ROBINS KAPLAN LLP
Tara D. Sutton, Bar No. 023199X (MN)
TSutton@RobinsKaplan.com
Holly H. Dolejsi, Bar No. 0390110 (MN)
HDolejsi@RobinsKaplan.com
800 LaSalle Plaza, Suite 2800
Minneapolis, MN 55402
Telephone: 612-349-8500
Facsimile: 612-339-4181
Pro Hac Vice Admission Motion to Be Filed

ROBINS KAPLAN LLP
Daniel L. Allender, Bar No. 264651
DAllender@RobinsKaplan.com
2049 Century Park East, Suite 3400
Los Angeles, CA 90067-3208
Telephone: 310-552-0130
Facsimile: 310-229-5800

Attorneys for Plaintiff Larry R. Schneider

ROBINS KAPLAN LLP
ATTORNEYS AT LAW
LOS ANGELES

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

LARRY R. SCHNEIDER,

Plaintiff,

v.

HOWMEDICA OSTEONICS CORP. d/b/a STRYKER ORTHOPAEDICS,

Defendant.

Case No. 8:17-cv-01286

COMPLAINT FOR:

1. Negligence
2. Strict Liability – Design Defect
3. Strict Liability – Manufacturing Defect
4. Strict Liability – Inadequate Warning
5. Breach of Express and Implied Warranties

JURY TRIAL DEMANDED

Plaintiff, LARRY R. SCHNEIDER, for his cause of action against the above-named defendant, alleges and states upon information and belief the following:

PARTIES, JURISDICTION, AND VENUE

1. Plaintiff LARRY R. SCHNEIDER is a citizen and resident of Mission Viejo, California, County of Orange.

2. Defendant, Howmedica Osteonics Corp., d/b/a Stryker Orthopaedics, (hereinafter "HOC") is a corporation organized and existing under the laws of New Jersey, with its principal place of business in Mahwah, New Jersey. Defendant does business throughout the United States, including in the State of California.

3. HOC is a wholly-owned subsidiary of Stryker Corporation ("Stryker"). HOC licenses the Stryker brand name for use of its prosthetic hip devices and pays Stryker a licensing fee.

4. Upon information and belief, at all times relevant herein, the employees of Defendant, its subsidiaries, affiliates, and other related entities were the agents, servants, and employees of Defendant, and were acting within the purpose and scope of said agency and employment. Wherever reference in this Complaint is made to any act or transaction of Defendant, such designation shall be deemed to mean that the principals, offices, employees, agents and/or representatives of the Defendant committed, knew of, performed, authorized, ratified and/or directed such transactions on behalf of Defendant while actively engaged in the scope of their duties.

5. This action is properly before the Court because complete diversity of citizenship exists between Plaintiff and Defendant. In addition, the amount in controversy claimed by Plaintiff exceeds $75,000. As a result, this Court has jurisdiction over this matter pursuant to 28 U.S.C. § 1332(a).

6. Defendant is subject to the in personam jurisdiction of this Court, and venue is therefore proper herein pursuant to 28 U.S.C. § 1391, because Defendant did (and does) business within the State of California and has had continuous and

systematic contacts with the State of California, and/or has consented to jurisdiction in the State of California. Upon information and belief, Defendant also advertised in this district, made material omissions and representations in this district, and breached warranties in this district.

FACTUAL ALLEGATIONS

A. Total Hip Arthroplasty Procedure

7. The hip joint is a ball-and-socket synovial joint formed by the articulation of the rounded head of the femur and the cup-like acetabulum of the pelvis. Both joint surfaces are covered with a strong but lubricated layer of articular hyaline cartilage. Over time, age and wear can break down the cartilage, allowing the femur head to rub directly against the acetabulum resulting in painful joint inflammation and immobility.

8. A total hip arthroplasty replaces the body's natural joint with prosthetic components. A typical total hip replacement system consists of four separate components: 1) a femoral stem; 2) a femoral head; 3) a liner; and 4) an acetabular shell. The surgeon removes the patient's natural femoral head, hollows-out the femoral canal, implants the prosthetic femoral stem, and attaches a femoral head to the neck of the stem. The acetabular shell is fixed to the acetabulum of the pelvis and fitted with a liner. The femoral head forms the hip joint when it is placed inside the polyethylene liner and acetabular shell.

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

9. At all times material hereto, Defendant developed, tested, assembled, manufactured, packaged, labeled, prepared, distributed, marketed, supplied, and/or sold the Accolade TMZF Femoral Stem and LFIT CoCr V40 Femoral Head, either directly or indirectly, to members of the general public, including Plaintiff.

10. In 2002, HOC received FDA clearance to sell its Accolade TMZF Femoral Hip Stem ("Accolade TMZF") in the United States. The Accolade TMZF

is a tapered non-porous coated femoral stem manufactured from a proprietary titanium alloy (TMZF) made of titanium, molybdenum, zirconia and iron, coated with Commercially Pure Titanium and Purefix hydroxylapatite.

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

12. The material combination of a titanium alloy stem, with a cobalt chromium femoral head (like the LFIT V40), has been reported 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 decades.

13. 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.

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

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

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

17. 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.

18. A Morse taper (a cone-within-a-cone) is used to mate the LFIT V40 Head with the Accolade TMZF stem. The bore (female portion) of the LFIT V40 Head is placed onto the tapered trunnion (male portion) of the Accolade TMZF 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).

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

20. According to Stryker's materials, the Accolade TMZF stem was developed to maximize a patient's hip range of motion, increase stability, and prevent dislocation. These materials also state that the Accolade TMZF stem is designed to be used with V40 Femoral Heads, which are offered in both Vitallium alloy (CoCrMo) and zirconia ceramic. The Accolade TMZF Stem is also designed with two neck angles, the standard 132 degrees and extended 127 degrees offset, to assist with joint stability and proper restoration of joint kinematics without lengthening the leg. The neck lengths are proportional relative to the patient's body geometry to accommodate a wider patient population using a standard femoral head.

21. Defendants claim in their promotional materials that the TMZF alloy "provides the opportunity to reduce the neck geometry thus optimizing the available range of motion while maintaining strength." Additionally, HOC states the "unique composition of titanium, molybdenum, zirconium, and iron, it achieves a superior combination of flexibility, strength, and notch resistance when compared to other alloys used in orthopaedic implants."

22 The Accolade TMZF Stem and LFIT Anatomic V40 Femoral Head were commonly used together. Defendant's promotional materials claim that the TMZF stem and Cobalt Chrome head were compatible and these materials

presented no concern for fretting and corrosion.

23. HOC advertised that an LFIT head better simulates a joint by allowing increased lubrication between the components, and that LFIT heads demonstrated a 28% reduction in linear wear over other CoCr heads in 100 patients at a minimum 3 year follow up.

24. The indications for use of both LFIT V40 Heads and Accolade TMZF stems include non-inflammatory degenerative joint disease, such as osteoarthritis and avascular necrosis.

25. At all times material hereto, HOC developed, tested, assembled, manufactured, packaged, labeled, prepared, distributed, marketed, supplied, and/or sold the Accolade TMZF and LFIT V40 Heads, either directly or indirectly, to members of the public within the State of California.

26. In 2012, HOC recalled its Rejuvenate and ABGII Hip Stems, both of which utilized the same TMZF titanium metal used in the Accolade Stem. The modular necks used with the Rejuvenate and ABGII Hip Stems were made out of Cobalt Chromium, just like the Stryker LFIT V40 head. The reason for the 2012 recall was due to excessive device failure due to fretting and corrosion at the taper junction where these dissimilar metals were joined.

27. Patients in whom Stryker Rejuvenate and ABG II had been implanted were experiencing device failure, symptoms and diagnostic findings similar to Plaintiff. Information disseminated by HOC at or about the time of the recall cited this failure mechanism as the reason for the recall.

28. Since the recall, revision rates for the Rejuvenate and ABG II have been reported to exceed 50% in a very short period of time.

29. Upon information and belief, HOC redesigned its Accolade Stem and abandoned the use of TMZF titanium. Instead, its new Accolade II Stem is manufactured from a different titanium alloy and is more compatible with V40 heads.

30. On or about August 29, 2016, Stryker issued a voluntary Class 2 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.

31. On or about October 11, 2016, Defendants sent an updated recall notification because additional customers and affected lots had been identified.

32. The recall notice fails to instruct surgeons to contact patients with the LFIT heads to instruct them to undergo a simple, inexpensive blood test that can be used to determine whether a patient is experiencing the corrosive process that can lead to catastrophic failure, like the one Plaintiff experienced. Specifically, the presence of elevated levels of cobalt, chromium, or titanium in the blood is a sign that a prosthetic hip is corroding.

33. Upon information and belief, the issues underlying Defendant's recall of the select LFIT heads extend to other sizes and lots not subject to the recall.

34. On or around January 06, 2009, Stryker issued a voluntary recall of certain sizes and lots of Accolade TMZF hip stems citing lack of tensile bond strength and crystallinity.

C. Plaintiff Allegations

35. On April 04, 2007, Plaintiff underwent a left total hip arthroplasty as a result of left hip degenerative joint disease. At that time, Plaintiff's surgeon implanted a Trident Hemispherical Acetabular Shell with a Trident X3 Polyethylene Insert, an Accolade TMZF femoral stem with an LFIT Anatomical V40 Femoral Head. At the time of this surgery, Plaintiff lived in New Jersey, and the surgery was performed in Philadelphia, Pennsylvania.

36. Seven years after his left total hip arthroplasty, Plaintiff experienced

dissociation of the femoral head from the trunnion.

37. Plaintiff underwent revision surgery on November 25, 2014, at which time Plaintiff's surgeon encountered dissociation of the femoral head from the trunnion, "femoral head which had come off the trunnion. The trunnion was severely worn and the head was generating all of the metal debris." The LFIT V40 cobalt chrome head and the Accolade TMZF stem were removed. At the time of this surgery, Plaintiff lived in New Jersey, and the surgery was performed in Philadelphia, Pennsylvania. Not long after that surgery, Plaintiff moved to California, where he has resided since that time.

38. As a direct and proximate result of HOC placing LFIT V40 Heads into the stream of commerce, both as an individual product line and in combination with the Accolade TMZF stem, Plaintiff has suffered, and continues to suffer, both injuries and damages including, but not limited to, past, present and future physical and mental pain and suffering; and past, present and future medical, hospital, rehabilitative and pharmaceutical expenses, and other related damages.

39. Plaintiff was unaware of any causal link between the injuries he suffered and any wrongdoing on the part of Defendant, or the defective nature of the hip device that was removed, due in part to the failures of Defendant to properly warn him and his physicians about the devices and their faulty nature. In or around December 2016, Plaintiff first became aware of a possible causal link when he saw a television advertisement advising of the link.

THE FEDERAL REQUIREMENTS

40. 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).

41. 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).

42. 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.

43. 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.

44. 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.

45. 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. § 360i.

46. 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.

47. 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.

48. Pursuant to federal regulations, manufacturers must report any reportable 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.

49. 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 *et seq*.

50. 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 *et seq*.

51. 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.

THE FDA "APPROVAL" PROCESS

52. The Medical Device Amendments to the Food, Drug, and Cosmetics Act of 1938 ("MDA") (1976), in theory, requires Class II medical devices, including the Accolade Hip Stem and LFIT Femoral Head, to undergo premarket approval by the FDA, a process which obligates the manufacturer to design and implement a clinical investigation and then submit the results of that investigation

to the FDA.

53. 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.

54. 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 probably benefit to health from the use of the device against any probable risk of injury or illness from such use.

55. A medical device on the market prior to the effective date of the MDA – a so-called "grandfathered" device – was not required to undergo pre-market 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 medical device approved prior to May 28, 1976). This exception to premarket approval is known as the "510(k)" process and simply 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" (allow) the new device for sale in the United States.

56. Rather than being approved by the FDA through the premarket approval process, Defendant instead received approval of the Accolade TMZF Stem and LFIT V40 Cobalt Chromium heads through the 510(k) clearance process.

57. As such, Defendant was able to market these hip devices with virtually no clinical or non-clinical trials or FDA review of the implants for safety and effectiveness.

CAUSES OF ACTION

FIRST CAUSE OF ACTION - NEGLIENCE

58. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein and further alleges as follows.

59. Defendant designed, manufactured, marketed, detailed, sold, and advertised, both to physicians and consumers, Accolade TMZF stems and LFIT V40 Heads.

60. As a result, Defendant had a duty to perform each of these functions reasonably and with reasonable and due care for the safety and well-being of patients in whom these devices would be implanted, including Plaintiff.

61. Defendant failed to use reasonable and due care for the safety and wellbeing of those in whom Accolade TMZF stems and LFIT V40 Heads would be implanted, including Plaintiff, in the following respects:

a. Defendant failed to adequately design and manufacture these devices to insure that they would not corrode, fret, deteriorate and induce metallosis and ALTR in patients.

b. Defendant failed to adequately warn of the increased risk of fretting, corrosion and heavy metal toxicity associated with the use of the Accolade TMZF Stem and LFIT V40 Cobalt Chromium femoral head;

c. Recommending use of components designed and manufactured with incompatible metals; namely, the combination of the titanium alloy in the Accolade TMZF stem with the cobalt-chromium in the LFIT V40 Heads;

d. Poor design of the bore of the LFIT V40 Heads such that it

resulted in taper lock failure, micro-motion of the Accolade TMZF trunnion within the LFIT V40 bore, corrosion and fretting;

e. Poor manufacturing practices such that the LIFT V40 bore and Accolade TMZF trunnion did not "fit" the way in which they were intended to fit, resulting in taper lock failure, micro-motion, corrosion and fretting;

f. Failing to establish and maintain adequate procedures to ensure that the specified design requirements for LFIT V40 Heads were met during the manufacturing process;

g. Failing to limit the type of femoral head components it recommended for use with the Accolade TMZF stem to those that would not promote micro-motion, taper lock failure, corrosion and fretting;

h. Use of the TMZF alloy that has a modulus of elasticity with far inferior stiffness characteristics than other available titanium alloys;

i. Use of the TMZF alloy which is known to have corrosion and fretting propensities, rather than another titanium alloy; and

j. Failing to restrict use of the TMZF stems with ceramic heads only.

62. Defendant made affirmative representations that these devices would not fret or corrode in the human body. These representations were false and misleading to both physicians and the consumer, including Plaintiff and Plaintiff's surgeon.

63. Defendant failed to manufacture LFIT V40 Heads to FDA-cleared and/o63Defendant's own internal specifications such that the taper lock between the LFIT V40 Head bore and the Accolade TMZF trunnion failed, resulting in micro-

motion, fretting and corrosion, and causing metallosis and ALTR in patients, including Plaintiff.

64. Defendant had actual knowledge prior to marketing the Accolade TMZF in combination with LFIT V40 Heads that a titanium alloy stem performed poorly when paired with cobalt/chromium head.

65. Defendant also had knowledge at the time the Accolade TMZF was introduced to the market that other HOC devices made of titanium alloy were experiencing corrosion, fretting, and failure at the trunnion-bore interface.

66. Nevertheless, Defendant either suppressed or ignored such knowledge, and marketed the LFIT V40 Heads as compatible with the Accolade TMZF, knowing full well that these two dissimilar metals historically performed poorly after implantation and were causing harm to patients when utilized in various hip implant devices.

67. Defendant, as manufacturer, supplier and seller of these orthopedic components had superior knowledge and owed a duty of care to their customers, orthopedic surgeons, and to the patients themselves in whom Accolade TMZF/ LFIT V40 Head combinations were being implanted.

68. Defendant breached its duty of care, and the conduct outlined above demonstrates Defendant's failure to exercise reasonable and appropriate care.

69. It was foreseeable that this wrongful conduct and these omissions would lead to premature failure of the Accolade TMZF / LFIT V40 Head combination, and cause severe, permanent, debilitating injuries to patients, including Plaintiff.

70. As a direct and proximate result of Defendant's breach of its duty, the Accolade TMZF and LFIT V40 Head implanted in Plaintiff prematurely and catastrophically failed, resulting in Plaintiff suffering all or some of the following: severe physical pain and suffering; emotional distress; mental anguish; loss of the capacity for the enjoyment of life; and incurred medical expenses. These damages

have occurred in the past and will continue into the future.

SECOND CAUSE OF ACTION

STRICT PRODUCTS LIABILITY – DEFECTIVE DESIGN

71. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein and further alleges as follows.

72. Defendant designed, manufactured, marketed, detailed, sold, and advertised, both to physicians and consumers, Accolade TMZF stems and LFIT V40 Heads.

73. The LFIT V40 Head implanted into Plaintiff's hip, both alone and in combination with the Accolade TMZF stem, was defective and unreasonably dangerous for its intended use as a hip prosthesis at the time it left HOC's control.

74. The Accolade TMZF is designed in such a way that when used as intended with an LFIT V40 Head, the combination causes serious, permanent, and devastating damage to patients in whom the devices are implanted. The damage and mechanism of injury have been previously described herein.

75. Defendant acted unreasonably in its design of the Accolade TMZF stem in combination with the LFIT V40 Head in that it failed to adopt a safer design that was practical and feasible. Such reasonable alternative design would have prevented or substantially reduced the risk of harm to Plaintiff without substantially impairing the usefulness, practicality, or desirability of the product.

76. Defendant's Accolade TMZF, in combination with the LFIT V40 Head, does not perform as safely as orthopedic surgeons and ordinary consumers would expect when used as intended or in a manner reasonably foreseeable to Defendant.

77. The risks of using the Accolade TMZF stem, in combination with an LFIT V40 Head, outweigh the benefits of using these devices.

78. There were safer alternative designs to the Accolade TMZF /LFIT V40 Head combination implanted in Plaintiff which in reasonable probability would

have prevented or significantly reduced the risk of the personal injuries suffered by Plaintiff without substantially impairing the product's utility and such safer alternative designs were economically and technologically feasible at the time the Accolade TMZF and LFIT V40 Head left the control of Defendant by the application of existing or reasonably achievable scientific knowledge.

79. As a direct and proximate result of the design defects in the Accolade TMZF/LFIT V40 Head combination, they prematurely and catastrophically failed, resulting in Plaintiff suffering suffered all or some of the following: severe physical pain and suffering; emotional distress; mental anguish; loss of the capacity for the enjoyment of life; and incurred medical expenses. These damages have occurred in the past and will continue into the future.

THIRD CAUSE OF ACTION

STRICT PRODUCTS LIABILITY – MANUFACTURING DEFECT

80. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein and further alleges as follows.

81 Defendant designed, manufactured, marketed, detailed, sold, and advertised, both to physicians and consumers, Accolade TMZF stems and LFIT V40 Heads.

82. The Accolade TMZF /LFIT V40 Head combination was designed for implantation into the human body and anticipated to function for fifteen or more years.

83. The Accolade TMZF/LFIT V40 Head combination was also designed to be compatible with human tissue and bone.

84. The Accolade TMZF/LFIT V40 Head combination implanted in Plaintiff, however, failed and was explanted after seven years.

85. The LFIT V40 Head implanted into the Plaintiff was manufactured in a substandard and defective manner, such that either:

a. The bore within the LFIT V40 Head was poorly machined or

fashioned so that it did not meet design specifications and therefore could not achieve the desired taper lock or cold weld with the trunnion of the Accolade TMZF;

b. The bore within the LFIT V40 Head was manufactured in such a manner that it did not maintain structural integrity as designed when implanted in a biologic environment;

c. The bore within the LFIT V40 Head was manufactured in such a manner that it did not maintain structural integrity as designed, when mated with a titanium alloy trunnion;

d. The specified design requirements for LFIT V40 Heads were not met during the manufacturing process;

e. The hydroxyapatite coating on the stem became loose and caused third body wear; and

f. Defendant failed to manufacture LFIT V40 Heads to FDA-cleared and/or Defendant's own internal specifications such that the taper lock between the LFIT V40 Head bore and the Accolade TMZF trunnion failed, resulting in micro-motion, fretting and corrosion, and causing metallosis and ALTR in patients, including Plaintiff.

86. As a direct and proximate result of the manufacturing defects in the LFIT V40 Head, Plaintiff suffered all or some of the following: severe physical pain and suffering; emotional distress; mental anguish; loss of the capacity for the enjoyment of life; and incurred medical expenses. These damages have occurred in the past and will continue into the future.

FOURTH CAUSE OF ACTION

STRICT PRODUCTS LIABILITY – FAILURE TO WARN

87. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein and further alleges as follows.

88. Defendant designed, manufactured, marketed, detailed, sold, and advertised, both to physicians and consumers, Accolade TMZF stems and LFIT V40 Heads.

89. Defendant knew or should have known that the LIFT V40 Heads it manufactured and distributed contained a manufacturing defect in the Head's bore which would prevent the Accolade TMZF trunnion from achieving the desired taper lock and result in taper lock failure and micro-motion.

90. Defendant also knew or should have known that the titanium alloy used in the Accolade TMZF stem was incompatible with the cobalt chromium in the LFIT V40 Heads which, in the presence of taper lock failure and micromotion, would lead to galvanic and crevice corrosion and fretting, and cause metallosis and ALTR in patients.

91. Defendant had a duty to warn surgeons about the risk of taper lock failure with its LFIT V40 Heads, and to warn surgeons about the risk of resulting micro-motion, corrosion, fretting, metallosis, and ALTR in patients who were implanted with this device.

92. The possibility of the devices fretting, corroding, causing metallosis and taper failure presents a substantial danger to a person implanted with these devices. An ordinary consumer or surgeon would not have recognized this potential side effect, particularly in light of the affirmative statements by Defendant that these components would not fret or corrode.

93. Defendant breached that duty by providing inadequate warnings (or no warnings at all) to surgeons that use of an LFIT V40 Head with an Accolade TMZF stem could result taper lock failure, corrosion and fretting, and cause substantial injury to the surgeon's patients.

94. If Defendant had warned orthopedic surgeons about the risk of taper lock failure with its LFIT V40 Heads, and that the resulting micro-motion would increase the risk of corrosion and fretting at the trunnion-bore interface, and that

such corrosion and fretting could lead to metallosis and ALTR in their patients, orthopedic surgeons (including Plaintiff's surgeon) would not have implanted the Accolade TMZF stem with an LFIT V40 Head, and Plaintiff would not have developed metallosis, ALTR and head dissociation, and would not have had to undergo a revision surgery seven years after his index surgery.

95. As a direct and proximate result of Defendant's failure to warn, Plaintiff suffered all or some of the following: severe physical pain and suffering; emotional distress; mental anguish; loss of the capacity for the enjoyment of life; and incurred medical expenses. These damages have occurred in the past and will continue into the future.

FIFTH CAUSE OF ACTION

BREACH OF EXPRESS AND IMPLIED WARRANTIES

96. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein and further alleges as follows.

97. At the time Plaintiff was implanted with the Accolade TMZF stem and LFIT V40 head, Defendant was in the business of selling and manufacturing these devices.

98. Through Defendant's public statements, descriptions and promises relating to the TMZF Stem, Defendant expressly and impliedly warranted, among other things, that the Accolade TMZF Stem was efficacious and safe for its intended use and was designed and constructed of materials that would prevent fretting and corrosion and would provide superior component longevity over competing products.

99. Through Defendant's public statements, descriptions and promises relating to the LFIT V40 Cobalt Chromium femoral head, Defendant expressly and impliedly warranted, among other things, that the LFIT V40 Cobalt Chromium femoral heads were efficacious and safe for its intended use and was designed and constructed of materials that would prevent fretting and corrosion and would

provide superior component longevity over competing products.

100. Product materials expressly warranted that "the TMZF alloy is specifically tailored for high performance in orthopaedic applications, optimizing the material properties that are key elements in the comfort of your patients and the long-term clinical success of the implant." Warrantors went on to state that "laboratory testing with TMZF further demonstrates improved wear resistance, reducing the potential for generation of particular metallic wear debris" as well as "[W]ith its demonstrated advantages in material properties, TMZF alloy, combined with Howmedica Osteonics' clinically successful implant geometries and coating technologies, takes orthopaedic design to new standards of performance."

101. These warranties came in the form of (i) publicly made written and verbal assurances of safety; (ii) press releases and dissemination via promotional information that was intended to create demand for the Accolade TMZF Stem and LFIT V40 Cobalt Chromium femoral head, but which contained material misrepresentations and failed to warn of the risks of the Accolade TMZF Stem and LFIT V40 Cobalt Chromium femoral head; (iii) verbal assurances made by Defendant's consumer relations personnel to the public about the safety of the Accolade TMZF Stem and LFIT V40 Cobalt Chromium femoral head and the downplaying of the risks of use associated with the Accolade TMZF Stem and LFIT V40 Cobalt Chromium femoral head; (iv) false and misleading written information supplied by Defendant.

102. When Defendant made these express warranties, Defendant knew the purpose for which the Accolade TMZF Stem and LFIT V40 Cobalt Chromium femoral head were to be used and warranted them to be in all respects safe and proper for such purpose, including their use in combination.

103. The Accolade Stem and LFIT V40 Cobalt Chromium femoral head do not conform to Defendant's representations in that these devices are not safe, fret, corrode, and produce metallic wear debris.

104. The Accolade Stem and LFIT V40 Cobalt Chromium femoral head manufactured and supplied by Defendants were not of merchantable quality and were not fit for the ordinary and/or particular purpose for which they were intended as, among other defects, they risks included fretting and corrosion and the likelihood of painful and debilitating revision surgery.

105. Plaintiff and his surgeon reasonably relied upon the skill and judgement of Defendant's as to whether the Accolade TMZF Stem and LFIT V40 Cobalt Chromium femoral head were of merchantable quality and fit/safe for their intended and particular use and purpose, and for use together.

106. Defendant knew, or had reason to know, that Plaintiff and his surgeon would reasonably rely upon the skill and judgment of Defendant as to whether the Accolade TMZF Stem and LFIT V40 Cobalt Chromium femoral head were of merchantable quality and fit/safe for their intended and particular use and purpose.

107. Contrary to such warranties, the Accolade Stem and LFIT V40 Cobalt Chromium femoral head did not conform to Defendant's promises, descriptions or affirmations of fact and were not of merchantable quality or adequately packaged, labeled, promoted or fit for the ordinary purposes for which such devices are used.

108. As a result of Defendant's breach of its express and implied warranties, Plaintiff was injured by the Accolade Stem and LFIT V40 Cobalt Chromium femoral head and suffered damages as a result.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff seeks judgment in his favor as follows:

A. Awarding the past and future costs of treatment for Plaintiff's injuries caused by the Accolade TMZF/LFIT V40 system;

B. Awarding damages for Plaintiff's physical pain and suffering;

C. Awarding damages for Plaintiff's mental and emotional anguish;

D. Awarding pre-judgment and post-judgment interest to Plaintiff;

E. Awarding the costs and expenses of this litigation to Plaintiff; and

F. For such further relief as this Court deems necessary, just and proper.

DEMAND FOR JURY TRIAL

Plaintiff demands a trial by jury on all issues so triable.

DATED: July 25, 2017

ROBINS KAPLAN LLP

By: /s/ Daniel L. Allender
Daniel L. Allender

ATTORNEYS FOR PLAINTIFF LARRY R. SCHNEIDER

DEMAND FOR JURY TRIAL

Plaintiff hereby demands trial by jury on all issues asserted herein as may be triable to a jury.

DATED: July 25, 2017

ROBINS KAPLAN LLP

By: /s/ Daniel L. Allender
Daniel L. Allender

ATTORNEYS FOR PLAINTIFF LARRY R. SCHNEIDER