

**UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK**

ANNAH MARIE GIDORA

Plaintiff,

**COMPLAINT AND DEMAND FOR JURY
TRIAL**

Civil Case No.:

-against-

HOWMEDICA OSTEONICS CORPORATION,
d/b/a STRYKER ORTHOPAEDICS, STRYKER
CORPORATION, and STRYKER SALE
CORPORATION,

Defendants.

Plaintiff, ANNAH MARIE GIDORA ("Plaintiff"), residing in Westchester County in the State of New York, by and through Plaintiff's attorneys, MUNAWAR & ANDREWS-SANTILLO, LLP, upon information and belief, and at all times hereinafter mentioned, alleges as follows:

INTRODUCTION AND SUMMARY OF ACTION

1. Defendants are in the for profit business of designing, manufacturing, marketing, promoting and selling hip replacement devices, including the "MDM X3 Mobile Bearing Hip System" (hereinafter the Device") The Device which includes, but is not limited to, Accolade II 127 Neck Angle Hip Stern, Acetabular Dome Hole Plug, Trident Acetabular Shell, Torx Cancellous Bone Screws, Modular Dual Mobility (MDM) Liner and Stryker LFIT V40. The Device is prone to fail years before its expected life. As a result of the Device's defects, patients, including the Plaintiff ANNAH MARIE GIDORA, that have had the Devices

implanted have endured, or will endure, unnecessary pain and suffering; debilitating lack of mobility; inflammation, causing damage death to surrounding tissue and bone; and a subsequent more difficult revision surgery to replace the faulty device, giving rise to still more debilitation, a prolonged recovery time, and an increased risk of complications and death from surgery Defendants, despite knowledge of the Device's defects have continued to aggressively market the Device, claiming it was a safe and effective hip replacement system.

2. Plaintiff's suffering could easily have been prevented. Plaintiff would not have suffered from unnecessary pain and debilitation, as well as the need to undergo subsequent revision surgery, had Defendants taken the affirmative step of recalling the Device, when complaints were made to the FDA regarding the Device's failures, or had Defendants at least warned the orthopedic surgical community and the public of the dangers of the Device so that those who had the Device implanted could be medically monitored for signs of failure of the Device. Plaintiff seeks redress for her injuries.

3. Plaintiff brings this action under the laws of the State of New York.

4. Plaintiff is over the age of majority and a citizen and resident of Westchester County in the State of New York. Plaintiff has been injured due to a defective medical prosthesis manufactured by Defendants.

5. Defendant, Howmedica Osteonics Corporation, d/b/a/ STRYKER ORTHOPAEDICS (hereinafter, "STRYKER") is, and at all times relevant to this Complaint was, a New Jersey Corporation with its principal place of business at 325 Corporate Drive, Mahwah, New Jersey 07430. STRYKER does business throughout the United States, including the State of New York.

6. Defendant, STRYKER CORPORATION (hereinafter, "STRYKER CORP"), is a

corporation organized and existing under the laws of Michigan, with its principal place of business in Kalamazoo, Michigan. STRYKER CORP does business throughout the United States, including the State of New York.

7. Defendant, STRYKER SALES CORPORATION (hereinafter, "STRYKER SALES") is a corporation organized and existing under the laws of Michigan, with its principal place of business in Kalamazoo, Michigan. STRYKER SALES does business throughout the United States, including the State of New York.

8. Defendants STRYKER, STRYKER CORP AND STRYKER SALES, designed, manufactured, marketed, promoted, and sold the MDM X3 Modular Dual Mobility Mobile Bearing Hip System that is the subject of this lawsuit. The employees of defendant, its subsidiaries, affiliates, and other related entities, as well as the employees of the Defendant's subsidiaries, affiliates, and other related entities, were the agents, servants and employees of Defendant, and at all relevant times, were acting within the purpose and scope of said agency and employment. Whenever reference in this Complaint is made to any act or transaction of Defendant, such allegations shall be deemed to mean that the principals, officers, employees, agents, and/or representatives of the Defendant committed, knew of, performed, authorized, ratified and/or directed such act or transaction on behalf of Defendant while actively engaged in the scope of their duties.

JURISDICTION AND VENUE

9. This Court has subject matter jurisdiction over the parties pursuant to 28 U.S.C. §1332(a) because Plaintiff and Defendants are citizens of different states and the amount in controversy exceeds \$75,000.00, exclusive of interest and costs.

10. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(a) and (c).

FACTUAL ALLEGATIONS

11. The defendants manufactured, sold and marketed the “MDM X3 MODULAR DUAL MOBILITY MOBILE BEARING HIP SYSTEM”, the Device, to the public, even though they knew, or should have known, of the danger that the device posed to the public. The Device was developed for both primary and revision total hip arthroplasty. The defendants marketed the device touting that it offered increased stability, longevity and advanced fixation for a wide range of patients.

12. A modular total hip replacement implant device typically consists of five separate components: a femoral stem, a femoral neck, a femoral head (or ball), a liner, and an acetabular shell (socket). Usually these components are made of metal and plastic.

13. These Devices were marketed with the claim that they would create a better, more unique fit for each individual patient. Indeed, Defendants marketed the Device as having many advantages over other hip replacement or hip resurfacing systems.

14. The “MDM X3 MODULAR DUAL MOBILITY MOBILE BEARING HIP SYSTEM”, according to the Stryker Defendants, was designed to provide the surgeons the ability to better personalize the biomechanics of each patient’s hip replacement implant.

15. The Stryker defendants further marketed the device claiming the device would restore hip stability, improve longevity of the implant and provide advanced fixation.

16. As a result of the Device’s defects, recipients of the Device have suffered symptoms including pain, swelling, inflammation, and damage to surrounding bone and tissue, and lack of mobility. As noted above, these symptoms are the result of possible loosening of the implant, where the implant does not stay attached to the bone in the correct position; fracture, where the bone around the implant may have broken; dislocation, where two parts of the implant

that move against each other are no longer aligned; or the spread of metal debris generated from the metal femur head and metal acetabular cup rubbing and rotating against each other. For these reasons, revision surgeries have been necessary to remove the faulty Devices. However, these revision surgeries present enormous risks to patients because they are technically more difficult than the original surgery to implant the Device, the patient is more at risk of complications and death, and the recovery time is prolonged as compared to the original hip replacement surgery.

17. The Defendants knew or should have known that the “MDM X3 MODULAR DUAL MOBILITY MOBILE BEARING HIP SYSTEM”, and its components, posed significant health risks based on the widely reported problems with the Device and other similarly designed hip implants. Even with this knowledge, the defendants recklessly and negligently sold, manufactured, marketed and distributed the defectively designed and/or defectively manufactured the Device in complete disregard for the safety of consumer and patients, including the Plaintiff.

18. The Defendants failed to warn surgeons and other consumers, including the Plaintiff, that the Device was not properly designed, manufactured, assembled and/or tested.

19. On or about January 30, 2014, the Plaintiff underwent right total hip replacement and the “MDM X3 MODULAR DUAL MOBILITY MOBILE BEARING HIP SYSTEM” and components was inserted and/or implanted into her body.

20. An employee and/or agent of Defendants provided the Device to Plaintiff’s orthopedist, who implanted the Device on January 30, 2014.

21. The “MDM X3 MODULAR DUAL MOBILITY MOBILE BEARING HIP SYSTEM” and components was expected to and did reach the Plaintiff without substantial change in the condition in which it was packaged, distributed, and sold by the defendants.

22. At all times material hereto, the “MDM X3 MODULAR DUAL MOBILITY MOBILE BEARING HIP SYSTEM” and components was used in a manner reasonably foreseeable to the defendants.

23. After the defendants’ device was implanted, Plaintiff began to experience pain ambulating including bending climbing (and descending stairs) lifting movements, pushing, sitting, walking and standing.

24. After the defendants’ device was implanted, an orthopedic surgeon confirmed joint clicking, joint stiffness, limited joint motion, limping, muscle stiffness, nocturnal awakening, nocturnal pain, joint locking, numbness, tenderness and tingling.

25. After the defendants’ device was implanted, an orthopedic surgeon confirmed the mechanical loosening of the internal right hip prosthetic joint of the defendants’ “MDM X3 MODULAR DUAL MOBILITY MOBILE BEARING HIP SYSTEM “and components.

26. As a result of the defendants’ conduct, on October 26, 2015, Plaintiff underwent a total hip revision.

27. As a direct and proximate result of the defendant’s conduct, Plaintiff was implanted with the Device, and had debilitating pain and other complications and required revision surgery to replace the Device.

28. During all material times, Plaintiff has been a resident of the State of New York.

29. On numerous occasions, Defendants met with orthopedic surgeons, including, on information and belief, with Plaintiff’s orthopedic surgeon, to promote “MDM X3 MODULAR DUAL MOBILITY MOBILE BEARING HIP SYSTEM” and components. At some or all of these meetings, a representative or representatives of STRYKER was present. During these meetings, STRYKER assured the orthopedic surgeons, including Plaintiff’s orthopedic surgeon,

that the MDM X3 Modular Dual Mobility Mobile Bearing Hip System and components was safe, effective, was the best product on the market, had an excellent track record, had very low wear, would last longer than traditional hip implants and had a low and acceptable failure rate. STRYKER continued to "defend" the Device even after they became aware of numerous and serious complications with it. STRYKER did not reveal their knowledge of numerous and serious complications and other "bad data" during their meetings with orthopedic surgeons, including Plaintiffs orthopedic surgeon.

30. Plaintiff's revision surgery has subjected her to much greater risks of future complications than she had before the revision surgery.

31. The Plaintiff suffered and continues to suffer injuries resulting and caused from the defective Device including and not limited to substantial pain and suffering, loss of mobility, loss of enjoyment of life, risk of life and emotional distress.

32. Defendants and their agents, apparent agents, servants and/or employees are liable and legally responsible to the Plaintiff for her injuries and damages pursuant to Titles 15 and 21 of the United States Code, Title 21 of the Code of Federal Regulations, New York Products Liability Statutes, New York Uniform Commercial Code, New York Public Health Laws New York General Business Law, and common law negligence, in one or more of the following respects in that they:

- a. placed into the market and into the stream of commerce, products, including MDM X3 Modular Dual Mobility Mobile Bearing Hip System and components, that were defective in design and materials and unreasonably dangerous;
- b. misrepresented to the general public, including the Plaintiff, that the MDM X3

Modular Dual Mobility Mobile Bearing Hip System and components were safe for their intended uses;

- c. designed, tested, manufactured, assembled, labeled, distributed, marketed, promoted and/or sold the MDM X3 Modular Dual Mobility Mobile Bearing Hip System and components that was dangerous and could not be used for its intended purpose without unreasonable risk of injury to persons including the Plaintiff;
- d. knew or should have known of the dangerous propensities of said MDM X3 Modular Dual Mobility Mobile Bearing Hip System and components yet continued its manufacture, distribution, assembly, promotion, marketing, and sales for substantial profit with complete disregard for the safety of consumers and patients such as the Plaintiff;
- e. failed to adequately and properly test the MDM X3 Modular Dual Mobility Mobile Bearing Hip System and components to ensure that it was free from defects and able to perform properly;
- f. failed to adequately design and manufacture the MDM X3 Modular Dual Mobility Mobile Bearing Hip System and components to insure that they would not corrode, erode, deteriorate, or cause a medical toxicity in patients including the Plaintiff;
- g. breached the implied warranty of merchantability and fitness and that the MDM X3 Modular Dual Mobility Mobile Bearing Hip System and components was not of merchantable quality or fit for its intended purpose;
- h. breached its express warranty made through their marketing campaigns,

promotional activities, product labeling, package inserts, and/or written and verbal assurances that the MDM X3 Modular Dual Mobility Mobile Bearing Hip System and components was safe and effective for use;

- i. failed to timely report adverse events, failures and malfunctions regarding the MDM X3 Modular Dual Mobility Mobile Bearing Hip System and components:
- j. failed to timely and adequately investigate adverse events, failures and malfunctions regarding the MDM X3 Modular Dual Mobility Mobile Bearing Hip System and components;
- k. failed to adequately and properly maintain records and/or reports regarding death, serious injury, and/or malfunction to ensure the safety and effectiveness of the MDM X3 Modular Dual Mobility Mobile Bearing Hip System and components;
- l. failed to adequately and properly follow and monitor the product once placed into the stream of commerce to determine any side effects including its potential to cause injury;
- m. failed to provide adequate warning regarding the propensity of the MDM X3 Modular Dual Mobility Mobile Bearing Hip System and components to cause injury;
- n. failed to warn the public including the Plaintiff that the MDM X3 Modular Dual Mobility Mobile Bearing Hip System and components was likely to fail and require complex revision surgery;
- o. failed to comply with federal requirements and regulations;

- p. failed to timely report adverse events, failures, and malfunctions, regarding the MDM X3 Modular Dual Mobility Mobile Bearing Hip System and components pursuant to 21 CFR Sec. 803.53
- q. failed to timely and adequately investigate adverse events, failures and malfunctions regarding the MDM X3 Modular Dual Mobility Mobile Bearing Hip System and components pursuant to 21 CFR Sec. 803.50;
- r. failed to timely and adequately report any and all information concerning product failures, and corrections pursuant to 21 CFR Sec. 803.52;
- s. failed to timely and/or adequately report to the FDA including a trend analysis, any reportable MDR events regarding the MDM X3 Modular Dual Mobility Mobile Bearing Hip System and components that necessitate remedial action to prevent an unreasonable risk of substantial harm to the public including the Plaintiff pursuant to 21 CFR Sec. 803.53;
- t. failed to timely and adequately report device corrections and/or removals regarding the MDM X3 Modular Dual Mobility Mobile Bearing Hip System and components pursuant to 21 CFR Sec. 806;
- u. failed to comply with FDA quality system requirements and regulations regarding design control, design, design validation, perfect performance and efficiency, and manufacturing and production standards pursuant to 21 CFR Sec. 820;
- v. failed to adequately and properly maintain records and/or reports regarding death, serious injury, and/or malfunction to assure the safety and effectiveness of the MDM X3 Modular Dual Mobility Mobile Bearing Hip System and

- components to 21 U.S.C. Sec. 360(i);
- w. failed to timely and fully inform the FDA of unanticipated adverse effects, increases in the evidence of adverse effects, or device failures necessitating labeling, manufacturing, or device modification;
 - x. marketed, distributed, and/or sold a misbranded product pursuant to 21 U.S.C. Sec. 352;
 - y. marketed, distributed, and/or sold an adulterated product pursuant to 21 U.S.C. Sec. 351.

FIRST CAUSE OF ACTION: NEGLIGENCE AGAINST DEFENDANTS

33. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows:

34. Defendant had a duty to exercise reasonable care in designing, researching, manufacturing, marketing, supplying, promoting, sale, testing, quality assurance, quality control, and/or distribution of the Device into the stream of commerce, including a duty to assure that the Device would not cause those who had it surgically implanted to suffer adverse harmful effects from it.

35. Defendant failed to exercise reasonable care in designing, researching, manufacturing, marketing, supplying, promoting, sale, testing, quality assurance, quality control, and/or distribution of the Device into interstate commerce in that Defendant knew or should have known that those individuals that had the Device surgically implanted were at risk for suffering harmful effects from it, including but not limited to, partial or complete loss of mobility, loss of range of motion, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished

enjoyment of life, as well as the need for a revision surgery to replace the Device with the attendant risks of complications and death from such further surgery.

36. The negligence of the Defendants, its agents, servants, and/or employees, included but not limited to the following acts and/or omissions:

- a) Negligently designing the Device in a manner which was dangerous to those individuals had the Device surgically implanted;
- b) Designing, manufacturing ,producing ,creating, and/or promoting the Device without adequately, sufficiently, or thoroughly testing it;
- c) Not conducting sufficient testing programs to determine whether or not the aforesaid Device was safe for use;
- d) Defendants herein knew or should have known that Device was unsafe and unfit for use by reason of the dangers to its users;
- e) Selling the Device without making proper and sufficient tests to determine the dangers to its users;
- f) Negligently failing to adequately and correctly warn Plaintiff or Plaintiff's physicians, hospitals and/or healthcare providers of the dangers of Device;
- g) Negligently failing to recall their dangerous and defective Device at the earliest date that it became known that the Device was, in fact, dangerous and defective;
- h) Failing to provide adequate instructions regarding safety precautions to be observed by surgeons who would reasonably and foreseeably come into contact with, and more particularly, implant the Device into their patients;
- i) Negligently advertising and recommending the use of the Device despite the fact that Defendants knew or should have known of its dangerous propensities;
- j) Negligently representing that the Device offered was safe for use for its intended purpose when, in fact, it was unsafe;
- k) Negligently manufacturing the Device in a manner which was dangerous to those individuals who had it implanted ;
- l) Negligently producing the Device in a manner which was dangerous to those individuals who had it implanted ;
- m) Negligently assembling the Device in a manner which was dangerous to those individuals who had it implanted;
- n) Defendants under-reported, underestimated and downplayed the serious danger of the Device;
- o) Failed to use due care in designing and manufacturing the Device so as to avoid the aforementioned risks to individuals that had the Devices surgically implanted;

- p) Failed to accompany their product with proper warnings;
- q) Failed to accompany their product with proper instructions for use;
- r) Failed to conduct adequate testing, including pre-clinical and clinical testing and post marketing surveillance to determine the safety of the Device;
- s) Willful, reckless and wanton misconduct in allowing this dangerous Device to be implanted in human beings without sufficient testing and with express knowledge of enhanced risks and
- t) Were otherwise careless and/or negligent.

37. Despite the fact that Defendants knew or should have known that the Device caused harm to individuals that had the Device surgically implanted, Defendants continued to market, manufacture, distribute and/or sell the Device.

38. Defendants knew or should have known that consumers such as Plaintiff would suffer foreseeable injury, and/or be at increased risk of suffering injury as a result of Defendants' failure to exercise ordinary care, as set forth above.

39. Defendants' negligence was the proximate cause of Plaintiff's physical, mental and emotional injuries and harm, and economic loss which Plaintiff has suffered and/or will continue to suffer.

40. By reason of the foregoing, Plaintiff experienced and/or will experience severe harmful effects including but not limited to partial or complete loss of mobility, loss of range of motion, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for a revision surgery to replace the Device with the attendant risks of complications and death from such further surgery, in a sum greater than the jurisdictional limitations of all lower courts which would otherwise have jurisdiction .

41. Further, as a result of the foregoing acts and omissions, Plaintiff has suffered

and/or will in the future suffer lost wages and a diminished capacity to earn wages.

42. In performing the foregoing acts and omissions, Defendant acted despicably, fraudulently, and with malice and oppression so as to justify an award of punitive and exemplary damages.

SECOND CAUSE OF ACTION
STRICT PRODUCTS LIABILITY (MANUFACTURING DEFECT)
AGAINST DEFENDANT

43. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows:

44. Defendant designed, manufactured, tested, marketed and distributed the Device into the stream of commerce.

45. The Device that was surgically implanted in Plaintiff was defective in its manufacture when it left the hands of Defendants in that it deviated from product specifications, posing a serious risk that it could fail early in patients therefore giving rise to physical injury, pain and suffering, debilitation, and the need for a revision surgery to replace the Device with the attendant risks of complications and death from such further surgery.

46. As a direct and proximate result of Defendants placement of the defective Device into the stream of commerce, Plaintiff experienced and/or will experience severe harmful effects including but not limited to partial or complete loss of mobility, loss of range of motion as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for a revision surgery to replace the Device with the attendant risks of complications and death from such further surgery.

47. Further, as a result of the foregoing acts and omissions, Plaintiff has suffered

and/or will in the future suffer lost wages and a diminished capacity to earn wages.

48. In performing the foregoing acts and omissions, Defendants acted despicably, fraudulently, and with malice and oppression so as to justify an award of punitive and exemplary damages.

THIRD CAUSE OF ACTION

STRICT PRODUCTS LIABILITY (DESIGN DEFECT) AGAINST DEFENDANTS

49. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows:

50. At all times herein mentioned, Defendant designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and/or distributed the Device as hereinabove described that was surgically implanted in Plaintiff.

51. At all times herein mentioned, the Device was in an unsafe, defective, and inherently dangerous condition for users such as Plaintiff that had the Device surgically implanted.

52. The Device was in an unsafe, defective, and inherently dangerous condition at the time it left Defendants' possession.

53. At all times herein mentioned, the Device was expected to and did reach the usual consumers, handlers, and persons coming into contact with said product without substantial change in the condition in which it was designed, produced, manufactured, sold, distributed, and marketed by Defendant.

54. The Device's unsafe, defective, and inherently dangerous condition was a cause of injury to Plaintiff.

55. The Device failed to perform as safely as an ordinary consumer would expect

when used in an intended or reasonably foreseeable manner.

56. Plaintiff's injuries resulted from use of the Device that was both intended and reasonably foreseeable by Defendant.

57. At all times herein mentioned, the Device posed a risk of danger inherent in the design which outweighed the benefits of that design.

58. At all times herein mentioned, the Device was defective and unsafe, and Defendants knew or had reason to know that said product was defective and unsafe, especially when used in the form and manner as provided by Defendants. At all times herein mentioned, the Defendant knew, or should have known, that the Device was in a defective condition, and was and is inherently dangerous and unsafe.

59. At the time of the implantation of the Device into Plaintiff, the aforesaid product was being used for the purposes and in a manner normally intended, namely for use as a hip replacement device.

60. Defendants, with this knowledge, voluntarily designed their Device in a dangerous condition for use by the public and, in particular, Plaintiff.

61. Defendants had a duty to create a product that was unreasonably dangerous for its normal, intended use.

62. Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed a defective product which, when used in its intended or reasonably foreseeable manner, created an unreasonable risk to the health of consumers and to Plaintiff, in particular, and Defendants are therefore strictly liable for the injuries sustained by Plaintiff.

63. As a direct and proximate result of Defendants placement of the defective Device into the stream of commerce, Plaintiff experienced and/or will experience severe harmful effects including but not limited to partial or complete loss of mobility, loss of range of motion, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for a revision surgery to replace the Device with the attendant risks of complications and death from such further surgery.

64. Further, as a result of the foregoing acts and omissions, Plaintiff has suffered and/or will in the future suffer lost wages and a diminished capacity to earn wages.

65. In performing the foregoing acts and omissions, Defendants acted despicably, fraudulently, and with malice and oppression so as to justify an award of punitive and exemplary damages.

FOURTH CAUSE OF ACTION
STRICT PRODUCTS LIABILITY (INADEQUATE WARNING)
AGAINST DEFENDANT

66. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows:

67. Defendant designed, manufactured, tested, marketed and distributed into the stream of commerce the Device. The Device placed into the stream of commerce by Defendant was defective due to inadequate warning, because Defendants knew or should have known that the Device could fail early in patients and therefore give rise to physical injury, pain and suffering, debilitation, and the need for a revision surgery to replace the Device with the attendant risks of complications and death from such further surgery, but failed to give consumers adequate warning of such risks.

68. Further, the Device placed into the stream of commerce by Defendant was surgically implanted in a manner reasonably anticipated by Defendant.

69. As a direct and proximate result of Defendant's placement of the defective Device into the stream of commerce, Plaintiff experienced and/or will experience severe harmful effects including but not limited to partial or complete loss of mobility, loss of range of motion, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for a revision surgery to replace the Device with the attendant risks of complications and death from such further surgery.

70. Further, as a result of the foregoing acts and omissions, Plaintiff has suffered and/or will in the future suffer lost wages and a diminished capacity to earn wages.

71. In performing the foregoing acts and omissions, Defendant acted despicably, fraudulently, and with malice and oppression so as to justify an award of punitive and exemplary damages...

FIFTH CAUSE OF ACTION

BREACH OF EXPRESS WARRANTY AGAINST DEFENDANT (N.Y. U.C.C. §2-313 et seq.)

72. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows:

73. Defendant designed, manufactured, tested, marketed and distributed the Device into the stream of commerce.

74. Defendant expressly warranted that the Device was a safe and effective hip replacement system and that it would fit better than traditional monolithic femoral stems and was thus appropriate for young and active patients.

75. Indeed, as set forth in detail above, Defendant made numerous representations about the quality, safety, effectiveness and expected lifetime of the Device which form express warranties.

76. The Device placed into the stream of commerce by Defendant did not conform to these express representations because they failed early thereby giving rise to unnecessary physical injury, pain and suffering, debilitation, and the need for a revision surgery to replace the Device with the attendant risks of complications and death from such further surgery. As a direct and proximate result of Defendant's breach of express warranties regarding the safety and effectiveness of the Device, Plaintiff experienced and/or will experience significant damages, including but not limited to physical injury, economic loss pain and suffering, and the need for further surgery to replace the faulty Device, and will continue to suffer such damages in the future.

77. In taking the actions and omissions that caused these damages, Defendant was guilty of malice, oppression and fraud, and Plaintiff is therefore entitled to recover punitive damages.

SIXTH CAUSE OF ACTION

**BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY AGAINST
DEFENDANTS**

(N.Y. U.C.C. SEC. 2-314 et seq.)

78. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows:

79. Defendant designed, manufactured, tested, marketed and distributed into the stream of commerce the Device.

80. At the time Defendant designed, manufactured, tested, marketed and distributed

into the stream of commerce the Device, Defendant knew the use for which the Device was intended, and impliedly warranted the Device to be of merchantable quality.

81. Plaintiff reasonably relied upon the skill and judgment of Defendant as to whether the Device was of merchantable quality.

82. Contrary to Defendant's implied warranties, the Device was not of merchantable quality or safe for the ordinary purposes for which it was to be used, because the Device was unreasonably dangerous and/or not reasonably fit for its intended, anticipated or reasonably foreseeable use as described above.

83. As a direct and proximate result of Defendant's breach of implied warranties regarding the safety and effectiveness of the Device, Plaintiff experienced and/or will experience significant damages, including but not limited to physical injury, economic loss, pain and suffering, and the need for further surgery to replace the faulty Device, and will continue to suffer such damages in the future.

84. In taking the actions and omissions that caused these damages, Defendant was guilty of malice, oppression and fraud, and Plaintiff is therefore entitled to recover punitive damages.

SEVENTH CAUSE OF ACTION

**BREACH OF IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE
AGAINST DEFENDANT (N.Y. U.C.C. § 2-315 et seq.)**

85. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows:

86. Defendant designed, manufactured, tested, marketed and distributed into the stream of commerce the Device.

87. At the time Defendant designed, manufactured, tested, marketed and distributed

into the stream of commerce the Device, Defendant knew the use for which the Device was intended, and impliedly warranted the Device to be of safe for such use.

88. Plaintiff reasonably relied upon the skill and judgment of Defendant as to whether the Device was safe for its intended use.

89. Contrary to Defendant's implied warranties, the Device was not of safe for its intended use or fit for the particular purpose for which it was designed, manufactured, tested, distributed or sold - for use and implantation as a total hip replacement system, because the Device was unreasonably dangerous and/or not reasonably fit for its intended, anticipated or reasonably foreseeable use as described above.

90. As a direct and proximate result of Defendant's breach of implied warranties regarding the safety and effectiveness of the Device, Plaintiff experienced and/or will experience significant damages, including but not limited to physical injury, economic loss, pain and suffering, and the need for further surgery to replace the faulty Device, and will continue to suffer such damages in the future.

91. In taking the actions and omissions that caused these damages, Defendant was guilty of malice, oppression and fraud, and Plaintiff is therefore entitled to recover punitive damages.

EIGHTH CAUSE OF ACTION

VIOLATION OF THE NEW YORK DECEPTIVE TRADE PRACTICES ACT AGAINST ALL DEFENDANT (N.Y. Gen. Bus.Law §§ 349 et seq.; 350-e et seq.)

92. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows:

93. Defendants unfairly, unconscionably, and deceptively advertised, marketed, sold, and represented the Device as a high-quality, safe and effective hip replacement system to

Plaintiff and Plaintiff's physicians.

94. Before they advertised, marketed, sold and represented the Device that was implanted in Plaintiff, Defendants knew or should have known of the unreasonable dangers and serious health risks that such a metal-on-metal total hip replacement system posed to patients like Plaintiff.

95. Plaintiff purchased and used the Device for personal use and thereby suffered ascertainable losses as a result of Defendant's actions in violation of the consumer protection laws.

96. Had Defendants not engaged in the deceptive conduct described herein, Plaintiff would not have purchased and/or paid for the Devices, and would not have incurred related medical costs and injury.

97. Defendants engaged in wrongful conduct while at the same time obtaining, under false pretenses, moneys from Plaintiff for the Device that would not have been paid had Defendants not engaged in unfair and deceptive conduct.

98. Unfair methods of competition or deceptive acts or practices that were proscribed by law, including the following: representing that goods or services have characteristics, ingredients, uses, benefits or quantities that they do not have; advertising goods or services with the intent not to sell them as advertised; and engaging in fraudulent or deceptive conduct that creates a likelihood of confusion or misunderstanding.

99. Plaintiff was injured by the cumulative and indivisible nature of Defendants' conduct.

100. The cumulative effect of Defendants' conduct directed at patients, physicians and consumers was to create demand for and sell the Device.

101. Each aspect of Defendants' conduct combined to artificially create sales of the Device.

102. 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 Device.

103. Had Defendants not engaged in the deceptive conduct described above, Plaintiff would not have purchased and/or paid for the Device, and would not have incurred related medical costs.

104. 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. Defendant's 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.

105. Defendants have engaged in unfair competition or unfair or deceptive acts or trade practices or have made false representations in violation of N.Y. Gen. Bus. Law §§ 349 et seq. and 350-e et seq.

106. Under the statute listed above to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising, Defendant are the suppliers, manufacturers, advertisers, and sellers, who are subject to liability under such legislation for unfair, deceptive, fraudulent and unconscionable consumer sales practices.

107. Defendants violated the statutes that were enacted in these states to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising, by knowingly and falsely representing that the Device was fit to be used

for the purpose for which it was intended, when in fact the Device was defective and dangerous, and by other acts alleged herein. These representations were made in uniform promotional materials.

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

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

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

111. As a direct and proximate result of Defendants' violations of the State's 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.

112. As specifically described in detail above, Defendant knew that the Device subjected patients to early failure, painful and harmful physical reactions, death of tissue, bone loss and the need for explants and revision surgery.

113. As a direct and proximate result of Defendant's representations, Plaintiff has experienced and/or will experience significant damages, including but not limited to permanent physical injury, economic loss, pain and suffering and underwent revision surgery to repair the physical damage caused by the Device.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for the following relief:

- I. Judgment in favor of Plaintiff and against Defendants, for damages in such amounts as may be proven at trial;
- II. Compensation for both economic and non-economic losses, including but not limited to medical expenses, loss of earnings, disfigurement, pain and suffering, mental anguish, and emotional distress, in such amounts as may be proven at trial;
- III. Punitive and/or exemplary damages in such amounts as may be proven at trial;
- IV. Attorney's fees and costs;
- V. Interest

Such further other legal and equitable relief as the Court may deem just and proper.

Dated: July 18, 2016
New York, New York

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