of Sauk Rapids, County of Benton, and State of Minnesota. Plaintiff Samuel Harms is and was at all relevant times the spouse of Plaintiff Judith Harms.
8. Defendant Zimmer, Inc. is a duly organized foreign corporation, organized under the laws of Delaware, with its principal place of business located in the City of Warsaw, State of Indiana. Defendant does business throughout the United States, including in the State of Minnesota.

9. Defendant Zimmer Holdings, Inc. n/k/a Zimmer Biomet Holdings, Inc. is a duly organized foreign corporation, organized under the laws of Delaware, with its principal place of business located in the City of Warsaw, State of Indiana. Defendant does business throughout the United States, including in the State of Minnesota.
10. Upon information and belief, for a period prior to September 2, 2008, and dates thereafter, Defendants Zimmer, Inc. and Zimmer Holdings, Inc. d/k/a Zimmer Biomet Holdings, Inc. conducted regular and substantial business in the State of Minnesota, including the regular shipping of orthopedic and joint replacement products, advertisements, and sales personnel into the State of Minnesota.
11. Upon information and belief, for a period prior to September 2, 2008, and dates thereafter, Zimmer was the designer, developer, manufacturer, importer, distributor, fabricator, wholesaler, retailer, supplier, marketer and/ or servicer of orthopedic and joint replacement products known as the Kinectiv® Hip System.
12. Upon information and belief, for a period prior to September 2, 2008 and dates thereafter, Zimmer regularly shipped the Kinectiv® Hip System into the State of Minnesota, and in particular, provided said products to St. Cloud Hospital and Joseph Nessler, M.D. in St. Cloud, Minnesota for implantation into human patients., including Plaintiff Judith Harms.
13. Upon information and belief, at all times pertinent to this action, Zimmer represented that the Kinectiv® Hip System was safe, fit, free from defects and suitable for implantation into human patients.

JURISDICTIONAL STATEMENT

14. Plaintiffs Judith and Samuel Harms are, and were at all relevant times, citizens of the State of Minnesota. Defendant Zimmer Inc. and its related Defendant entities are, and

were at all relevant times, citizens of the State of Indiana. Plaintiffs are seeking monetary damages in excess of $75,000. This Court therefore has jurisdiction based on diversity of citizenship pursuant to 28 U.S.C. § 1332.

15. Defendants are subject to the *in personam* jurisdiction of this Court, and venue is therefore proper herein pursuant to 28 U.S.C. § 1391, because Defendants did (and do) business within the State of Minnesota, and they have consented to jurisdiction in the State of Minnesota. Upon information and belief, Defendants also advertised in this District, made material omissions and representations in this District and breached warranties in this District.

FACTS

I. History of the Zimmer M/L Taper with Kinectiv® Technology Hip Implant System

16. Zimmer, Inc. and Zimmer Holdings, Inc. n/k/a Zimmer Biomet Holdings, Inc, were the designers, manufacturers, and suppliers of the Zimmer M/L Taper with Kinectiv® Technology Hip Implant System and related components on the market.
17. Zimmer warranted the Kinectiv® Hip System and placed the devices into the United States stream of commerce in 2007.
18. Before it set-out to design the dual-modular Kinectiv® Hip System in 2002, Zimmer knew of the danger to human beings if cobalt-chromium metal debris from its products was released into the body through corrosion, micromotion, and/or fretting.
19. Before placing the Kinectiv® 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, fretting, 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 patient-consumers.

20. Despite the knowledge of what might cause corrosion and fretting, the new design Zimmer came up with in the early 2000s, and eventually used for the Kinectiv® Hip System called for a modular product with multiple junctions and a neck designed to be thinner in all planes as compared to the M/L Taper product previously introduced onto the market by Zimmer.

21. The changes in design of the Kinectiv® Hip System, which were different from the M/L Taper include, without limitation: (a) the introduction of a modular neck, increasing flexibility, (b) addition of dual modular junctions, and, (c) variation in the geometry of available components of the neck, both longer and shorter with different angle.

22. The Kinectiv® Hip System is part of a modular system that consists of an acetabular component, femoral head, femoral neck, and the instrumentation necessary for implantation of these components.

23. The Kinectiv® Hip System neck was/is made of titanium which is more flexible than cobalt-chromium (hereinafter, "CoCr") and was designed to be paired with a dissimilar metal – CoCr femoral head.

24. The femoral stem has a porous coating of titanium plasma spray.

25. The head/neck modular connection of the femoral stem assembly is a 12/14 taper designed to mate with the corresponding bore of a metal or ceramic femoral head component.

26. In a modular neck-stem design, such as the Kinectiv® Hip System, there is a "double taper." The resulting junctions are subject to both axial and bending stresses, and others.

27. The dual-modular design of Kinectiv® Hip System doubled the locations where micromotion and fretting can occur, not only at each individual junction, but stemming from the dynamic created by two junctions.

28. The design and selection of material at the dual junctions has an effect on the durability and survivability of the individual component(s) and system as a whole *in vivo.*

29. The Kinectiv® Hip System, although marketed as not being subject to the "metal on metal" designs (because it retains use of a plastic liner to separate the head from the cup), created a new source of metal on metal problems.

30. The mechanical environment of the dual modular junctions places the Kinectiv® Hip System at increased risk for metal-on-metal 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.

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

32. Each additional modular interface introduces a contributing source for metal wear particle and debris generation. These junctions exponentially compound and accelerate the wear debris generation process.

33. Corrosion is time-sensitive and accelerated by 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 Kinectiv® Hip System.

34. For decades, there were concerns in the orthopedic community about employment of this "dual"' modularity. Specifically, it was believed that the additional distal junction of the stem and neck would be a potential site of stem fracture, junction instability and particulate debris generation.

35. The Zimmer Kinectiv® Hip System taper is a 12/14 size with threading on the taper. The 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.

36. The significance of the Kinectiv® Hip System taper threading is: (1) it protects ceramic heads and (2)it 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.

37. The decision to allow the use of dissimilar metals and a CoCr head (rather than solely a ceramic head) in the Zimmer Kinectiv® Hip System created an unreasonable risk and made it defective.

38. The concept that corrosion might occur at the head-neck taper junction of a total hip prosthesis was first described in the early 1980s. When Zimmer designed the Zimmer Kinectiv® Hip System, with dual modularity, this concept had to be a consideration.

II. The Approval and Marketing of the Zimmer M/L Taper with Kinectiv® Technology Hip Implant System

39. The Kinectiv® Hip System, and its related components, were cleared under a process used by the United States Food and Drug Administration (hereinafter, "FDA") 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.

40. The first components of the Zimmer M/L Taper with Kinectiv® Technology Hip Implant System were cleared for sale in the United States according to Section 510(k) in January, 2007.

41. Zimmer designed, manufactured, promoted, sold and/or marketed the Kinectiv® Hip System to be "implanted in a wide variety of patient types", including, but not limited to: "younger patients; elderly patients; and hip fracture patients". *Zimmer M/L Taper Hip Prosthesis with Kinectiv® Technology*, 97-7713-001-00 Rev. 2 1012-H16 7.5ML, 2007.

42. Defendants were aware of the problems caused by the increased modularity at the time they designed, manufactured, marketed, distributed and/or sold the Kinectiv® Hip System.

43. The unorthodox modular design of the Kinectiv® Hip System was not sufficiently tested before introduction into the market.

44. 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 work(s) directly with the surgeon, but failed to do so.

45. Defendants mass-marketed this product rather than educating and training surgeons on the limited number of circumstances in which the benefits of a modular design might justify its use over a single unit design.

46. Defendants failed to warn, educate, and train physicians regarding the risk of the modular metal on metal problem (hereinafter MMOM).

47. Had Zimmer sufficiently tested the Kinectiv® Hip System (or acknowledged the dangers revealed by suspicious data from its own testing) or had Zimmer fully investigated the safety of predicate products identified in its FDA approval packet (such as the Wright Profemur or Stryker LFIT V40), the intrinsic design problems of the Kinectiv® Hip System would have been undeniable.

48. 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 selection of a CoCr head rather than a ceramic head significantly increases the risk of corrosion, Zimmer's premarket testing only used ceramic heads, Zimmer never performed corrosion testing utilizing both modular junctions at the same time, and Zimmer never performed any clinical trials and/or studies prior to marketing the Kinectiv® Hip System.

49. Although the United States does not have a complete and accurate database which can be used to track problems with hip implants, the Australian Registry can provide information regarding how a product is performing in comparison to other products.

50. According to the Australian registry of devices implanted in Australia between September 1999 and December 2013, comparing the Kinectiv® Hip System with all other total conventional hip prostheses, this prosthesis, the Kinectiv® Hip System has been identified as having a significantly higher revision rate. The Kinectiv® Hip System has a revision rate of 4.6 percent after four years, which is 50% higher than the average revision rate of 2.9 percent for all other hip implants.

51. Zimmer continues to market the CoCr heads for use with the titanium necks in the Zimmer M/L Taper with Kinectiv® Technology Hip Implant System.

52. Zimmer marketed the Kinectiv® Hip System stating: "[y]ears of extensive engineering design, laboratory testing, testing, and clinical consultation have been devoted to optimizing the structural integrity and junction debris characteristics of the Kinectiv® implants. The development and testing of this system not only addressed typical implant performance requirements but criteria exclusive to modular junctions as well. Specifically, these requirements included: 1) Proximal Implant Strength, 2) Fretting/Corrosion, and 3) Junction Stability." In other words, Defendants specifically marketed the Zimmer M/L Taper with Kinectiv® Technology Hip Implant System to alleviate the concerns of doctors and patients who may have heard about fretting and corrosion problems with competitors' hip implant devices. *Performance Evaluation of Kinectiv® ® Technology,* S. Meulink, et. al, 2009.

53. Despite these reassurances, the defective design and manufacture of the Kinectiv® Hip System, with a CoCr modular femoral head, generates excessive fretting and corrosion occurring at the neck-stem and head-neck 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 the toxic metallic elements, often reflected in elevated blood serum and/or urine testing levels.

54. Prior to Plaintiff's hip replacement surgery, Defendants knew or should have known that the Kinectiv® Hip System was defective, dangerous, inappropriate in patients like Plaintiff, and caused unjustified complications in many patients, including bone cysts;

pseudotumors, metallosis, and osteolysis; high levels of metal ions in the blood stream, such as chromium and cobalt; detachment, increased likelihood of disconnection and/or loosening of the acetabular cup; loosening of the femoral component; and other complications requiring revision surgery and causing life long side effects and future risks.

55. Despite legal and moral obligations to cease promoting, marketing, and selling the Kinectiv® Hip System, Defendants did not notify physicians or patients of the device's propensity to fail and cause other serious complications.

56. Defendants' labeling and other education and marketing materials explained none of these risks.

57. After placing the Kinectiv® Hip System into the stream of commerce, the Defendants had an ongoing duty to conduct continuing research and post-market surveillance of this and similarly designed products, in order to provide the medical community with updated information regarding this product.

58. Defendants did not perform adequate post- market evaluation, or provide subsequent warnings and education to medical providers.

59. Defendants had a strong monetary incentive to not reveal the dangers associated with the Kinectiv® Hip System.

60. Upon information and belief, Kinectiv® Hip System is considerably more expensive to customers and more profitable to Defendants, than are other traditional systems, including single block systems.

III. Plaintiff Judith Harm's Kinectiv® Hip System

61. On or about September 2, 2008, Judith Harms underwent a total arthroplasty of her left hip with insertion of the Zimmer Kinectiv Hip System performed by Joseph Nessler, M.D. at St. Cloud Hospital in Saint Cloud, Minnesota. The Zimmer products implanted during this procedure (hereafter "Plaintiff's Kinectiv® Hip System") were:

    a. Zimmer M/L Taper Hip Prosthesis with Kinectiv® Technology;

        i. LOT 60917850; REF 00-7713-007-00

    b. Zimmer Kinectiv® Technology Modular Neck; and,

        i. LOT 60898513; REF 00-7848-003-00

    c. Zimmer CoCr 12/14 Versys Hip System Femoral Head.

        i. LOT 61023016; REF 8018-36-02

62. At the time that Judith Harms received her total left hip arthroplasty on or about September 2, 2008, she received defective, dangerous, hazardous and unsafe products designed, manufactured, distributed and supplied by Zimmer.

63. Upon information and belief, the recommendation that Plaintiff receive this type of implant was driven by Defendants' misinformation regarding the significant risks of metal on metal micromovement, fretting, corrosion, and consequent debris, which misinformation was provided to and relied on by Plaintiff's surgeon.

64. The surgical repair and recovery of Judith Harms' left hip was initially represented as successful in eliminating her pain and restrictions.

65. Subsequent to her hip implant, Plaintiff developed metallosis due to fretting and wear at the head-neck taper junction.

66. Diagnosis of the metallosis was delayed due to Plaintiff's surgeon having been left uninformed of the potential for this risk and complication when using the Kinectiv® Hip System.

67. On or about October 23, 2015, Plaintiff's surgeon performed a left hip revision surgery on Judith Harms at Saint Cloud Hospital located in Saint Cloud, Minnesota due to debilitating metallosis stemming from the faulty Kinectiv® Hip System implanted in September 2008. The October 2015 revision surgery revealed pericapsular necrotic tissue, thickened capsule and a brown metallic stained fluid in the area of the hip device. Black sludge was identified where the Zimmer metal head was disimpacted from the Zimmer neck.

68. A new, ceramic head was implanted, along with a new liner and modular neck.

69. As a result of the metallosis caused by Plaintiff's Kinectiv® Hip System, Plaintiff suffered extensive pain, long term consequences from metallosis, endured an invasive revision surgery, and increased risk of future complications. The injuries were physically and emotionally painful.

70. Defendants recklessly, knowingly, intentionally, and fraudulently misrepresented to the medical community and the general public, including Plaintiff and Plaintiff's healthcare providers, that the Kinectiv® Hip System was safe and effective for its intended use.

71. Plaintiff's healthcare providers reasonably relied on Zimmer in selecting the Kinectiv® Hip System for Plaintiff, for recommending the Kinectiv® Hip System to Plaintiff, and making implant decisions related to the Kinectiv® Hip System.

72. Specifically, Defendants misrepresented and actively concealed material facts that they knew or should have known regarding the safety and performance of the Kinectiv® Hip System, including, but not limited to:

    a. The Kinectiv® Hip System was not as safe as other available hip devices;

    b. The Kinectiv® Hip System had an unacceptably high rate of failures (or was likely to have an unreasonably high rate of failures) requiring revision surgery;

    c. The safety and performance of the Kinectiv® Hip System was not adequately tested and/or known by Defendants;

    d. Patients implanted with the Kinectiv® Hip System were at increased risk of experiencing painful and debilitating product failure and were more likely to undergo revision surgery than patients using other hip implant devices;

    e. While use of the plastic liner in the Kinectiv® Hip System avoided metal-on-metal problem, the modular design, and in particular use of scalloping at the neck, introduced significant risk of additional metal-on-metal problems;

    f. The Kinectiv® Hip System was designed, manufactured, marketed, promoted, distributed, and sold negligently, defectively, and/or improperly;

    g. The engineering to accomplish a modular system created and exacerbated the metal-on-metal exposure and risks;

    h. Metal corrosion was more likely to occur, and would occur with greater severity, as compared to other hip replacement products;

    i. Metal ion debris would be released into the patient's body; and

    j. Safer alternatives were available.

73. Defendants' conduct was negligent, willful, wanton, and reckless.

74. To Plaintiff's detriment, Plaintiff and Plaintiff's healthcare providers justifiably relied on and/or were induced by Defendants' misrepresentations and/or active concealment to recommend, purchase, implant, and/or use the Kinectiv® Hip System.

75. As a direct, legal, and proximate result of Defendants' misrepresentations and active concealment of material facts, Plaintiff has suffered injuries as set for the herein.

COUNT I

STRICT PRODUCTS LIABILITY – MANUFACTURING DEFECT

76. All previous paragraphs are incorporated herein by reference.

77. At all times relevant hereto, Defendants designed, manufactured, tested, distributed, sold, marketed and/or promoted the Kinectiv® Hip System. At all times relevant hereto, Kinectiv® Hip System was expected to, and did, reach prescribing physicians and consumers, including Plaintiff and Plaintiff's physician, without a substantial change in the condition in which it was sold.

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

79. At all times relevant hereto, Plaintiffs healthcare provider reasonably followed the instructions provided by Defendants.

80. At all times relevant hereto, the Kinectiv® Hip System was dangerous, unsafe and defective in manufacture. Such defects included, but were not limited to, a tendency to (a) generate 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.

81. Upon information and belief, the Kinectiv® Hip System implanted in Plaintiff was defectively manufactured and differed from the manufacturer's design and specifications or from typical units of the same product line.

82. The defective Kinectiv® Hip System caused Plaintiff's resulting metallosis and contributed to cause the subsequent need for revision surgery.

83. As a direct, legal, and proximate result of the defective manufacture of Kinectiv® Hip System implanted in Plaintiff, Plaintiff sustained injuries that are permanent and ongoing in nature, including but not limited to the following compensable injuries: past and future medical bills, future medical risks, hip instability, lost enjoyment of life, physical pain and suffering, emotional distress, and loss of household services damages.

WHEREFORE, Plaintiff respectfully requests that Plaintiff be granted relief against Defendants, as contained in the Prayer For Relief.

COUNT II

STRICT PRODUCTS LIABILITY – FAILURE TO WARN

84. All previous paragraphs are incorporated herein by reference.

85. At all times relevant hereto, Defendants researched, developed, designed, tested, manufactured, distributed, sold, marketed and/or promoted the Kinectiv® Hip System, in the course of same, directly advertised or marketed the product to health care professionals and consumers, including Plaintiff, or persons responsible for consumers, and therefore had a duty to warn of the risks associated with the use of the Zimmer Kinectiv® System.

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

87. The Kinectiv® Hip System was defective and unreasonably dangerous when it left the possession of Defendants in that it contained an absence of warnings alerting the medical community and patients as to the dangerous risks associated with the Kinectiv® Hip System when used for its intended and reasonably foreseeable purpose.

88. The risks associated with the Kinectiv® 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.

89. At all times relevant hereto, Plaintiff and Plaintiffs healthcare providers used Kinectiv® Hip System for its intended or reasonably foreseeable purpose.

90. Plaintiff and Plaintiffs healthcare providers could not with the exercise of due care have discovered any defect of the Kinectiv® Hip System and were reasonable to assume that defendants had 1) performed adequate pre-market testing, and 2) had provided physicians with sufficient education and training to make appropriate and safe medical decisions for patients.

91. Defendants knew or should have known, by the use of scientific knowledge available before, at and after the time of manufacture, distribution and sale of the Kinectiv® Hip System, of potential risks and side effects associated with the Kinectiv® Hip System.

Defendants knew or should have known of the defective condition, characteristics, and risks associated with the product.

92. The warnings and instructions provided with the Kinectiv® Hip System did not adequately warn of the potential risk and side effects.

93. The warnings and instructions provided with the Kinectiv® Hip System did not adequately educate and train medical providers as to the risk of side effects, or the cost-benefit analysis necessary for justified use of this product versus safer alternative designs.

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

95. Defendants failed to timely and reasonably warn of material facts regarding the safety and efficacy of the Zimmer Kinectiv® 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 Kinectiv® Hip System, or no consumer, including Plaintiff, would have purchased and/or used the Zimmer Kinectiv® Hip System.

96. As a direct, legal, and proximate result of Defendants' failure to warn, Plaintiff sustained injuries as set forth above in paragraphs 65-69.

97. Defendants' failure to adequately warn, educate, and train of the potential risks and side effects of the Kinectiv® Hip System contributed to cause the injuries suffered by Plaintiff.

WHEREFORE, Plaintiff respectfully requests that Plaintiff be granted relief against Defendants, as contained in the Prayer For Relief.

COUNT III

STRICT PRODUCTS LIABILITY – DEFECTIVE DESIGN

98. All previous paragraphs are incorporated herein by reference.

99. At all times relevant hereto, Defendants designed, manufactured, distributed, sold, marketed and/or promoted the Kinectiv® Hip System implanted in Plaintiff.

100. At all times relevant hereto, the Kinectiv® Hip System was expected to, and did reach prescribing physicians and consumers, including Plaintiff and Plaintiff's physician, without a substantial change in the condition in which it was sold.

101. At all times relevant hereto, Plaintiff and Plaintiff's healthcare providers used the Kinectiv® Hip System for its intended or reasonably foreseeable purpose, and pursuant to instruction, guidance, education and training specifically provided Defendants.

102. At all times relevant hereto, the Kinectiv® Hip System was dangerous, unsafe and defective in design including but not limited to a femoral neck with dual modular tapers and mixed metal junctions resulting in a 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.

103. The Zimmer Kinectiv® Hip System is defective in design because the increased risk for failure requiring revision surgery is unreasonably greater than other hip implants.

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

105. Such risks were scientifically knowable to Defendants.

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

107. 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.

108. Plaintiff and Plaintiff's healthcare providers could not with the exercise of due care have discovered any defect of the Zimmer M/L Taper with Kinectiv® Technology Hip Implant System and were reasonable to assume that defendants had 1) performed adequate pre-market testing, and 2) had provided physicians with sufficient education and training to make appropriate and safe medical decisions for patients.

109. The Zimmer M/L Taper with Kinectiv® Technology Hip Implant System was defective in design because there existed a reasonable alternative design that would have reduced the risk posed by the subject Zimmer M/L Taper with Kinectiv® Technology Hip Implant System.

110. As a direct, legal, and proximate result of Defendants' dangerous design, Plaintiff sustained injuries as set forth above in paragraph 65-69.

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

WHEREFORE, Plaintiff respectfully requests that Plaintiff be granted relief against Defendants, as contained in the Prayer For Relief.

COUNT IV

NEGLIGENCE

112. All previous paragraphs are incorporated herein by reference.

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

114. Defendants had a duty to exercise reasonable care in the advertising and sale of the Kinectiv® Hip System, including a duty to warn Plaintiff and other consumers, of the dangers associated with the Zimmer M/L Taper with Kinectiv® Technology Hip Implant System that were known or should have been known to Defendants at the time of the sale of the Zimmer M/L Taper with Kinectiv® Technology Hip Implant System to the Plaintiff.

115. At all times relevant hereto, Defendants knew or should have known that the unconventional modular design of the Kinectiv® Hip System was generating the potential for metal on metal problems, vulnerabilities, and injuries.

116. Defendants failed to perform sufficient clinical trials and other pre-marketing evaluations to determine risk and efficacy of the Kinectiv® Hip System.

117. Such testing would have revealed the increased risk of failure and tendency to cause metallosis.

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

119. 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 modular design.

120. A reasonable sales representative of the product under the same or similar circumstances would have provided physicians and customers with information and training regarding the risks associated with foreseeable metal on metal problems stemming from the modular design, so that physicians and patients could make educated decisions as to whether any benefits of a modular system outweighed the increased risks.

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

122. 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 Kinectiv® Hip System to cause or create metal on metal complications.

123. As a direct, legal, and proximate result of Defendants' negligence, Plaintiff sustained injuries as set forth above in paragraph 65-69.

124. Defendants' negligence contributed to cause the injuries suffered by Plaintiff.

WHEREFORE, Plaintiff respectfully requests that Plaintiff be granted relief against Defendants, as contained in the Prayer For Relief.

COUNT V

NEGLIGENT MISREPRESENTATION

125. All previous paragraphs are incorporated herein by reference.

126. Defendants had a duty to truthfully represent to the medical community, the FDA, Plaintiffs healthcare providers and Plaintiff whether the Kinectiv® Hip System had been properly tested and found to be safe and effective for its intended use.

127. Defendants knew or should have known the representations regarding the safety and performance of the Kinectiv® Hip System were in fact untested, or were false.

128. 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.

129. Defendants failed to exercise ordinary care in determining the truth or falsity of their representations, and thereby falsely misrepresented to the medical community, to Plaintiffs physicians and to Plaintiff, the safety and performance of the Kinectiv® Hip System.

130. Defendants breached their duty to present truthful representations by knowingly, or by want of ordinary care, misrepresenting the safety and performance of the M/L Taper System.

131. As a direct, legal, and proximate result of Defendants' negligent and intentional misrepresentation, Plaintiff sustained injuries as set forth above in paragraph 65-69.

132. Defendants' negligent and intentional misrepresentation contributed to cause the injuries suffered by Plaintiff.

WHEREFORE, Plaintiff respectfully requests that Plaintiff be granted relief against Defendants, as contained in the Prayer For Relief.

COUNT VI

BREACH OF EXPRESS WARRANTY

133. All previous paragraphs are incorporated herein by reference.

134. At all times relevant hereto, the Kinectiv® Hip System implanted in Plaintiff was defective and unreasonably and inherently dangerous for its intended purpose.

135. Notwithstanding that Defendants knew or should have known of the defective nature of the Kinectiv® Hip System, the Defendants failed to give any notice or warnings, and instead placed the defective product into the stream of commerce.

136. As a designer, manufacturer, distributer, marketer, promoter, and supplier of the Kinectiv® Hip System, the Defendants expressly warranted that it was fit and safe for its intended purpose.

137. The Kinectiv® Hip System was defective when it was provided to Plaintiff and was not altered or changed before being implanted.

138. The Kinectiv® Hip System did not perform safely as warranted.

139. The Kinectiv® Hip System was unfit for its intended purpose.

140. As a direct, legal, and proximate result of Defendants' conduct, Plaintiff sustained injuries as set forth above in paragraph 65-69.

141. Defendants' breach of express warranty contributed to cause the injuries suffered by Plaintiff.

WHEREFORE, Plaintiff respectfully requests that Plaintiff be granted relief against Defendants, as contained in the Prayer For Relief.

COUNT VII

BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY

142. All previous paragraphs are incorporated herein by reference.

143. At all times relevant, the Kinectiv® Hip System implanted in Plaintiff was defective, and unreasonably and inherently dangerous to intended users, like the Plaintiff.

144. Notwithstanding that Defendants knew or should have known of the defective nature of the Kinectiv® Hip System, the Defendants failed to give any notice or warnings, and instead placed the defective product into the stream of commerce.

145. As a designer, manufacturer, distributer, marketer, promoter, and supplier of the Kinectiv® Hip System, the Defendants impliedly warranted that it was fit and safe for its intended purpose.

146. The Kinectiv® Hip System was defective when it was provided to Plaintiff and was not altered or changed before being implanted.

147. The Kinectiv® Hip System did not perform safely as warranted.

148. The Kinectiv® Hip System was unfit for its intended purpose.

149. As a direct, legal, and proximate result of Defendants' conduct, Plaintiff sustained injuries as set forth above in paragraphs 65-69.

150. Defendants' breach of implied warranty contributed to cause the injuries suffered by Plaintiff.

WHEREFORE, Plaintiff respectfully requests that Plaintiff be granted relief against Defendants, as contained in the Prayer For Relief.

COUNT VIII

VIOLATIONS OF MINNESOTA CONSUMER FRAUD ACT

(Minn. State. § 325F.69)

151. All previous paragraphs are incorporated herein by reference.

152. The Minnesota Consumer Fraud Act prohibits false and misleading statements and false promises made in connection with the sale of any merchandise.

153. Plaintiff has standing to bring this action pursuant to Minnesota's private attorney general statute, Minn. Stat. § 8.31, subd. 3a which reads: "any person injured by a violation of any of the laws referred to in subdivision 1 may bring a civil action and recover damages, together with costs and disbursements, including costs of investigation and reasonable attorney 's fees, and receive other equitable relief as determined by the court."

154. Defendants are a person as defined by Minn. Stat. § 325F.68, subd.3.

155. The Zimmer M/L Taper with Kinectiv® Technology Hip Implant System is merchandise within the meaning of Minn. Stat. § 325F.68, subd. 2.

156. The Kinectiv® Hip System System is and has been advertised and sold within the meaning of Minn. Stat. § 325F.68, subd. 4.

157. Defendants are violating and have violated the Minnesota Consumer Fraud Act by representing that the Kinectiv® Hip System is safe for the use in the human body, and failing to disclose that the Zimmer M/L Taper with Kinectiv® Technology Hip Implant

System(s) received by Plaintiff contain manufacturing defects and has been manufactured in violation of federal regulations and is "misbranded" and "adulterated" within the meaning of federal regulations.

158. Zimmer communicated the false and misleading statements to the public in general and specifically to Plaintiff, with the intention that Plaintiff would rely on the statements and in connection with the sale of the Zimmer Kinectiv® Hip System.

159. As a direct and proximate result of Zimmer's violation, Plaintiff has been damaged in an amount to be proven at trial.

COUNT IX

LOSS OF CONSORTIUM

160. All previous paragraphs are incorporated herein by reference.

161. As a further direct result of Zimmer's wrongful conduct and liability as described and alleged above, Plaintiff SAMUEL HARMS has lost, and will in the future continue to lose, his wife's companionship, aid, comfort, society, services, protection and consortium, all to his damage in an amount greater than $75,000.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment against Defendants and request:

1. Awarding compensatory damages;
2. Awarding pre-judgment and post-judgment interest to Plaintiffs;
3. Awarding all statutory damages and relief;

4. Awarding the costs and the expenses of this litigation to Plaintiffs;
5. Awarding reasonable attorneys' fees and costs to Plaintiffs as provided by law;
6. Granting Plaintiff equitable relief in the nature of disgorgement;
7. Granting all such other relief as the Court deems necessary, just and proper.

DEMANDED 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.

Dated: May 18, 2018

Respectfully submitted,

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

Judith Harms and Samuel Harms

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

(c) Attorneys *(Firm Name, Address, and Telephone Number)*

[redacted]

DEFENDANTS

Zimmer, Inc., Zimmer Holdings, Inc., n/k/a Zimmer Biomet Holdings, Inc.

County of Residence of First Listed Defendant
(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 U.S.C. § 1391

Brief description of cause:
Defective hip implant causing injury

VII. REQUESTED IN COMPLAINT:

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

DEMAND $ 75,000.00

CHECK YES only if demanded in complaint:

JURY DEMAND: ☒ Yes ❒ No

VIII. RELATED CASE(S) IF ANY

(See instructions):

JUDGE _____ DOCKET NUMBER _____

DATE
05/18/2018

SIGNATURE OF ATTORNEY OF RECORD
[redacted]

FOR OFFICE USE ONLY

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