UNITED STATES DISTRICT COURT
DISTRICT OF MAINE

MARK IRVING and LORRAINE IRVING Plaintiffs, v. HOWMEDICA OSTEONICS CORPORATION d/b/a STRYKER ORTHOPEDICS Defendant.	)	Civil Action No. _____ COMPLAINT & DEMAND FOR JURY TRIAL

NOW COMES Plaintiffs Mark Irving and Lorraine Irving (hereafter "Plaintiff" and/or "Plaintiffs"), by and through the undersigned attorneys, Fitzgerald Law Group, LLC, and bring this action against Defendant Howmedica Osteonics Corporation d/b/a Stryker Orthopedics Corporation ("Defendant", "Defendants," "Howmedica" or "Stryker"), for personal injuries suffered as a proximate result of Plaintiff's use of a prosthetic hip system with components including but not limited to the LFIT Anatomic CoCr V40 Femoral Head and Accolade TMZF Plus Femoral Stem (hereafter "Stryker Hip System"). Plaintiff makes the following allegations based upon individual personal knowledge as to Plaintiff's own acts, and upon information and belief, as well as upon Plaintiff's attorneys' investigative efforts as to Defendants' actions and misconduct and in support allege as follows:

JURISDICTION & VENUE

1. 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.

2. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391 because the Defendants tested, studied, researched, designed, formulated, manufactured, inspected, labeled,

packaged, promoted, advertised, marketed, distributed, and/or sold the Stryker Hip System within this judicial district; because Plaintiff Mark Irving was implanted with the defective Stryker Hip System and was thereafter injured by the Stryker Hip System in this judicial district; and because Defendants are subject to personal jurisdiction within the State of Maine.

TAG ALONG ACTION

3. This is a potential tag-along action and, in accordance with 28 U.S.C. § 1407, the case should be transferred to the United States District Court for the District of Massachusetts for inclusion in *In Re: Stryker LFIT V40 Femoral Head Products Liability Litigation*, MDL No. 2768 (Hon. Indira Talwani).

THE PARTIES

4. Plaintiff Mark Irving is an adult resident and citizen of Windham, Maine.

5. Plaintiff Lorraine Irving is an adult resident and citizen of Windham, Maine. At all times relevant to this action, Plaintiff Lorraine Irving was the lawful and loving spouse to Plaintiff Mark Irving.

6. Defendant Howmedica Osteonics Corporation is a corporation organized and existing under the laws of New Jersey, with its principal place of business in Mahwah, New Jersey. Howmedica Osteonics Corporation is a wholly-owned subsidiary of Stryker Orthopedics Corporation ("Stryker"). Howmedica licenses the Stryker brand name for use of its prosthetic hip devices and pays Stryker a licensing fee. At all times relevant to this action, Howmedica tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold the Stryker Hip System in interstate commerce and throughout the State of Maine and generated substantial revenue as a result.

7. 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 Howmedica, 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.

MISNOMER/ALTER-EGO

8. In the event any parties are misnamed or not included herein, it is Plaintiffs' contention that such a misnomer and/or such parties are/were "alter egos" of parties named herein. Alternatively, Plaintiffs contend that such "corporate veils" should be pierced to hold such parties properly included in the interest of justice.

GENERAL FACTUAL ALLEGATIONS

A. Total Hip Arthroplasty

9. The hip joint, scientifically referred to as the acetabulofemoral joint, is the joint between the femur (the thigh bone) and the acetabulum (the hip socket) of the pelvis, and its primary function is to support the weight of the body in both static (*i.e.*, standing) and dynamic (*i.e.*, walking or running) postures.

10. Total hip replacement, also known as total hip arthroplasty, is a surgical procedure in which the patient's hip joint is resurfaced and replaced with an artificial implant which is designed to replicate the human anatomy – that is, the relatively simple ball and socket structure of the human hip joint.

11. Hip replacement surgery traditionally consists of several stages. First, the orthopedic surgeon removes the top of the femur, or thighbone. Next, the orthopedic surgeon reams or hollows out a portion of the top of the femur and inserts a metal femoral stem into the remaining femur bone. The surgeon then uses a hammer to strike an artificial "ball" or femoral head typically made of a metal alloy, stainless steel or ceramic onto the top end of the femoral stem. Next, the surgeon reams out the patient's natural acetabulum and inserts an acetabular cup in the resulting space. In some hip implant systems, a metal, plastic or ceramic liner is then fitted inside the acetabular cup. Finally, the

surgeon fits the ball-shaped femoral head into the liner of the acetabular cup where it should move easily, without friction or pain to the patient.

12. Total hip replacement is most commonly used to treat joint failure caused by osteoarthritis. Other indications for total hip replacement include rheumatoid arthritis, femoral head fracture, avascular necrosis, arthritis associated with Paget's disease of the bone, and ankylosing spondylitis. The aims of the procedure are pain relief and improvement in hip function. Hip replacement is usually considered only after other non-surgical options, such as pain medications and physical therapy, have failed.

13. Total hip replacement is a common medical procedure performed on more than 420,000 patients in the U.S. each year. In 2010, the prevalence of total hip and total knee replacement in the total U.S. population was 0.83% and 1.52%, respectively. Prevalence was higher among women than among men and increased with age, reaching 5.26% for total hip replacement and 10.38% for total knee replacement at eighty years of age. These estimates correspond to 2.5 million individuals (1.4 million women and 1.1 million men) with total hip replacement and 4.7 million individuals (3.0 million women and 1.7 million men) with total knee replacement in 2010.

14. Traditional hip replacement devices consisted of a monobloc stem, which was a femoral stem with a single neck/head option all constructed from a single piece of metal. Monobloc stems made restoring a patient's leg length and femoral offset challenging and increased the component inventory at healthcare facilities.

15. The concept of "modularity" was introduced into the design of hip prostheses and has become increasingly common in the last two decades. Modularity aimed to provide surgeons with additional versatility when attempting to restore normal biomechanical function in patients.

16. Modularity can be exhibited at the juncture between the femoral head and the trunnion of the femoral stem. The trunnion is the tapered top end of the femoral stem upon which the femoral

head is affixed. The trunnion has a taper angle that is wider at the proximal than distal end. The bore of the femoral head (i.e. the hollow portion of the inside of the ball) has a corresponding taper angle. When the two components are affixed together the corresponding taper angles allow for an interference fit between the femoral head and femoral stem. The contact area between the inside of the bore of the femoral head (the female taper surface) and the trunnion of the femoral stem (the male taper surface) is known as the taper interface.

17. The taper interface is designed to prevent motion when assembled; however, studies have demonstrated that over time micromotion can develop at a malfunctioning taper interface causing fretting between the femoral head and femoral stem damage which can result in the generation of metal debris wearing off the component parts. Studies have also shown that over time corrosion can occur at a malfunctioning taper interface which can result in a similar release of metal ions, particularly cobalt and/or chromium, off the component parts.

18. Whether caused by fretting or corrosion, the release of metal debris and/or ions can result in elevated serum metal ion levels, adverse local tissue reactions, pseudotumor formation, tissue destruction, metallosis, the need for revision surgery and, in some cases, systemic effects of metal ion toxicity, including neurologuical (fatigue, weakness, poor coordination, cognitive dysfunction depression, vertigo, visual and hearing impairment, and peripheral neuropathy), hematological (polycythaemia), endocrine (hypothyroidism), and cardiac (arrhythmias and cardiomyopathy) complications.

19. A hip implant should not cause metallosis to a patient in which it is implanted. Although a small amount of asymptomatic or non-toxic corrosion or metal debris may occur with a well-functioning device, a hip implant that causes an excessive amount of corrosion or metal debris sufficient to cause elevated serum metal ion levels, adverse local tissue reactions, pseudotumor formation, tissue destruction, metallosis, and/or the need for revision surgery creates an unreasonable

risk of injury.

20. The concern that fretting and corrosion damage could occur at the head-neck taper interface of a modular hip prosthesis was first reported in the early 1980's. Since that time, increasingly numerous studies and reports have demonstrated that a malfunctioning taper interface between a metal femoral head and metal femoral stem may be susceptible to fretting and corrosion damage resulting in elevated serum metal ion levels, adverse local tissue reactions, pseudotumor formation, tissue destruction, metallosis, the need for revision surgery.

21. As the total hip replacement became more common among younger patients who want to maintain a physically active lifestyle, alternative bearing surfaces such as cross-linked polyethylene, ceramic-on-ceramic and metal-on-metal have been developed to address the issue of wear.

B. History of the Accolade TMZF Plus Femoral Stem and LFIT Anatomic CoCr V40 Femoral Head

22. On October 9, 2002, Howmedica received FDA clearance to sell its Accolade TMZF Plus Femoral Hip Stem ("Accolade TMZF Plus") in the United States. The Accolade TMZF Plus is a tapered, non-porous coated femoral stem manufactured from a Ti-6Al-4V substrate material with a coating consisting of commercially pure titanium and Purefix hydroxylapatite.

23. The Accolade TMZF Plus is designed to be used with LFIT Anatomic CoCr V40 femoral heads.

24. The material combination of a titanium alloy stem (like the Accolade TMZF Plus) with a cobalt chromium femoral head (like the LFIT V40) has been found to cause fretting and corrosion. Scientists have reported the occurrence of significant fretting and corrosion caused by the combination of dissimilar metals and/or micro-motion at the junction between the stem trunnion and head bore dating back to the 1980's.

25. Despite the known problems associated with pairing dissimilar metals and/or micro-motion at the junction between the metal stem and metal head, Defendant represented and warranted in its marketing materials that its proprietary alloys will not fret or corrode.

26. Defendant manufactures, markets, and sells ceramic femoral heads that are compatible with the Accolade TMZF Plus. Upon information and belief, an Accolade TMZF Plus stem paired with a ceramic femoral head will not experience fretting and corrosion.

27. A femoral head commonly paired with the Accolade TMZF Plus is the LFIT Anatomic CoCr V40 Femoral Head ("LFIT V40 Head").

28. On August 22, 2006, Howmedica received FDA clearance to sell the LFIT V40 Head with X3 polyethylene liners in the United States.

29. The LFIT (Low Friction Ion Treatment) manufacturing process embeds nitrogen ions under high energy into the cobalt/chromium surface of large femoral heads, for the purported purpose of improving surface wettability, allowing increased lubrication between components, and decreasing frictional forces against the X3 liner. The LFIT V40 Heads were (and are) offered in 36mm, 40mm, and 44mm diameters.

30. A Morse taper (a cone-within-a-cone) is used to mate the LFIT V40 Head with the Accolade TMZF Plus stem. The bore (female portion) of the LFIT V40 Head is placed onto the tapered trunnion (male portion) of the Accolade TMZF Plus stem and impacted by the surgeon using a Stem Head Impactor tool. The stresses created by compression of the wall of the bore by the trunnion results in a cold-welding or locking of the head/stem taper interface (i.e. taper lock).

31. Failure of the taper lock or cold-weld between the LFIT V40 Head bore and the Accolade TMZF Plus trunnion allows micro-motion between these components and promotes corrosion and fretting.

32. The indications for use of both LFIT V40 Heads and Accolade TMZF Plus stems

include non-inflammatory degenerative joint disease, such as osteoarthritis and avascular necrosis.

33. At all times material hereto, Howmedica developed, tested, assembled, manufactured, packaged, labeled, prepared, distributed, marketed, supplied, and/or sold the Accolade TMZF Plus and LFIT V40 Heads, either directly or indirectly, to members of the public within the State of Maine, including hospitals, surgeons, and the Plaintiff.

34. On or around January 6, 2009, Stryker issued a voluntary recall of certain sizes and lots of Accolade TMZF Plus femoral stems citing lack of tensile bone strength and crystallinity.

35. On or about August 29, 2016, Stryker issued a voluntary recall of certain sizes and lots of LFIT V40 Heads manufactured prior to 2011 citing a "higher than expected" incidence of taper lock failure. Stryker identified various "potential hazards" associated with LFIT V40 Head taper lock failure, including "excessive metallic debris" which could result in an "inflammatory response" and "adverse local tissue reaction" ("ALTR") and require additional surgery to revise or replace the product.

36. The Medical Device Amendments to the Food, Drug, and Cosmetics Act of 1938 ("MDA"), in theory, requires medical devices like the Stryker Hip System to undergo premarket approval by the FDA, a process which obligates the manufacturer to design and implement a clinical investigation and to submit the results of that investigation to the FDA.

37. Premarket approval is a rigorous process that requires a manufacturer to submit what is typically a multivolume application that includes, among other things, full reports of all studies and investigations of the device's safety and effectiveness that have been published or should reasonably be known to the applicant; a full statement of the device's components, ingredients, and properties and of the principle or principles of operation; a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and when relevant, packing and installation of, such device; samples or device components required by the FDA; and a specimen

of the proposed labeling.

38. The FDA may grant premarket approval only if it finds that there is reasonable assurance that the medical device is safe and effective and must weigh any probable benefit to health from the use of the device against any probable risk of injury or illness from such use.

39. A medical device on the market prior to the effective date of the MDA – a so-called "grandfathered" device – is not required to undergo premarket approval. In addition, a medical device marketed after the MDA's effective date may bypass the rigorous premarket approval process if the device is "substantially equivalent" to a "grandfathered" pre-MDA device (i.e., a device approved prior to May 28, 1976).

40. This exception to premarket approval is known as "510(k) clearance" which only requires the manufacturer to notify the FDA under section 510(k) of the MDA of its intent to market a device at least 90 days prior to the device's introduction on the market, and to explain the device's substantial equivalence to a pre-MDA predicate device. The FDA may then "clear" the new device for sale in the United States.

41. All the component parts comprising Plaintiff's Stryker Hip System were cleared for marketing by the FDA pursuant to the 510(k) of the MDA or were marketed without receiving either 510(k) clearance or pre-market approval by the FDA.

42. Had Defendants conducted clinical trials of the Stryker Hip System before the device was first released on the market, they would have discovered at that time the propensity of the device to undergo significant fretting and/or corrosion at the femoral head-stem taper juncture resulting elevated serum metal ion levels, adverse local tissue reactions, pseudotumor formation, tissue destruction, metallosis, the need for revision surgery and, in some cases, systemic effects of metal ion toxicity, including neurologuical (fatigue, weakness, poor coordination, cognitive dysfunction depression, vertigo, visual and hearing impairment, and peripheral neuropathy), hematological

(polycythaemia), endocrine (hypothyroidism), and cardiac (arrhythmias and cardiomyopathy) complications.

43. At all times relevant to this action, Defendants were aware of the problems with the Stryker Hip System's design and its propensity to undergo fretting and/or corrosion at the femoral head-stem taper interface resulting in elevated serum metal ion levels, adverse local tissue reactions, pseudotumor formation, tissue destruction, metallosis, the need for revision surgery and, in some cases, systemic effects of metal ion toxicity, including neurologuical (fatigue, weakness, poor coordination, cognitive dysfunction depression, vertigo, visual and hearing impairment, and peripheral neuropathy), hematological (polycythaemia), endocrine (hypothyroidism), and cardiac (arrhythmias and cardiomyopathy) complications.

44. At all times relevant to this action, Defendants failed to recognize the defects in the Stryker Hip System due to poor and inadequate quality assurance procedures, including the failure of Howmedica to implement appropriate physical, manual, x-ray, microscopic and other inspections of the Stryker Hip System. Howmedica also failed to implement or utilize adequate safeguards, tests, inspections, validation, monitoring and quality assessments to ensure the safety of the Stryker Hip System.

45. At the time the Stryker Hip System was manufactured and sold to patients including the Plaintiff, the device was defectively manufactured and unreasonably dangerous, and did not conform to the federal regulations subjecting patients to risks of injury.

46. At all times relevant to this action, Howmedica's inadequate manufacturing processes led to material flaws in the quality systems at its manufacturing facilities.

47. At all times relevant to this action, Howmedica failed to perform adequate testing of the Stryker Hip System, including its components and subassemblies, to ensure that the Stryker Hip System functioned properly during and after implantation.

48. As a result of these manufacturing and quality control problems associated with the manufacture of the Stryker Hip System, the device was inadequately and defectively manufactured making it adulterated, and outside of the specifications expressly approved by the FDA.

49. On or before the date of Plaintiff's initial hip surgery, Defendants knew or should have known that the Stryker Hip System was failing and causing serious complications after implantation in many patients. Such complications included, but were not limited to, elevated serum metal ion levels, adverse local tissue reactions, pseudotumor formation, tissue destruction, metallosis, the need for revision surgery and, in some cases, systemic effects of metal ion toxicity, including neurologuical (fatigue, weakness, poor coordination, cognitive dysfunction depression, vertigo, visual and hearing impairment, and peripheral neuropathy), hematological (polycythaemia), endocrine (hypothyroidism), and cardiac (arrhythmias and cardiomyopathy) complications. Defendants, however, actively concealed the true information and spread false information through, among other things, marketing and promotional materials, advertisements, and communications and meetings with orthopedic surgeons and other healthcare providers.

50. Before the date of Plaintiff's initial hip replacement surgery, Defendants knew or should have known that the Stryker Hip System was defective and unreasonably dangerous to patients and that the product had an unacceptable failure and complication rate.

51. Defendants had legal obligations to stop promoting, marketing, selling and defending the Stryker Hip System. Defendants should have instead notified physicians who had implanted the Stryker Hip System of the device's propensity for fretting and corrosion at the femoral head-stem taper interface, and for some patients to develop extremely adverse reactions to the high level of metal debris generated by wear of the device. Defendants should have attempted to convey this same information to patients who had been implanted with the Stryker Hip System. Nonetheless, Defendants did not notify doctors or patients of the risks the Stryker Hip System presented. Instead,

Defendants concealed this material information, while continuing to market, promote, distribute, sell, and defend the Stryker Hip System.

THE FEDERAL REQUIREMENTS

52. Federal regulation states: "Recall means a firm's removal or correction of a marketed product that the Food and Drug Administration considers to be in violation of the laws it administers and against which the agency would initiate legal action, e.g. seizure." See 21 CFR § 7.3 (g).

53. Federal regulation states: "Recall classification means the numerical designation, i.e., I, II or III, assigned by the Food and Drug Administration to a particular product recall to indicate the relative degree of health hazard presented by the product being recalled." See 21 CFR § 7.3 (m).

54. Federal regulation states: "Class II is a situation in which use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote." See 21 CFR § 7.3 (m).

55. The classification of the product withdrawals and corrections of the Defendant's devices (described above) as Class II Recalls by the FDA confirms by definition that the devices were in violation of federal law and that initiation of legal action or seizure would be indicated for these devices.

56. Pursuant to federal law, a device is deemed to be adulterated if, among other things, it fails to meet established performance standards, or if the methods, facilities or controls used for its manufacture, packing, storage or installation are not in conformity with federal requirements. See 21 U.S.C. § 351.

57. Pursuant to federal law, a device is deemed to be misbranded if, among other things, its labeling is false or misleading in any particular manner, or if it is dangerous to health when used in the manner prescribed, recommended or suggested in the labeling thereof. See 21 U.S.C. § 352.

58. Pursuant to federal law, manufacturers are required to comply with FDA regulation of

medical devices, including FDA requirements for records and reports, in order to prohibit introduction of medical devices that are adulterated or misbranded, and to assure the safety and effectiveness of medical devices. In particular, manufacturers must keep records and make reports if any of its medical devices may have caused or contributed to death or serious injury, or if the devices have malfunctioned in a manner likely to cause or contribute to death or serious injury. Federal law also mandates that the FDA establish regulations requiring a manufacturer of a medical device to report promptly to FDA any correction or removal of a device undertaken to reduce a risk to health posed by the device, or to remedy a violation of federal law by which a device may present a risk to health. See 21 U.S.C. § 360 (i).

59. Pursuant to FDA regulation, adverse events associated with a medical device must be reported to FDA within 30 days after the manufacturer becomes aware that (a) a device may have caused or contributed to death or serious injury, or (b) that a device has malfunctioned and would be likely to cause or contribute to death or serious injury if the malfunction was to recur. Such reports must contain all information reasonably known to the manufacturer, including any information that can be obtained by analysis, testing, or other evaluation of the device, and any information in the manufacturer's possession. In addition, manufacturers are responsible for conducting an investigation of each adverse event, and must evaluate the cause of the adverse event. See 21 CFR § 803.50.

60. Pursuant to federal regulations, manufacturers of medical devices must also describe in every individual adverse event report whether remedial action was taken with regard to the adverse event, and whether the remedial action was reported to FDA as a removal or correction of the device. See 21 CFR § 803.52.

61. Pursuant to federal regulations, manufacturers must report any reportable MDR event or events, including a trend analysis that necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health, to the FDA within 5 business days after becoming aware of

such event or events. See 21 CFR § 803.53.

62. Pursuant to federal regulation, device manufacturers must report promptly to FDA any device corrections and removals, and maintain records of device corrections and removals. FDA regulations require submission of a written report within ten working days of any correction or removal of a device initiated by the manufacturer to reduce a risk to health posed by the device, or to remedy a violation of the Act caused by the device, which may present a risk to health. The written submission must contain, among other things, a description of the event giving rise to the information reported, the corrective or removal actions taken, and any illness or injuries that have occurred with use of the device, including reference to any device report numbers. Manufacturers must also indicate the total number of devices manufactured or distributed which are subject to the correction or removal, and provide a copy of all communications regarding the correction or removal. See 21 CFR § 806.

63. Pursuant to federal regulation, manufacturers must comply with specific quality system requirements promulgated by FDA. These regulations require manufacturers to meet design control requirements, including but not limited to conducting design validation to ensure that devices conform to defined user needs and intended uses. Manufacturers must also meet quality standards in manufacture and production of the devices. Manufacturers must establish and maintain procedures for implementing corrective actions and preventive actions, and investigate the cause of nonconforming products and take corrective action to prevent recurrence. Manufacturers are also required to review and evaluate all complaints and determine whether an investigation is necessary. Manufacturers are also required to use statistical techniques, where necessary, to evaluate product performance. See 21 CFR § 820.

64. Pursuant to federal regulations, a manufacturer must report to the FDA any new indications for use of a device, labeling changes, or changes in the performance or design

specifications, circuits, components, ingredients, principle of operation or physical layout of the device. Federal regulations require that: "A PMA supplement must be submitted when unanticipated adverse effects, increases in the incidence of anticipated adverse effects, or device failures necessitate a labeling, manufacturing, or device modification." See 21 CFR § 814.

65. Specifically, it is believed that with respect to LFIT V40 Heads, the Defendant failed to timely report adverse events; failed to timely conduct failure investigations and analysis; failed to timely report any and all information concerning product failures and corrections; failed to timely and fully inform FDA of unanticipated adverse effects, increases in the incidence of adverse effects, or device failures necessitating a labeling, manufacturing or device modification; failed to conduct necessary design validation; and, sold a misbranded and adulterated product

SPECIFIC FACTUAL ALLEGATIONS

66. On December 2, 2011, Plaintiff Mark Irving underwent a left total hip replacement. The surgery was performed by Dr. Stephen Kelly at Mercy Hospital in Portland, Maine.

67. During the procedure, Plaintiff Mark Irving was implanted with the following components:

a. LFIT Anatomic V40 CoCr Femoral Head, Size: 36mm, Offset: +0mm, Ref. No. 6260-9-136, Lot No. MKPER4;

b. Accolade TMZF Plus Hip Stem, Size: #2.5, Neck Length: 30mm, Stem Length: 118mm, Ref. No. 6021-2530, Lot No. 37983802;

c. Trident PSL HA Cluster Acetabular Shell, Size: 56mm, Ref. No. 542-11-56F, Lot No. MKMTE0;

d. Trident X3 Polyethylene Insert, Inner Diameter: 36mm, Ref. No. 623-00-36F, Lot No. MKL224; and

e. Torx 6.5 mm Cancellous Bone Screw, Ref. No. 2030-6525-1, Lot. No. MKR05H.

68. After implantation, Plaintiff Mark Irving developed pain in his replaced left hip. Metal ion testing demonstrated elevated cobalt and chromium levels.

69. On October 20, 2016, Plaintiff Mark Irving underwent a left hip revision surgery. The procedure was performed by Dr. Brian McGrory at Maine Medical Center in Portland, Maine. During the revision surgery, Dr. McGrory confirmed that hip implant failure was due to mechanically assisted crevice corrosion at the juncture between the LFIT V40 Head and Accolade TMZF Plus stem.

70. As a direct, proximate and legal consequence of the defective nature of the Stryker Hip System as described herein, Plaintiff has suffered and continues to suffer permanent and debilitating injures and damages, including but not limited to, significant pain and discomfort; gait impairment; poor balance; difficulty walking; component part loosening, impingement and/or detachment; metallosis; soft tissue damage; adverse local tissue reaction; and other injuries presently undiagnosed, which all require ongoing medical care. As a further direct, proximate and legal consequence of the defective nature of the Stryker Hip System, Plaintiff has sustained and will sustain future damages, including but not limited to additional revision surgeries; cost of medical care; rehabilitation; home health care; lost wages; loss of earning capacity; mental and emotional distress; and pain and suffering.

FIRST CAUSE OF ACTION
STRICT LIABILITY – MANUFACTURING DEFECT

71. Plaintiff hereby incorporates by reference all previous paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

72. Prior to, on, and after the dates of Plaintiff's initial hip surgery, and at all times relevant this action, Defendants tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold the Stryker Hip System for implantation into consumers, such as Plaintiff, by orthopedic surgeons in the United States.

73. The Stryker Hip System was "defective" and "unreasonably dangerous" when it entered the stream of commerce and was received by Plaintiff, because it was dangerous to an extent beyond that which would be contemplated by the ordinary consumer. At no time did Plaintiff have reason to believe that the Stryker Hip System was in a condition not suitable for its proper and intended use.

74. At all times herein mentioned, the Defendants tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold the Stryker Hip System, which was implanted in Plaintiff, such that it was dangerous, unsafe, and defective in manufacture. The defects in manufacture include but are not limited to the following respects:

a. that the Stryker Hip System has the propensity to undergo fretting and corrosion at the femoral head-stem taper juncture causing serious complications in patients;

b. that the Stryker Hip System differed from the manufacturer's intended design or specifications, or from other typical units of the same product line;

b. that the Defendants failed to conduct adequate mechanical testing, including corrosion fatigue or other wear testing, on components, subassemblies and/or the finished Stryker Hip System;

c. that Defendants failed to test an adequate number of sample devices on an ongoing basis;

c. that Defendants failed to take adequate steps to specifically identify failure modes with clarity and to suggest methods to monitor, avoid, and/or prevent further failures;

d. that Defendants failed to identify and/or note the significance of any testing

that resulted in failure of the Stryker Hip System;

e. that Defendants failed to take corrective actions to eliminate or minimize further failures of the Stryker Hip System;

f. that Defendants failed to adequately explain performance specifications for the components, subassemblies, and/or the finished Stryker Hip System;

g. that Defendants failed to adequately explain or justify all test conditions and acceptance criteria for the Stryker Hip System;

h. that Defendants failed to perform adequate testing in an environment that adequately simulated in vivo conditions;

i. that Defendants failed to perform adequate testing of the Stryker Hip System, including its components and subassemblies, to ensure that the Stryker Hip System functioned properly during and after implantation;

k. that Defendants failed to perform adequate quality assurance testing and validation before and after sterilization.

l. that the bore within LFIT V40 Head was poorly machined resulting in an inability to achieve the desired taper lock with the trunnion of the Accolade TMZF Plus stem;

m. that the bore within the LFIT V40 Head was constructed in a manner that it did not maintain structural integrity *in vivo* within a biologic environment; and

n. that the bore within the LFIT V40 Head was constructed in a manner that it did not maintain structural integrity when mated with the Accolade TMZF Plus stem.

75. Plaintiff's physicians employed the Stryker Hip System in the manner in which it was intended and recommended to be used, making such use reasonably foreseeable to Defendants.

76. The Stryker Hip System as tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold by Defendants reached Plaintiff without substantial change in its condition.

77. As alleged herein, Defendants knew and had reason to know that the Stryker Hip System caused increased risks of harm to the Plaintiff and other consumers. Defendants consciously disregarded these increased risks of harm by failing to warn of such risks; unlawfully concealing the dangerous problems associated with implantation of the Stryker Hip System; and continuing to market, promote, sell and defend the device.

78. As alleged herein, the defects in manufacture of the Stryker Hip System were a substantial factor in causing Plaintiffs' injuries.

79. As a direct, proximate and legal consequence of Defendants' wrongful conduct as described herein, including the defective manufacture of the Stryker Hip System, Plaintiff has sustained and will continue to sustain severe and debilitating injuries, including but not limited to, significant pain and discomfort; gait impairment; poor balance; difficulty walking; component part loosening, impingement and/or detachment; metallosis; soft tissue damage; adverse local tissue reaction; dislocation; and other injuries presently undiagnosed, which all require ongoing medical care. As a further direct, proximate and legal consequence of the defective nature of the Stryker Hip System, Plaintiff has sustained and will sustain future damages, including but not limited to additional revision surgeries; cost of medical care; rehabilitation; home health care; lost wages; loss of earning capacity; mental and emotional distress; 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
STRICT LIABILITY – DESIGN DEFECT

80. Plaintiff hereby incorporates by reference all previous paragraphs of this Complaint as

if fully set forth herein and further alleges as follows:

81. Prior to, on, and after the dates of Plaintiff's initial hip surgery, and at all times relevant to this action, Defendants tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold the Stryker Hip System for implantation into consumers, such as Plaintiff, by physicians and orthopedic surgeons in the United States.

82. The Stryker Hip System was defective in design and unreasonably dangerous when it entered the stream of commerce and was received by Plaintiff, because it was dangerous to an extent beyond that which would be contemplated by the ordinary consumer. At no time did Plaintiff have reason to believe that the Stryker Hip System was in a condition not suitable for its proper and intended use.

83. The Stryker Hip System was defective in design and unreasonably dangerous when it entered the stream of commerce and was received by Plaintiff, because the foreseeable risks exceeded or outweighed the purported benefits associated with the device.

84. At all times relevant to this action, the Defendants tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold the Stryker Hip System, which was implanted in Plaintiff, such that it was dangerous, unsafe, and defective in design.

85. The Stryker Hip System implanted in Plaintiff is defective in design in all or some of, and without limitation, the following respects:

a. The device is constructed from incompatible metals; namely, the combination of the titanium alloy in the Accolade TMZF stem with the cobalt-chromium in the LFIT V40 Heads;

b. There is a misfit between the bore of the LFIT V40 Head and the trunnion of the Accolade TMZF Plus stem which results in taper lock failure, micro-motion of the Accolade TMZF Plus trunnion within the LFIT V40 Head, and fretting and corrosion damage; and

c. The device has the propensity to undergo fretting and/or corrosion at the femoral head-stem taper juncture causing serious complications in patients.

86. Plaintiff's physicians employed the Stryker Hip System in the manner in which it was intended to be used, making such use reasonably foreseeable to Defendants.

87. The Stryker Hip System as tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold by Defendants reached Plaintiff without substantial change in its condition.

88. As alleged herein, Defendants knew and had reason to know that the Stryker Hip System caused increased risks of harm to the Plaintiff and other consumers. Defendants consciously disregarded these increased risks of harm by failing to warn of such risks; unlawfully concealing the dangerous problems associated with implantation of the Stryker Hip System; and continuing to market, promote, sell and defend the Stryker Hip System.

89. As alleged herein, the defects in design of the Stryker Hip System were a substantial factor in causing Plaintiff's injuries.

90. Defendants failed to develop and make available alternative products that were designed in a safe or safer manner, even though such products were feasible and marketable at the time Defendants sold the Stryker Hip System to Plaintiff.

91. As a direct, proximate and legal consequence of Defendants' wrongful conduct as described herein, including the defective design of the Stryker Hip System, Plaintiff has sustained and will continue to sustain severe and debilitating injuries, including but not limited to, significant pain

and discomfort; gait impairment; poor balance; difficulty walking; component part loosening, impingement and/or detachment; metallosis; soft tissue damage; adverse local tissue reaction; dislocation; and other injuries presently undiagnosed, which all require ongoing medical care. As a further direct, proximate and legal consequence of the defective nature of the Stryker Hip System, Plaintiff has sustained and will sustain future damages, including but not limited to additional revision surgeries; cost of medical care; rehabilitation; home health care; lost wages; loss of earning capacity; mental and emotional distress; 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.

THIRD CAUSE OF ACTION
STRICT LIABILITY – FAILURE TO WARN

92. Plaintiff hereby incorporates by reference all previous paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

93. Prior to, on, and after the dates of Plaintiff's initial hip surgery, and at all times relevant to this action, Defendants tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold the Stryker Hip System for implantation into consumers, such as Plaintiff, by physicians and orthopedic surgeons in the United States.

94. The Stryker Hip System was defective and unreasonably dangerous when it entered the stream of commerce and was received by Plaintiff, because it was dangerous to an extent beyond that which would be contemplated by the ordinary consumer. At no time did Plaintiff have reason to believe that the Stryker Hip System was in a condition not suitable for its proper and intended use.

95. The Stryker Hip System was defective in design and unreasonably dangerous when it entered the stream of commerce and was received by Plaintiff, because the foreseeable risks exceeded or outweighed the purported benefits associated with the device.

96. The Stryker Hip System posed increased risks of harm and side effects that were known or knowable to Defendants by the use of scientific knowledge available before, at and after

the time of manufacture, distribution, and sale of the Stryker Hip System to Plaintiff.

97. Defendants knew or should have known of the defective condition, dangerous characteristics, and risks associated with the Stryker Hip System as alleged herein.

98. Defendants consciously disregarded the increased risks of harm by failing to adequately warn of such risks; unlawfully concealing the dangerous problems associated with implantation of the Stryker Hip System; and continuing to market, promote, sell and defend the Stryker Hip System.

99. The Stryker Hip System that was manufactured, distributed, and sold by the Defendants to Plaintiff was in a defective condition that was unreasonably dangerous to any user or ordinary consumer of the device, including Plaintiff.

100. Such ordinary consumers, including Plaintiff, would not and could not have recognized or discovered the potential risks and side effects of the Stryker Hip System as alleged herein.

101. The instructions for use, directions and warnings provided by Defendants with the Stryker Hip System failed to adequately convey the potential risks and side effects of the Stryker Hip System and the dangerous propensities of the device, which risks were known or were reasonably scientifically knowable to Defendants.

102. The Stryker Hip System was expected to and did reach Plaintiff and his orthopedic surgeon without substantial change in its condition as manufactured, distributed, and sold by Defendants.

103. Plaintiff's orthopedic surgeon used the Stryker Hip System in the manner in which it was intended to be used, making such use reasonably foreseeable to Defendants.

104. The lack of adequate instructions for use, directions and warnings with the Stryker Hip System prior to, on, and after the dates of Plaintiff's initial hip surgery were a substantial factor in causing Plaintiff's injuries, losses and damages as alleged herein.

105. Defendants failed to develop and make available alternative products that were

designed in a safe or safer manner, even though such products were feasible and marketable at the time Defendants sold the Stryker Hip System to Plaintiff.

106. As a direct, proximate and legal consequence of Defendants' wrongful conduct as described herein, including Defendants' lack of sufficient instructions or warnings, Plaintiff has sustained and will continue to sustain severe and debilitating injuries, including but not limited to, significant pain and discomfort; gait impairment; poor balance; difficulty walking; component part loosening, impingement and/or detachment; metallosis; soft tissue damage; adverse local tissue reaction; dislocation; and other injuries presently undiagnosed, which all require ongoing medical care. As a further direct, proximate and legal consequence of the defective nature of the Stryker Hip System, Plaintiff has sustained and will sustain future damages, including but not limited to additional revision surgeries; cost of medical care; rehabilitation; home health care; lost wages; loss of earning capacity; mental and emotional distress; 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.

FOURTH CAUSE OF ACTION
NEGLIGENCE – DESIGN, MANUFACTURE & SALE

107. Plaintiff hereby incorporates by reference all previous paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

108. Prior to, on, and after the dates of Plaintiff's initial hip surgery, and at all times relevant to this action, Defendants had a duty to exercise reasonable care in testing, study, research, design, formulation, manufacture, inspection, labeling, packaging, promotion, advertisement, marketing, distribution and sale of the Stryker Hip System for implantation into consumers, such as Plaintiff, by physicians and surgeons in the United States.

109. Prior to, on, and after the dates of Plaintiff's initial hip surgery, Defendants failed to exercise reasonable care and were negligent and careless in the testing, study, research, design, formulation, manufacture, inspection, labeling, packaging, promotion, advertisement, marketing, distribution and sale of the Stryker Hip System.

110. Prior to, on, and after the dates of Plaintiff's initial hip surgery, Defendants failed to

perform adequate evaluation and testing of the Stryker Hip System, where such adequate evaluation and testing would have revealed the device's propensity to undergo fretting and corrosion at the femoral head-stem taper juncture causing serious complications in patients.

111. Prior to, on, and after the dates of Plaintiff's initial hip surgery, Defendants had received complaints from healthcare providers that the Stryker Hip System caused serious complications including but not limited to fretting and corrosion at the femoral head-stem taper juncture, but Defendants nonetheless consciously decided not to perform any further testing on the Stryker Hip System; investigate the root cause of these complications; suspend sales and distribution of the device; or warn physicians and patients of the propensity of the Stryker Hip System to undergo fretting and corrosion at the femoral head-stem taper juncture causing serious complications in patients.

112. Defendants' failure to exercise reasonable care in the design, testing, distribution, manufacture, advertising, sales, and marketing prior to, on, and after the dates of Plaintiff's initial hip surgery was a substantial factor in causing Plaintiffs' injuries, losses, and damages, as alleged herein.

113. As alleged herein, Defendants knew and had reason to know that the Stryker Hip System caused increased risk of harm to Plaintiff and other consumers. Defendants consciously disregarded this increased risk of harm by failing to warn of such risks; unlawfully concealing the dangerous problems associated with implantation of the Stryker Hip System; and continuing to market, promote, sell and defend the Stryker Hip System.

114. As a direct, proximate and legal consequence of Defendants' wrongful conduct as described herein, including Defendants' failure to exercise reasonable care as described herein, Plaintiff has sustained and will continue to sustain severe and debilitating injuries, including but not limited to, significant pain and discomfort; gait impairment; poor balance; difficulty walking; component part loosening, impingement and/or detachment; metallosis; soft tissue damage; adverse local tissue reaction; dislocation; and other injuries presently undiagnosed, which all require ongoing medical care. As a further direct, proximate and legal consequence of the defective nature of the

Stryker Hip System, Plaintiff has sustained and will sustain future damages, including but not limited to additional revision surgeries; cost of medical care; rehabilitation; home health care; lost wages; loss of earning capacity; mental and emotional distress; 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.

FIFTH CAUSE OF ACTION
NEGLIGENCE – FAILURE TO WARN

115. Plaintiff hereby incorporates by reference all previous paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

116. Prior to, on, and after the dates of Plaintiff's initial hip surgery, and at all relevant times, Defendants tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold the Stryker Hip System for implantation into consumers, such as Plaintiff, by physicians and orthopedic surgeons in the United States.

117. Prior to, on, and after the dates of Plaintiff's initial hip surgery, Defendants knew or should have known that the Stryker Hip System was dangerous or was likely to be dangerous when used in a reasonably foreseeable manner. Such danger included the propensity of the Stryker Hip System's to undergo fretting and/or corrosion at the femoral head-stem taper juncture causing serious complications in patients.

118. Prior to, on, and after the dates of Plaintiff's initial hip surgery, Defendants knew or reasonably should have known that the users of the device, including Plaintiff, would not realize the dangers presented by the device.

119. Prior to, on, and after the dates of Plaintiff's initial hip surgery, Defendants failed to adequately warn of the dangers presented by the device and/or failed to instruct on the safe use of the device. Such failures to warn and/or instruct included, but were not limited to failing to advise of the known or knowable risks, dangers, and side effects associated with the use of the Stryker Hip System; failing to properly advise of the means and methods available for the elimination of the risks, dangers, and side effects associated with the Stryker Hip System; failing to warn physicians about the

risks, dangers, and side effects associated with the Stryker Hip System, including the propensity of the Stryker Hip System's to undergo fretting and/or corrosion at the femoral head-stem taper juncture causing serious complications in patients; and failing to warn consumers about the risks, dangers, and side effects associated with the Stryker Hip System, including the propensity of the Stryker Hip System to undergo fretting and/or corrosion at the femoral head-stem taper juncture causing serious complications in patients.

120. Reasonable manufacturers and distributors, under the same or similar circumstances prior to, on, and after the dates of Plaintiff's initial hip surgery, would have adequately warned of the dangers presented by the Stryker Hip System, or provided adequate instructions for the safe use of the Stryker Hip System.

121. Prior to the dates of Plaintiff's initial hip surgery, the Stryker Hip System had already caused numerous known reports of fretting and/or corrosion at the taper juncture between the femoral head and femoral stem. Defendants consciously decided neither to warn physicians or patients of the Stryker Hip System's increased propensity to cause these serious complications, nor of the signs and symptoms of these complications.

122. Defendants' negligent failure to warn Plaintiff, Plaintiff's orthopedic surgeon or Plaintiff's other healthcare providers prior to, on, and after the dates of Plaintiff's initial hip surgery was a substantial factor in causing Plaintiffs' injuries, losses and damages as described herein.

123. As alleged above, Defendants knew and had reason to know that the Stryker Hip System caused an increased risk of harm to Plaintiff and other consumers. Defendants consciously disregarded this increased risk of harm by failing to warn of such risks; unlawfully concealing the dangerous problems associated with implantation of the Stryker Hip System; and continuing to market, promote, sell and defend the Stryker Hip System.

124. As a direct, proximate and legal consequence of Defendants' wrongful conduct as described herein, including Defendants' negligent failure to warn, Plaintiff has sustained and will continue to sustain severe and debilitating injuries, including but not limited to, significant pain and

discomfort; gait impairment; poor balance; difficulty walking; component part loosening, impingement and/or detachment; metallosis; soft tissue damage; adverse local tissue reaction; dislocation; and other injuries presently undiagnosed, which all require ongoing medical care. As a further direct, proximate and legal consequence of the defective nature of the Stryker Hip System, Plaintiff has sustained and will sustain future damages, including but not limited to additional revision surgeries; cost of medical care; rehabilitation; home health care; lost wages; loss of earning capacity; mental and emotional distress; 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.

SIXTH CAUSE OF ACTION
BREACH OF IMPLIED WARRANTIES

125. Plaintiff hereby incorporates by reference all previous paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

126. Defendants impliedly warranted that the Stryker Hip System, which Defendants tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold to Plaintiff, was merchantable and fit and safe for ordinary use.

127. Defendants further impliedly warranted that the Stryker Hip System, which Defendants tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold, was fit for the particular purpose for which it was intended and was sold.

128. Contrary to these implied warranties, the Stryker Hip System was defective, unmerchantable, and unfit for its ordinary use when sold, and unfit for the particular purpose for which it was sold.

129. As a direct, proximate and legal consequence of Defendants' wrongful conduct as described herein, including Defendants' breach of implied warranties, Plaintiff has sustained and will continue to sustain severe and debilitating injuries, including but not limited to, significant pain and

discomfort; gait impairment; poor balance; difficulty walking; component part loosening, impingement and/or detachment; metallosis; soft tissue damage; adverse local tissue reaction; dislocation; and other injuries presently undiagnosed, which all require ongoing medical care. As a further direct, proximate and legal consequence of the defective nature of the Stryker Hip System, Plaintiff has sustained and will sustain future damages, including but not limited to additional revision surgeries; cost of medical care; rehabilitation; home health care; lost wages; loss of earning capacity; mental and emotional distress; 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.

SEVENTH CAUSE OF ACTION
BREACH OF EXPRESS WARRANTIES

130. Plaintiff hereby incorporates by reference all previous paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

131. Defendants expressly warranted to Plaintiff by and through Defendants and/or their authorized agents or sales representatives, in publications, product information, instructions for use, sales and marketing materials, the internet, and other communications intended for physicians, patients, Plaintiff, and the general public, that the Stryker Hip System was safe, effective, fit and proper for its intended use.

132. In allowing the implantation of the Stryker Hip System, Plaintiff and Plaintiff's physicians relied on the skill, judgment, representations, and the express warranties of Defendants.

133. These warranties and representations were false in that the Stryker Hip System was not safe and was unfit for the uses for which it was intended.

134. Through the sale of the Stryker Hip System, Defendants are merchants pursuant to Section 2-314 of the Uniform Commercial Code.

135. Defendants breached their warranty of the mechanical soundness of the Stryker Hip System by continuing sales and marketing campaigns highlighting the safety and efficacy of the device, when Defendants knew of the defects, risk and propensity of the device to undergo fretting and/or corrosion at the femoral head-stem taper juncture causing serious complications in patients.

136. As a direct, proximate and legal consequence of Defendants' wrongful conduct as described herein, including Defendants' breach of express warranties, Plaintiff has sustained and will continue to sustain severe and debilitating injuries, including but not limited to, significant pain and discomfort; gait impairment; poor balance; difficulty walking; component part loosening, impingement and/or detachment; metallosis; soft tissue damage; adverse local tissue reaction; dislocation; and other injuries presently undiagnosed, which all require ongoing medical care. As a further direct, proximate and legal consequence of the defective nature of the Stryker Hip System, Plaintiff has sustained and will sustain future damages, including but not limited to additional revision surgeries; cost of medical care; rehabilitation; home health care; lost wages; loss of earning capacity; mental and emotional distress; 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.

EIGHTH CAUSE OF ACTION
NEGLIGENT MISREPRESENTATION

137. Plaintiff hereby incorporates by reference all previous paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

138. At the time Defendants tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold the Stryker Hip System to Plaintiff, Defendants knew or should have known of the use for which the device was intended and the serious risks and dangers associated with such use of the Stryker Hip System.

139. Defendants owed a duty to orthopedic surgeons, other healthcare providers and to consumers of the Stryker Hip System, including Plaintiff, to accurately and truthfully represent the risks of Stryker Hip System.

140. Defendants breached their duty by misrepresenting and/or failing to adequately warn Plaintiff's orthopedic surgeon, the medical community, Plaintiff, and the public about the risks of the Stryker Hip System, which Defendants knew or in the exercise of diligence should have known.

141. Among Defendants' numerous misrepresentations and misleading omissions are

Defendants' assurances that the Stryker Hip System was safe, had an excellent track record and low failure rate. Defendants stated or implied to orthopedic surgeons that any problem with the Stryker Hip System in a particular patient was attributable to "surgical technique" or patient factors such as body mass index, bone composition, and post-implantation activity level. Defendants made such statements even after they became aware of numerous and serious complications with the Stryker Hip System. Defendants did not reveal (and instead concealed) their knowledge of numerous and serious complications and other bad data during their meetings with orthopedic surgeons.

142. Despite their knowledge of serious problems with the Stryker Hip System, Defendants urged their sales representatives to continue marketing the Stryker Hip System, and distributed medical literature and other communications to surgeons in an effort to mislead them and the general public about the risks associated with the Stryker Hip System.

143. As a direct, proximate and legal consequence of Defendants' wrongful conduct as described herein, including Defendants' negligent misrepresentations, Plaintiff has sustained and will continue to sustain severe and debilitating injuries, including but not limited to, significant pain and discomfort; gait impairment; poor balance; difficulty walking; component part loosening, impingement and/or detachment; metallosis; soft tissue damage; adverse local tissue reaction; dislocation; and other injuries presently undiagnosed, which all require ongoing medical care. As a further direct, proximate and legal consequence of the defective nature of the Stryker Hip System, Plaintiff has sustained and will sustain future damages, including but not limited to additional revision surgeries; cost of medical care; rehabilitation; home health care; lost wages; loss of earning capacity; mental and emotional distress; 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.

NINTH CAUSE OF ACTION
INTENTIONAL MISREPRESENTATION

144. Plaintiff hereby incorporates by reference all previous paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

145. Defendants, having undertaken to test, study, research, design, formulate, manufacture, inspect, label, package, promote, advertise, market, distribute and sell the Stryker Hip System, owed a duty to provide accurate and complete information to Plaintiff, his orthopedic surgeon, and the public regarding the safety and efficacy of the Stryker Hip System.

146. However, Defendants misled Plaintiff, Plaintiff's orthopedic surgeon, and the public into believing that the Stryker Hip System was safe and effective for use in total hip replacement surgery; engaged in deceptive, misleading and unconscionable promotional, marketing and sales tactics to convince orthopedic surgeons and patients to use the Stryker Hip System, even though Defendants knew or should have known that the Stryker Hip System was unreasonably dangerous as alleged herein. Defendants also failed to warn orthopedic surgeons and the public about the serious risks associated with the use of the Stryker Hip System.

147. Defendants' advertising campaigns, marketing materials and promotional items, by containing affirmative misrepresentations and omissions, falsely and deceptively sought to create the image and impression that the Stryker Hip System was safe for human use and had no unacceptable risks.

148. Defendants purposefully concealed, failed to disclose, misstated, downplayed and understated the risks associated with the use of the Stryker Hip System. Defendants, through sales, marketing and promotional practices as well as through the publication of medical literature, deceived orthopedic surgeons, Plaintiff, other patients, and the public. Defendants falsely and deceptively kept relevant information from orthopedic surgeons, the FDA and the public, including Plaintiff, regarding the safety of the Stryker Hip System.

149. Defendants expressly denied that the Stryker Hip System created an increased risk of injury and took affirmative steps to prevent the discovery and dissemination of any evidence regarding the increased likelihood of injury from the Stryker Hip System.

150. Defendants did not accurately report the results of adverse events by fraudulently and intentionally withholding from the FDA, orthopedic surgeons, Plaintiff, and the public, the truth

regarding Stryker Hip System's failures for years, all the while undertaking sales, marketing and promotional campaigns to sell the Stryker Hip System. Defendants received reports of the Stryker Hip System defects from various sources, including those alleged herein, and intentionally withheld this information, while continuing to sell the Stryker Hip System for implantation in patients such as Plaintiff.

151. Further, even as Defendants disclosed some information regarding the Stryker Hip System's defects, the disclosures were incomplete and misleading.

152. Through their wrongful conduct, Defendants effectively deceived and misled the scientific and medical communities regarding the risks and benefits of the Stryker Hip System. Defendants failed to fully inform orthopedic surgeons, Plaintiff, other patients and the public of the true risks associated with the Stryker Hip System, defects that were known to Defendants, and continued to assure orthopedic surgeons and patients that the Stryker Hip System was safe and effective for the purpose of continuing to derive substantial profits from the sale of the Stryker Hip System.

153. Through their advertising campaigns, sales and marketing materials and promotional items, Defendants falsely and deceptively misrepresented and omitted a number of material facts regarding the Stryker Hip System.

154. Defendants possessed evidence demonstrating the Stryker Hip System caused serious injuries. Nevertheless, Defendants continued to market the Stryker Hip System by providing false and misleading information with regard to the device's safety and efficacy to Plaintiff and Plaintiff's orthopedic surgeon.

155. Among Defendants' numerous misrepresentations and misleading omissions to Plaintiff, Plaintiff's orthopedic surgeon and the public were Defendants' assurances that the Stryker Hip System was safe and had a low failure rate. Defendants stated or implied to orthopedic surgeons that any problem with the Stryker Hip System in a particular patient was attributable to "surgical technique" or patient factors such as body mass index, bone composition, and post-implantation

activity level. Defendants made such statements even after they became aware of numerous and serious complications with the Stryker Hip System. Defendants did not reveal (and instead concealed) their knowledge of numerous and serious complications and other bad data during their meetings with orthopedic surgeons.

156. Despite their knowledge of the risks with the Stryker Hip System, Defendants urged their sales representatives to continue marketing the Stryker Hip System, and distributed medical literature and other communications to orthopedic surgeons in an effort to mislead them and the public about the serious risks associated with the use of the Stryker Hip System.

157. Defendants engaged in all the acts and omissions alleged herein with the intent that Plaintiff's orthopedic surgeon and Plaintiff would rely on the misrepresentation, deception and concealment in deciding to implant and use the Stryker Hip System rather than another Stryker product or a competitors' product.

158. Plaintiff and Plaintiff's orthopedic surgeon justifiably relied to their detriment on Defendants' intentional and fraudulent misrepresentations and this reliance proximately caused Plaintiff's injuries and damages as alleged herein.

159. As a direct, proximate and legal consequence of Defendants' wrongful conduct as described herein, including Defendants' deceptive, misleading and unconscionable promotional and sales methods, Plaintiff has sustained and will continue to sustain severe and debilitating injuries, including but not limited to, significant pain and discomfort; gait impairment; poor balance; difficulty walking; component part loosening, impingement and/or detachment; metallosis; soft tissue damage; adverse local tissue reaction; dislocation; and other injuries presently undiagnosed, which all require ongoing medical care. As a further direct, proximate and legal consequence of the defective nature of the Stryker Hip System, Plaintiff has sustained and will sustain future damages, including but not limited to additional revision surgeries; cost of medical care; rehabilitation; home health care; lost wages; loss of earning capacity; mental and emotional distress; 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.

TENTH CAUSE OF ACTION
FRAUD

160. Plaintiff hereby incorporates by reference all previous paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

161. At the time Defendants sold the Stryker Hip System to Plaintiff, Defendants were in a unique position of knowledge concerning the safety and effectiveness of the Stryker Hip System, which knowledge was not possessed by Plaintiff or his orthopedic surgeon, and Defendants thereby held a position of superiority over Plaintiff and his orthopedic surgeon.

162. Through their unique knowledge and expertise regarding the defective nature of the Stryker Hip System, and through their statements to orthopedic surgeons and patients in advertisements, sales and marketing materials, promotional items, instructions for use, product information and other communications, Defendants professed to Plaintiff that they had knowledge of the truth of the representation that the Stryker Hip System was safe and effective for its intended use and was not defective.

163. Defendants' representations to Plaintiff, Plaintiff's orthopedic surgeon, the medical community, and the public were unqualified statements made to induce Plaintiff and Plaintiff's orthopedic surgeon to purchase and use the Stryker Hip System; and Plaintiff and his orthopedic surgeon relied upon these statements when purchasing the devices and implanting them into patients.

164. Defendants have made numerous misrepresentations and misleading omissions to Plaintiff, Plaintiff's orthopedic surgeon and the public. Among these misrepresentations are Defendants' assurances to orthopedic surgeons that the Stryker Hip System was safe and had a low failure rate. Defendants stated or implied to orthopedic surgeons that any problem with the Stryker Hip System in a particular patient was attributable to "surgical technique" or patient factors such as body mass index, bone composition, and post-implantation activity level. Defendants made such statements even after they became aware of numerous and serious complications with the Stryker Hip System. Defendants did not reveal (and instead concealed) their knowledge of numerous and serious

complications and other bad data during their meetings with orthopedic surgeons.

165. Despite their knowledge of serious risks with the Stryker Hip System, Defendants urged their sales representatives to continue marketing the Stryker Hip System, and distributed medical literature and other communications to orthopedic surgeons in an effort to mislead them and the public about the risks and reasons for the Stryker Hip System's failures.

166. Defendants took unconscionable advantage of their superior knowledge and engaged in constructive fraud in their relationship with Plaintiff. Plaintiff reasonably relied on Defendants' representations to his detriment as described herein.

167. As a direct, proximate and legal consequence of Defendants' wrongful conduct as described herein, including Defendants engaging in constructive fraud in their relationship with Plaintiff and his physicians, Plaintiff has sustained and will continue to sustain severe and debilitating injuries, including but not limited to, significant pain and discomfort; gait impairment; poor balance; difficulty walking; component part loosening, impingement and/or detachment; metallosis; soft tissue damage; adverse local tissue reaction; dislocation; and other injuries presently undiagnosed, which all require ongoing medical care. As a further direct, proximate and legal consequence of the defective nature of the Stryker Hip System, Plaintiff has sustained and will sustain future damages, including but not limited to additional revision surgeries; cost of medical care; rehabilitation; home health care; lost wages; loss of earning capacity; mental and emotional distress; 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.

ELEVENTH CAUSE OF ACTION
LOSS OF CONSORTIUM

168. Plaintiff hereby incorporates by reference all previous paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

169. At all times relevant to this action, Plaintiff Lorraine Irving was the lawful and loving spouse of Plaintiff Mark Irving.

170. As a direct, proximate and legal consequence of Defendants' wrongful conduct as described herein, whether through strict liability or negligence, Plaintiff Lorraine Irving suffered and will continue to suffer the loss of support, companionship, service, love, affection, society, intimate relations and other elements of consortium all to the detriment of their marital relationship for which she is entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

PUNITIVE DAMAGES

171. Plaintiff hereby incorporates by reference all previous paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

172. Plaintiff is entitled to punitive damages because the Defendants' breaches of their duties to Plaintiffs were deliberate, intentional, and/or motivated by malice or ill will to Plaintiff.

173. Defendants intentionally misled Plaintiff, his orthopedic surgeon, the medical community, and the public at large by making false representations about the safety and efficacy of the Stryker Hip System.

174. Defendants intentionally downplayed, understated and/or misrepresented their actual knowledge of the potential for serious injury with the use of Stryker Hip System despite available information demonstrating that the Stryker Hip System was likely to cause serious injuries to patients implanted with the device.

175. Defendants were in possession of evidence demonstrating that the Stryker Hip System caused serious injuries to consumers. Nevertheless, Defendants continue to market the Stryker Hip System by providing false and misleading information to the Plaintiff and the public with regard to the safety and efficacy of the device.

176. Defendants' outrageous actions as described herein were performed willfully, intentionally, and with malice in their disregard for the rights of the Plaintiff and the general public.

177. Accordingly, Plaintiff seeks and is entitled to punitive or exemplary damages in an amount to be determined at trial.

CONDITIONS PRECEDENT

178. All conditions precedent to Plaintiffs' right to recover herein and to Defendants' liability have been performed or have occurred.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment against the Defendants, jointly and severally, as follows:

1. Compensatory damages, 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. Special damages, in excess of the amount required for federal diversity jurisdiction and in an amount to fully compensate Plaintiffs for all of their injuries and damages, both past and present, including but not limited to, past and future medical expenses, costs for past and future rehabilitation and/or home health care, lost income or wages, loss of earning capacity, permanent disability, including permanent instability and loss of balance, pain and suffering, and loss of consortium;

3. Punitive damages as allowed by law;

4. Double or triple damages as allowed by law;

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.

JURY DEMAND

Plaintiff demands a trial by jury of all claims asserted in this Complaint.

Dated: November 9, 2017

Respectfully submitted,
FITZGERALD LAW GROUP, LLC

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