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RACHELLE L. HARZ
J.S.C.

SUPERIOR COURT OF NEW JERSEY
LAW DIVISION: BERGEN COUNTY

CASE NO. 624
MASTER DOCKET NO. BER-L-7851-17
CIVIL ACTION

IN RE STRYKER LFIT CoCr V40 FEMORAL HEADS HIP IMPLANT LITIGATION

This Document Relates to all Cases

MASTER PLEADING IMPLEMENTATION ORDER

This Multicounty Litigation having been assigned to the Honorable Rachelle L. Harz, J.S.C., pursuant to the Supreme Court's Order of May 16, 2017, and the parties having met and conferred regarding long and short form pleadings as required in Case Management Order #2; and the Court having reviewed the joint submission by counsel; and for good cause shown;

IT IS on this 17th day of November 2017,

ORDERED,

PROCEDURE FOR MASTER PLEADINGS

A. This Order sets forth the Court's instructions regarding Master Pleadings in this Multicounty Litigation (Case No. 624) ("MCL"). In light of the number of Complaints filed to date and the likelihood of additional filings in the future in this MCL (No. 624), and the inefficiencies of drafting those Complaints and individual Answers to those Complaints, the Parties have agreed to the following procedures for the use of Master Pleadings. Nothing in this Order is intended to (or does) alter the applicable provisions of the New Jersey Court Rules, except as otherwise provided herein or in any subsequent Order. These procedures apply to all cases pending against Defendant Howmedica Osteonics Corp. ("HOC") in MCL No. 624 and to

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all actions against HOC that have been or will in the future be originally filed in or transferred to this MCL No. 624.[1]

B. All claims pleaded in the Master Complaint will supersede and replace all claims pleaded in any previously filed Complaint.

C. Plaintiffs' Liaison/Lead Counsel shall promptly file in MCL No. 624 the Master Complaint on behalf of all Plaintiffs asserting claims in MCL No. 624, in the form attached hereto as Exhibit 1.

D. Attached as Exhibit 2 hereto is a Master Short Form Complaint, submitted by Plaintiffs' Liaison/Lead Counsel, which is an abbreviated form that future Plaintiffs must complete in lieu of filing new standalone Complaints. All Short Form Complaints shall adopt the Master Complaint by reference and shall contain, at a minimum, for each individual case:

i. The name of the Plaintiff(s);

ii. The city and state where the Plaintiff(s) currently resides;

iii. The city and state in which Plaintiff's HOC hip replacement system was implanted and the date of the implantation;

iv. The basis for subject matter jurisdiction in this Court;

v. The nature of any alleged injury or injuries;

vi. Whether the Plaintiff is alleging s/he underwent a revision surgery as a result of the injuries alleged by Plaintiff in this litigation and, if so, the city, state, and date of the revision surgery;

[1] HOC is the party responsible for the design, manufacture, and marketing of the hip implant components at issue in this litigation. Defendants other than HOC do not waive, and expressly preserve, such arguments, including those based on lack of personal jurisdiction.

vii. If applicable, the date of death of the implanted individual;

viii. Which causes of action in the Master Complaint Plaintiff(s) adopts (including whether any Plaintiff(s) is asserting a claim for loss of consortium, survival, or wrongful death), which Plaintiff(s) may indicate by checking the applicable box on the Short Form Complaint;

ix. Any additional legal counts, Defendants and supporting allegations; and

x. Whether Plaintiff(s) demands a jury trial.

E. Any Plaintiff who filed (or files) a Complaint in MCL No. 624 or had (or has) a Complaint transferred to this MCL before the date of this order must file a Short Form Complaint in his or her case within 30 days of the filing of the Master Complaint. For purposes of statutes of limitations and statutes of repose, any such Plaintiff shall be deemed to have filed his or her Complaint as of the date he or she filed his or her original Complaint and not the date of the Master Complaint or the date he or she filed his or her Short Form Complaint.

F. Any Plaintiff who files a Complaint directly in MCL No. 624 on or after the date on which the Plaintiffs' Liaison/Lead Counsel files the Master Complaint may file a Short form Complaint. For purposes of statutes of limitations and statutes of repose, any such Plaintiff shall be deemed to have filed his or her Complaint as of the date he or she filed his or her Short Form Complaint and not the date of the Master Complaint.

G. Any Plaintiff who files a Complaint that is transferred to MCL No. 624 on or after the date of this order must file a Short Form Complaint within 30 days of the date of transfer. For purposes of statutes of limitations and statutes of repose, any such Plaintiff shall be deemed to have filed his or her Complaint as of the date he or she filed his or her original Complaint in a

different judicial district and not the date of the Master Complaint or the date he or she filed his or her Short Form Complaint.

H. Nothing in this Order shall limit Plaintiffs' right to seek leave of Court to amend a Short Form Complaint as provided in the New Jersey Court Rules.

I. Within sixty (60) days of the date of filing of the Master Complaint, HOC shall file a Master Answer to the Master Complaint or shall file, pursuant to the New Jersey Court Rules, a motion seeking dismissal, in whole or in part, of the Master Complaint. If HOC files a Motion to Dismiss the Master Complaint and such Motion does not result in the dismissal of the Master Complaint in its entirety, HOC shall file a Master Answer within sixty (60) days of the date on which the Court issues a ruling as to HOC's Motion to Dismiss, provided that the Court does not grant the Plaintiffs' Executive Committee ("PEC") leave to amend the Master Complaint. If the Court grants the PEC leave to amend the Master Complaint, within thirty (30) days of such Order, the Plaintiffs' Liaison/Lead Counsel shall file an Amended Master Complaint. HOC shall file a Master Answer or Motion to Dismiss the Amended Master Complaint, in whole or in part, within thirty (30) days after the date of filing the Amended Master Complaint.

J. The Master Answer shall be deemed to be the Answer to all properly served Complaints, whether Short Form or otherwise, in any case now or in the future pending in MCL No. 624, including those cases transferred to MCL No. 624 pursuant to R. 4:3-2 and 4:3-3, or originally filed in MCL No. 624. HOC is hereby relieved of the obligation to file any further Answer to any Complaint not yet answered and/or any Complaint in a case subsequently transferred to MCL No. 624, unless otherwise ordered by this Court. For cases in MCL No. 624

that do not utilize the Master Complaint (if any), the Master Answer will be deemed to answer those allegations that correspond to the allegations of the Master Complaint and will be deemed a denial of any allegations not contained in the Master Complaint.

K. The adoption of the Master Answer in every case is without prejudice to HOC later moving to dismiss certain counts alleged in the Master Complaint (at the appropriate time in any individual Plaintiff's action), asserting any affirmative defenses, filing an Amended Answer to address specifically any individual Complaints, or otherwise challenging the sufficiency of any claim or cause of action in any Complaint under the applicable state's law, including cases that may be selected for inclusion in a discovery pool or bellwether trial pool. Any proposed Order submitted to this Court for a process for selecting cases for inclusion in a discovery pool or bellwether trial pool must include a proposed procedure for the filing of dispositive motions applicable to those cases. Furthermore, by agreeing to procedures for filing the Master Complaint and Short form Complaints, HOC has not agreed to or admitted the allegations set forth in those documents, nor has HOC conceded or waived its right to dispute the legal validity of the claims alleged therein.

L. As set forth herein, after the Master Answer has been filed in MCL No. 624, it will be deemed adopted in every case. As a result, following the filing of the Master Answer, any Plaintiff who wishes to dismiss voluntarily any case originally filed in or transferred to MCL No. 624 must comply with R. 4:37-1.

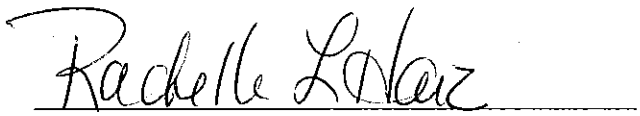
M. As set forth in the Stipulation attached as Exhibit 3, the Parties agree that Plaintiffs will name only Howmedica Osteonics Corp. as a defendant in the Master Complaint or

any Short Form Complaint. HOC lead/liaison MCL counsel, Gibbons P.C., will only accept service of complaints filed in MCL No. 624 on behalf of Howmedica Osteonics Corp. only.

N. For service of Howmedica Osteonics Corp., Plaintiffs must email a properly executed Summons and Filed Complaint to LFITV40NJMCL_HOCeservice@gibbonslaw.com. The email system will generate an automated response to the sender upon receipt of an e-mail to the designated address. This automated response will confirm receipt of the e-mail and shall constitute proof of service as to Howmedica Osteonics Corp. Defendant will not otherwise respond to emails sent to the above e-mail address. Plaintiffs shall make proof of service to the Court as required by R. 4:4-7. Acceptance of electronic service shall not constitute a waiver of any defense.

O. Notwithstanding the provisions of this Order regarding Master Pleadings, HOC does not waive service and a copy of the Summons and all Complaints must be served in accordance with the New Jersey Court Rules.

IT IS SO ORDERED:



Rachelle L. Harz, J.S.C.

EXHIBIT 1

IN RE: STRYKER LFIT CoCr V40 FEMORAL HEADS HIP IMPLANT LITIGATION **Plaintiff(s)** **vs.** **HOWMEDICA OSTEONICS CORPORATION, a New Jersey Corporation, d/b/a STRYKER ORTHOPAEDICS,** JILL DOE MANUFACTURERS (1-10), JACK DOE WHOLESALERS (1-10), JAKE DOE SELLERS (1-10), JANE DOE DISTRIBUTORS and MARKETERS (1-10), JIM DOE HEALTH CARE PROVIDERS (1-10), and JEAN DOE (1-10), **Defendants**	**SUPERIOR COURT OF NEW JERSEY** **LAW DIVISION: BERGEN COUNTY** **MASTER DOCKET NO. BER-L-** 7859 -17 **CASE NO. 624**

MASTER LONG FORM COMPLAINT AND JURY DEMAND FOR LFIT CoCr V40 FEMORAL HEAD CASES

COME NOW, MDL Plaintiffs, by and through the undersigned and their individual counsel, and bring this Master Long Form Complaint as an administrative device to set forth potential claims that individual Plaintiffs may assert in this litigation

against Defendants Howmedica Osteonics d/b/a Stryker Orthopaedics, (hereinafter collectively "Defendant" and "Stryker"). In accordance with Case Management Order #3 and Implementing Order dated ___ of this Court, all allegations pled herein are deemed pled in any previously filed Complaint and in any Short Form Complaint hereafter filed. Further pursuant to Case Management Order #3 and Implementing Order dated ___ of this Court, each individual Plaintiff shall amend his or her complaint no later than thirty (30) days after the date of selection for bellwether consideration, identifying the actual claims he or she intends to pursue at trial and setting forth specific allegations to conform with applicable state law specific to the individual Plaintiff's claims. This Master Long Form Complaint shall be subject to further Order of the Court regarding any future amendments and related motion practice.

Plaintiffs allege as follows:

INTRODUCTION

1. This is an action for damages relating to Defendants' design, research, development, testing, assembling, manufacturing, packaging, labeling, preparing, distributing, marketing, advertising, promoting, supplying, and/or selling the defective product sold under the name "LFIT™ CoCr V40™ Femoral Head" (hereinafter "LFIT V40", "Defective Device", or "Device") and compatible femoral stem components with V40 interface to be used in conjunction with the LFIT™ CoCr V40™ Femoral Head (hereinafter "Defective Compatible Component(s)").

2. Defendants developed, manufactured, promoted and sold the LFIT™ CoCr V40™ Femoral Head for placement into women and men's hips as a replacement

implanted device. Defendants' Device was placed into the stream of interstate commerce and was implanted in Plaintiffs.

3. Defendants developed, manufactured, promoted and sold several femoral stems with V40 interface designed to be used in conjunction with the LFIT™ CoCr V40™ Femoral Head for placement into women and men's hips as a replacement implanted device. Defendants' Defective Compatible Components were placed into the stream of interstate commerce and was implanted in Plaintiffs.

4. As a direct and proximate result of Defendants placing these Defective Devices into the stream of commerce, Plaintiffs have suffered and continue to suffer both injuries and damages, including, but not limited to: bodily injury; severe physical pain and suffering; emotional distress; disability; physical impairment; disfigurement; mental anguish; inconvenience; aggravation of a pre-existing condition; loss of the capacity for the enjoyment of life; the costs of medical care and expenses; loss of earnings; and loss of the ability to earn money, all of which damages and losses will continue in the future.

5. A patient's natural hip joint connects the thigh (femur) bone of her leg to her pelvis. The hip joint is characterized as a ball and socket joint. The socket is the cup shaped portion of the acetabulum into which the femoral head (ball) at the top of the femur bone inserts and articulates. Both the femoral head and acetabular socket are covered with cartilage forming a natural surface upon which the parts may move freely.

6. In some patients, cartilage can be damaged due to either trauma, disease or aging (arthritis). When this occurs, a hip replacement may be indicated. A total hip replacement utilizes parts manufactured from metal alloys, plastic, or ceramic to replace a

patient's damaged native anatomy. A total hip replacement typically consists of four separate components: (1) a femoral stem, (2) a femoral head, (3) an acetabular liner, and (4) an acetabular shell. The procedure requires removing the arthritic femoral head and replacing the patient's natural anatomy with a femoral stem upon which a femoral head is impacted. The acetabulum is then reamed to accommodate the acetabular shell into which, once fixed, the liner is then placed. Once all the parts are inserted, the ball articulates within the acetabular liner much like the patient's natural hip.

7. The Defective Devices were intended to replace patient's damaged or diseased natural anatomy. The Defective Devices are indicated for patients requiring total hip arthroplasty.

8. On April 11, 2001, Defendants received clearance from the Food and Drug Administration (hereinafter referred to as the "FDA") to market the LFIT™ CoCr V40™ Femoral Head in the United States pursuant to Section 510(k) of the Food, Drug and Cosmetic Act. A medical device cleared under Section 510(k) does not have to go through any clinical study to gain clearance by the FDA, meaning it does not have to be tested in a single human being before placed on the market.

9. On August 22, 2006, Defendants received clearance from the FDA to market the LFIT™ Anatomic CoCr V40™ Femoral Head in the United States pursuant to Section 510(k) of the Food, Drug and Cosmetic Act.

10. Defendant's entire line of chrome cobalt femoral heads were designed to be utilized with a wide variety of Stryker V40 taper femoral stems more fully described below.

11. The V40 taper is unique to Stryker's implant components and is not utilized by other orthopedic device manufacturers. "V40" simply refers to the angular mismatch between the trunnion on the femoral stem and the female taper in the bore of the chrome cobalt head. When the femoral head is impacted onto the stem's trunnion, the dissimilar angles of the trunnion and the head's female taper form a "press fit." This "taper junction," otherwise known as a Morse Taper, relies on the dissimilar angles to obtain fixation. At the connection between Stryker's V40 chrome cobalt head and Stryker's V40 femoral stem trunnion, poor design and material choices lead to micro-motion, fretting, corrosion and ultimately failure of the device due to the generation of metal wear debris. In the most extreme circumstances, corrosion fueled by motion and accompanied by massive metal loss can result in the femoral head falling off the femoral stem, a phenomenon described in the medical literature as catastrophic dissociation. To date, Stryker's V40 tapers are the only commercially available stem/head combinations to have suffered these catastrophic failures.

12. Stryker's V40 tapers are more prone to *in vivo* motion, fretting, corrosion and production of metallic debris than other commercially available femoral replacement systems.

13. The corrosion and metallic debris produced by the Defective Devices can result in Adverse Local Tissue Reaction ("ALTR") and tissue necrosis (death), among other things.

14. On or about August 29, 2016, Defendants issued an "Urgent Medical Device Recall Notification" involving certain lots of LFIT V40 Heads manufactured prior to 2011.

15. At all times material hereto, the V40 Heads and stems implanted in Plaintiffs were designed, manufactured, marketed, retailed, distributed, and/or supplied by Defendants.

16. After implantation of the Defective Devices, Plaintiffs suffered from the consequences of one or more of the following; fretting, corrosion, release of metal ions and/or metal wear debris followed by pain, disability, destruction of tissue, the development of fluid collections and pseudotumor and the necessity of revision surgery (removal and replacement).

17. Failure of the Defective Devices has led to Plaintiffs having to undergo revision surgery to remove the Defective Devices, or in some instances despite revision surgery being indicated, Plaintiffs are unable to undergo revision due to other medical conditions.

18. Frequent findings during revision surgery are the presence of turbid, milky fluid collection, large pseudotumor formation, discolored or friable soft tissue and bone, bone and soft tissue necrosis, and detachment or tearing of muscle.

PARTIES

19. Plaintiffs are citizens and/or residents and/or visitors of the United States who were implanted with the LFIT™ CoCr V40™ Femoral Head.

20. Defendant Howmedica Osteonics Corp. 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. Defendant Howmedica Osteonics d/b/a Stryker Orthopaedics is a wholly owned subsidiary of the parent corporation, Stryker Corporation.

21. Upon information and belief, at all times herein mentioned, the employees of Defendants, their subsidiaries, affiliates, and other related entities, as well as the employees of each of the individual Defendants' subsidiaries, affiliates, and other related entities, were the agents, servants and employees of Defendants, and at all relevant times, were acting within the purpose and scope of said agency and employment. Whenever reference in this Complaint is made to any act or transaction of Defendants, such designations shall be deemed to mean that the principals, officers, employees, agents, and/or representatives of the Defendants committed, knew of, performed, authorized, ratified and/or directed such transactions on behalf of Defendants while actively engaged in the scope of their duties.

JURISDICTION AND VENUE

22. Venue in this action properly lies in Bergen County as the Defendant conducts substantial business in this county.

23. Defendant, Howmedica Osteonics Corp (hereinafter "HOWMEDICA"), d/b/a STRYKER ORTHOPAEDICS is a corporation organized and existing under the laws of New Jersey having its principal place of business located at 325 Corporate Drive, Mahwah, NJ 07430 and conducts business throughout the United States.

24. Jill Doe Manufacturers (1-10), Jack Doe Wholesalers (1-10), Jake Doe Sellers (1-10), Jane Doe Distributors and Marketers (1-10), Jim Doe Health Care Providers (1-10), and Jean Doe (1-10), are corporations, partnerships, companies, persons or other entities involved in the marketing, design, development, manufacture, testing, selling, labeling, packaging, advertising, promoting, supplying, distribution, implantation or release of the Products, whose identities are not presently known by Plaintiffs. The Doe defendants are sued individually in their official capacity.

THE LFIT™ CoCr V40™ FEMORAL HEAD

25. Defendants manufacture medical devices worldwide, including total hip replacement systems and products.

26. Beginning in 2001, Stryker obtained its first FDA clearance to sell V40 taper chrome cobalt femoral heads. Over the ensuing decade, Stryker obtained several more clearances to extend its line of V40 femoral heads culminating with its August 22, 2006, clearance from the FDA to market the largest LFIT™ Anatomic CoCr V40™ Femoral Heads.

27. The LFIT V40 is a femoral head indicated for patients requiring total hip arthroplasty.

28. The LFIT V40 can be used interchangeably with all of Stryker's femoral stems with a V40 style trunnion, including those described herein.

29. According to Defendants' materials, the LFIT V40 and X3® Liners were developed to address clinical factors associated with dislocation, strength and wear.

30. Stryker's promotional material touts that 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 liner. The LFIT V40 Heads were (and are) offered in a variety of diameters.

31. A Morse taper (a cone-within-a-cone) is used to mate the LFIT V40 Head with the different stems. The bore (female portion) of the LFIT V40 Head is placed onto the tapered trunnion (male portion) of the stem and impacted by the surgeon using a Stem Head Impactor tool. The stresses created by the dissimilar V40 angles compress the wall of the bore thereby locking it onto the femoral stem trunnion.

32. The defective design of Defendants' V40 tapers allows the head to move on the stem which promotes corrosion and fretting.

33. Defendants manufactured several of their femoral stems using a proprietary metal alloy called "TMZF." TMZF is an acronym that stands for **T**itanium, **M**olybdnum, **Z**irconium, and **F**e, the chemical symbol for iron, the main elements of the TMZF alloy. Unlike most titanium alloys used in orthopaedic implants, which are alpha + beta type ($\alpha+\beta$-type) alloys, TMZF is a beta type (β-type) alloy. Unlike $\alpha+\beta$-type alloys, which contain vanadium as the alloying element, β-type alloys (like TMZF) are vanadium-free and the principal alloying elements typically consist of niobium, molybdenum, tantalum, or iron.

34. Stryker's proprietary TMZF titanium alloy causes a significant amount of toxic corrosion when it is implanted in contact with CoCr (cobalt/chrome), like the LFIT V40 Femoral Head.

35. Stryker knew or should have known at the time it sold the implants to the Plaintiffs in this case that its proprietary TMZF alloy should not be mated to CoCr products.

36. Although all Stryker V40 stems are subject to failure when mated with a V40 chrome cobalt head, TMZF stems are more prone to failure when used in combination with LFIT V40 Heads.

37. In 2012, Stryker was forced to recall several thousand ABG II and Rejuvenate femoral stems because of corrosion that occurred when Stryker's proprietary TMZF titanium stem was utilized with a modular femoral neck made of cobalt/chrome. In addition to what Stryker already knew (or should have known) about the dangers of mating its TMZF alloy with CoCr, the ABG II and Rejuvenate stem recall provided even more notice to Stryker about the significant danger to patients in whom products made of TMZF and CoCr are implanted. These dangerous products include the LFIT V40 femoral heads (which are made of CoCr) and femoral stems made of TMZF.

38. At the same time Stryker recalled its Rejuvenate and ABG II TMZF femoral stems, it redesigned its most popular stem, the Accolade TMZF and substituted a new titanium alloy for TMZF thus eliminating a substantial majority of all TMZF products from its hip implant line.

39. Upon information and belief, Defendants represented and warranted in its marketing and sale of the LFIT V40 Heads that its proprietary materials alleviate problems of corrosion and wear when, in fact, Stryker knew or should have known that the LFIT V40 would cause extreme and unusual amounts of corrosion and wear when used with any femoral stem compatible with the LFIT V40 head.

40. At all times material hereto, Defendants developed, tested, assembled, manufactured, packaged, labeled, prepared, distributed, marketed, supplied, and/or sold the defective LFIT V40 either directly or indirectly, to members of the general public within the United States and in the State of New Jersey, including hospitals, surgeons, and Plaintiffs.

VARIOUS STEMS ARE COMPATIBLE WITH THE DEFECTIVE DEVICE

A. The Accolade® TMZF Femoral Stem

41. At all times material hereto, Defendants developed, tested, assembled, manufactured, packaged, labeled, prepared, distributed, marketed, supplied, and/or sold the Accolade® TMZF Plus Femoral Hip Stem ("Accolade TMZF Plus"), either directly or indirectly, to members of the public within the United States including the State of New Jersey, including hospitals, surgeons, and the Plaintiff.

42. The indications for use of both LFIT V40 Heads and Accolade TMZF Plus stems include patients who require total hip arthroplasty.

43. On October 09, 2002, Defendants received FDA clearance pursuant to Section 510(k) to sell its Accolade TMZF Plus in the United States. The Accolade TMZF Plus is a tapered non-porous coated femoral stem manufactured from a TMZF substrate

material with a coating consisting of Commercially Pure Titanium and Purefix hydroxyapatite.

44. The Accolade® TMZF Plus is designed to be used with a number of bearing surface components comprised of a modular ball (artificial femoral head), including the LFIT™ CoCr V40™ femoral heads.

45. A femoral head commonly paired with the Accolade TMZF Plus is the LFIT V40.

46. 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 locking of the head/stem taper interface.

47. Failure of the V40 taper interface allows micro-motion of these components and promotes fretting which then promotes corrosion.

48. The material combination of a titanium alloy stem, with a cobalt chromium femoral head (like the LFIT V40), has been observed to cause corrosion. And as is discussed in detail above, Defendant knew or should have known at the time it sold these implants to Plaintiffs that its proprietary TMZF titanium alloy would cause severe and unusual corrosion when put in contact with cobalt/chrome components. Defendants also knew or should have known that this severe and unusual corrosion would predispose the

hip implant to premature failure, necessitating a complex, risky, and painful revision surgery.

49. Defendants manufacture, market, and sell 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.

50. 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.

B. Accolade II® Femoral Stem

51. At all times material hereto, Defendants developed, tested, assembled, manufactured, packaged, labeled, prepared, distributed, marketed, supplied, and/or sold the Accolade® II Femoral Hip System ("Accolade II"), either directly or indirectly, to members of the public within the United States including in the State of New Jersey, including hospitals, surgeons, and the Plaintiff.

52. The indications for use of both LFIT V40 Heads and Accolade II stems include patients requiring total hip arthroplasty.

53. On March 10, 2011, HOC received FDA clearance pursuant to Section 510(k) to sell its Accolade II in the United States. The Accolade II 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.

54. The Accolade II stem is a hip replacement prosthesis. It is indicated for patients requiring total hip arthroplasty.

55. The Accolade II is a titanium stem is manufactured utilizing a proprietary titanium alloy consisting of titanium, aluminum, and vanadium. Howmedica's alloy was designed and patented by Defendants.

56. The Accolade II Stem is a monoblock, single piece, artificial hip replacement device that is designed to be implanted into the patient's femur. The Accolade II Stem is designed to be used with a number of bearing surface components comprised of the modular ball or artificial femoral head and an acetabular cup or socket, including the LFIT™ CoCr V40™ femoral head.

57. A femoral head commonly paired with the Accolade II is the LFIT™ CoCr V40™ Femoral Head.

58. A Morse taper (a cone-within-a-cone) is used to mate the LFIT V40 Head with the Accolade II stem. The bore (female portion) of the LFIT V40 Head is placed onto the tapered trunnion (male portion) of the Accolade II 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 locking of the head/stem taper interface.

59. Failure of the V40 taper interface allows micro-motion of these components and promotes corrosion and fretting.

60. 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.

61. Defendants marketed the LFIT V40 cobalt chromium femoral head to be paired with the Accolade II Stem to help maximize a patient's hip movement, as well as stability and dislocation resistance.

62. Defendants manufacture, market, and sell ceramic femoral heads that are compatible with the Accolade II. Upon information and belief, an Accolade II stem paired with a ceramic femoral head will not experience fretting and corrosion. Defendants did develop and obtain clearance for the Accolade II stem in 2011 which curiously is the year that the recall of the LFIT™ CoCr V40™ Femoral Head terminates, suggesting that Defendants hoped that the Accolade II would replace the TMZF Accolade stem and obviate the problems observed with fretting and corrosion when the TMZF stems were paired with the LFIT™ CoCr V40™ Femoral Heads. However, evidence suggests that the Accolade II titanium alloy when paired with the LFIT™ CoCr V40™ Femoral Head causes corrosion and tissue damage within a short period of time in some patients and said problems could have been detected had defendant done proper testing and clinical trials.

C. <u>Restoration™ Femoral Hip Stem</u>

63. At all times material hereto, Defendants developed, tested, assembled, manufactured, packaged, labeled, prepared, distributed, marketed, supplied, and/or sold the Restoration Modular Hip System ("Restoration"), Restoration HA Stem ("Restoration HA") and Restoration PS Stem ("Restoration PS"), either directly or indirectly, to

members of the public within the United States including the State of New Jersey, including hospitals, surgeons, and the Plaintiff.

64. The indications for use of both LFIT V40 Heads and Restoration, or Restoration HA or Restoration PS stems include patients requiring total hip arthroplasty.

65. On April 3, 2002, HOC received FDA clearance through the 510(k) process to sell its Restoration Modular Hip Stem in the United States. The Restoration stem is comprised of a proximal body, distal stem, and locking bolt and is fabricated from Titanium (Ti6Al-4v) Alloy.

66. The Restoration HA is a fully-coated, titanium stem with PureFixHA hydroxyapatite coating.

67. The Restoration PS is a forged-titanium plasma-sprayed implant.

68. The Restoration stem is designed to be used with a number of bearing surface components comprised of the modular ball, including the LFITV40 Femoral Head, and an acetabular cup or socket.

69. A femoral head commonly paired with the Restoration is the LFIT™ CoCr V40™ Femoral Head.

70. A Morse taper (a cone-within-a-cone) is used to mate the LFIT V40 Head with the Restoration stem. The bore (female portion) of the LFIT V40 Head is placed onto the tapered trunnion (male portion) of the Restoration 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 locking of the head/stem taper interface.

71. Failure of the V40 taper interface allows micro-motion of these components and promotes corrosion and fretting.

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

73. Defendants marketed the LFIT V40 cobalt chromium femoral head to be paired with the Restoration stem to help maximize a patient's hip movement, as well as stability and dislocation resistance.

74. Defendants manufacture, market, and sell ceramic femoral heads that are compatible with the Restoration stem. Upon information and belief, a Restoration stem paired with a ceramic femoral head will not experience fretting and corrosion.

D. <u>The Rejuvenate® Monolithic Stem</u>

75. At all times material hereto, Defendants developed, tested, assembled, manufactured, packaged, labeled, prepared, distributed, marketed, supplied, and/or sold the Rejuvenate Monolithic Hip Stem ("Rejuvenate Monolithic"), either directly or indirectly, to members of the public within the United States including the State of New Jersey, including hospitals, surgeons, and the Plaintiff.

76. The indications for use of both LFIT™ V40 Heads and Rejuvenate Monolithic stems include patients requiring total hip arthroplasty.

77. On December 29, 2008, HOC received FDA clearance pursuant to Section 510(k) to sell its Rejuvenate Monolithic in the United States. The Rejuvenate Monolithic

Stem is a monoblock, single piece replacement device made of TMZF alloy with a plasma sprayed coating of commercially pure (CP) titanium and PureFix HA.

78. The Rejuvenate Monolithic hip stem differs from the Rejuvenate Modular Hip System in that it is a monoblock device and is not implanted with a modular neck component. The Rejuvenate Monolithic Hip Stem was not subject to the recall in 2012 and is not subject to the consolidated litigation involving the Stryker Rejuvenate and ABG II Modular Hip Systems.

79. The Rejuvenate Monolithic stem is designed to be used with a number of bearing surface components comprised of a modular ball or artificial femoral head, including LFIT™ CoCr V40™ femoral heads.

80. A femoral head commonly paired with the Rejuvenate Monolithic stem is the LFIT V40.

81. A Morse taper (a cone-within-a-cone) is used to mate the LFIT V40 Head with the Rejuvenate Monolithic stem. The bore (female portion) of the LFIT V40 Head is placed onto the tapered trunnion (male portion) of the Rejuvenate Monolithic 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 locking of the head/stem taper.

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

83. 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 for decades.

84. Defendants manufacture, market, and sell ceramic femoral heads that are compatible with the Rejuvenate Monolithic Stem. Upon information and belief, a Rejuvenate Monolithic stem paired with a ceramic femoral head will not experience fretting and corrosion.

85. 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.

E. <u>The ABG II Monolithic Femoral Stem</u>

86. At all times material hereto, Defendants developed, tested, assembled, manufactured, packaged, labeled, prepared, distributed, marketed, supplied, and/or sold the ABG II Monolithic Hip Stem ("ABG II Monolithic"), either directly or indirectly, to members of the public within the United States including the State of New Jersey, including hospitals, surgeons, and the Plaintiff.

87. The indications for use of both LFIT™ V40 Heads and ABG II Monolithic stems include patients requiring total hip arthroplasty.

88. On May 25, 2011, HOC received FDA clearance pursuant to Section 510(k) to sell its ABG II Monolithic in the United States. The ABG II Monolithic Stem is a monoblock, single piece, replacement device made of TMZF alloy with a roughened hydroxlapatite coating in the proximal region.

89. The ABG II Monolithic hip stem differs from the ABG II Modular Hip System in that it is a monoblock device and is not implanted with a modular neck component. The ABG II Monolithic Hip Stem was not subject to the recall in 2012 and is not subject to the consolidated litigation involving the Stryker Rejuvenate and ABG II Modular Hip Systems.

90. The ABG II Monolithic stem is designed to be used with any number of bearing surface components comprised of a modular ball or artificial femoral head, including LFIT™ CoCr V40™ femoral heads.

91. A femoral head commonly paired with the ABG II Monolithic stem is the LFIT V40.

92. A Morse taper (a cone-within-a-cone) is used to mate the LFIT V40 Head with the ABG II Monolithic stem. The bore (female portion) of the LFIT V40 Head is placed onto the tapered trunnion (male portion) of the ABG II Monolithic 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 locking of the head/stem taper interface.

93. Failure of the V40 taper interface allows micro-motion of these components and promotes corrosion and fretting.

94. 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 for decades.

95. Defendants manufacture, market, and sell ceramic femoral heads that are compatible with the ABG II Monolithic Stem. Upon information and belief, an ABG II Monolithic stem paired with a ceramic femoral head will not experience fretting and corrosion.

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

F. <u>The Hipstar® Femoral Stem</u>

97. At all times material hereto, Defendants developed, tested, assembled, manufactured, packaged, labeled, prepared, distributed, marketed, supplied, and/or sold the Hipstar Femoral Hip Stem ("Hipstar"), either directly or indirectly, to members of the public within the United States including the State of New Jersey, including hospitals, surgeons, and the Plaintiff.

98. The indications for use of both LFIT™ V40 Heads and Hipstar stems include patients requiring total hip arthroplasty.

99. On May 5, 2006, HOC received FDA clearance pursuant to Section 510(k) to sell its Hipstar stem in the United States. The Hipstar stem is a tapered non-porous coated femoral stem manufactured from a TMZF titanium alloy.

100. The Hipstar is designed to be used with several bearing surface components comprised of a modular ball or artificial femoral head, including LFIT™ CoCr V40™ femoral heads.

101. A femoral head commonly paired with the Hipstar is the LFIT V40.

102. A Morse taper (a cone-within-a-cone) is used to mate the LFIT V40 Head with the Hipstar stem. The bore (female portion) of the LFIT V40 Head is placed onto the tapered trunnion (male portion) of the Hipstar 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 locking of the head/stem taper interface.

103. Failure of the V40 taper interface allows micro-motion of these components and promotes corrosion and fretting.

104. 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 for decades.

105. Defendants manufacture, market, and sell ceramic femoral heads that are compatible with the Hipstar. Upon information and belief, a Hipstar stem paired with a ceramic femoral head will not experience fretting and corrosion.

106. 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.

G. Citation TMZF HA Stem

107. At all times material hereto, Defendants developed, tested, assembled, manufactured, packaged, labeled, prepared, distributed, marketed, supplied, and/or sold the Citation TMZF HA femoral stem ("Citation TMZF"), either directly or indirectly, to members of the public within the United States including the State of New Jersey, including hospitals, surgeons, and the Plaintiff.

108. The indications for use of both LFIT™ V40 Heads and Citation TMZF stems include patients requiring total hip arthroplasty.

109. On January 21, 2000, HOC received FDA clearance pursuant to Section 510(k) to sell its Citation TMZF in the United States. The Citation TMZF is a tapered femoral stem manufactured from a TMZF Alloy and coated with CP Titanium plasma spray coating and Pure-Fix™ HA.

110. The Citation TMZF is designed to be used with several bearing surface components comprised of a modular ball or artificial femoral head, including LFIT™ CoCr V40™ femoral heads.

111. A femoral head commonly paired with the Citation TMZF is the LFIT V40.

112. A Morse taper (a cone-within-a-cone) is used to mate the LFIT V40 Head with the Citation TMZF stem. The bore (female portion) of the LFIT V40 Head is placed

onto the tapered trunnion (male portion) of the Citation 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 locking of the head/stem taper interface.

113. Failure of the V40 taper interface allows micro-motion of these components and promotes corrosion and fretting.

114. 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 for decades.

115. Defendants manufacture, market, and sell ceramic femoral heads that are compatible with the Citation TMZF stem. Upon information and belief, a Citation TMZF stem paired with a ceramic femoral head will not experience fretting and corrosion.

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

H. The Meridian® PA Femoral Stem

117. At all times material hereto, Defendants developed, tested, assembled, manufactured, packaged, labeled, prepared, distributed, marketed, supplied, and/or sold the Meridian PA Hip Stem ("Meridian"), either directly or indirectly, to members of the

public within the United States including the State of New Jersey, including hospitals, surgeons, and the Plaintiff.

118. The indications for use of both LFIT™ V40 Heads and Meridian stems include patients requiring total hip arthroplasty.

119. On January 19, 1995, HOC received FDA clearance pursuant to Section 510(k) to sell its Meridian Stem in the United States. The Meridian stem is a tapered femoral stem manufactured from a TMZF Alloy or Ti-6AI-4V titanium alloy and coated with CP Titanium plasma spray.

120. The Meridian stem is designed to be used with several bearing surface components comprised of a modular ball or artificial femoral head, including LFIT™ CoCr V40™ femoral heads.

121. A femoral head commonly paired with the Meridian stem is the LFIT V40.

122. A Morse taper (a cone-within-a-cone) is used to mate the LFIT V40 Head with the Meridian stem. The bore (female portion) of the LFIT V40 Head is placed onto the tapered trunnion (male portion) of the Meridian 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 locking of the head/stem taper interface.

123. Failure of the V40 taper interface allows micro-motion of these components and promotes corrosion and fretting.

124. 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 for decades.

125. Defendants manufacture, market, and sell ceramic femoral heads that are compatible with the Meridian stem. Upon information and belief, a Meridian stem paired with a ceramic femoral head will not experience fretting and corrosion.

126. 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.

I. The Exeter® V40™ Femoral Stem

127. At all times material hereto, HOC developed, tested, assembled, manufactured, packaged, labeled, prepared, distributed, marketed, supplied, and/or sold the Exeter V40 Hip stem ("Exeter V40"), either directly or indirectly, to members of the public within the United States including the State of New Jersey, including hospitals, surgeons, and the Plaintiff.

128. The indications for use of both LFIT™ V40 Heads and Exeter V40 stems include patients requiring total hip arthroplasty.

129. The Exeter stem was previously approved for use with Zirconia, alumina ceramic, Biolox® Delta ceramic and stainless steel heads. On September 20, 2011, HOC received FDA clearance pursuant to Section 510(k) to sell its Exeter stem in the United States with the LFIT V40 Head. The Exeter stem is a V40 tapered stem made with Material Orthinox™ stainless steel.

130. The Exeter V40 is designed to be used with several bearing surface components comprised of a modular ball or artificial femoral head, including LFIT™ CoCr V40™ femoral heads.

131. A femoral head commonly paired with the Exeter V40 is the LFIT V40.

132. A Morse taper (a cone-within-a-cone) is used to mate the LFIT V40 Head with the Exeter V40 stem. The bore (female portion) of the LFIT V40 Head is placed onto the tapered trunnion (male portion) of the Exeter V40 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 locking of the head/stem taper interface.

133. Failure of the V40 taper interface allows micro-motion of these components and promotes corrosion and fretting.

134. The material combination of a stainless steel 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 for decades.

135. Defendant manufactures, markets, and sells ceramic femoral heads that are compatible with the Exeter V40 stem. Upon information and belief, an Exeter V40 stem paired with a ceramic femoral head will not experience fretting and corrosion.

136. 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.

J. The Reliance® PF Femoral Stem

137. At all times material hereto, Defendants developed, tested, assembled, manufactured, packaged, labeled, prepared, distributed, marketed, supplied, and/or sold the Reliance® Femoral Hip Stem ("Reliance"), either directly or indirectly, to members of the public within the United States including the State of New Jersey, including hospitals, surgeons, and the Plaintiff.

138. The indications for use of both LFIT™ V40 Heads and Reliance stems include patients requiring total hip arthroplasty.

139. On April 9, 1997, Defendants received FDA clearance pursuant to Section 510(k) to sell its Reliance stem in the United States. The Reliance stem is a tapered femoral stem manufactured from forged cobalt- chromium-molybdenum (Vitallium®) alloy.

140. The Reliance stem is designed to be used with several bearing surface components comprised of a modular ball or artificial femoral head, including LFIT™ CoCr V40™ femoral heads.

141. A femoral head commonly paired with the Reliance stem is the LFIT V40.

142. A Morse taper (a cone-within-a-cone) is used to mate the LFIT V40 Head with the Reliance stem. The bore (female portion) of the LFIT V40 Head is placed onto the tapered trunnion (male portion) of the Reliance 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 locking of the head/stem taper interface.

143. Failure of the V40 taper interface allows micro-motion of these components and promotes corrosion and fretting.

144. Failure of the V40 Taper causes micro-motion and mechanical wear, which results in the release of toxic metal particles into the surrounding tissues of the hip. Scientists have reported on the known potential for injury associated with metallic wear particles in hip implants for decades.

145. Defendants manufacture, market, and sell ceramic femoral heads that are compatible with the Reliance stem. Upon information and belief, a Reliance stem paired with a ceramic femoral head will not experience fretting and corrosion.

146. 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.

K. Other Stryker Femoral Stems

147. At all times material hereto, Defendants developed, tested, assembled, manufactured, packaged, labeled, prepared, distributed, marketed, supplied, and/or sold additional femoral stems "Other Femoral Stems" not listed above, either directly or indirectly, to members of the public within the United States including the State of New Jersey, including hospitals, surgeons, and the Plaintiff.

148. The indications for use of the LFIT™ V40 Heads and the Other Femoral Stems include patients requiring total hip arthroplasty.

149. The Other Femoral Stems are designed to be used with a number of bearing surface components comprised of a modular ball or artificial femoral head, including LFIT™ CoCr V40™ femoral heads.

150. Femoral heads commonly paired with Other Femoral Stems are the LFIT V40.

151. A Morse taper (a cone-within-a-cone) is used to mate the LFIT V40 Head with the Other Femoral Stems. The bore (female portion) of the LFIT V40 Head is placed onto the tapered trunnion (male portion) of the Other Femoral Stems 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 locking of the head/stem taper interface.

152. Failure of the V40 taper interface allows micro-motion of these components and promotes corrosion and fretting.

153. The material combination of the titanium alloy of the Other Femoral Stems 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 for decades.

154. Defendant manufactures, markets, and sells ceramic femoral heads that are compatible with the Other Femoral Stems. Upon information and belief, Other Femoral Stems paired with a ceramic femoral head will not experience fretting and corrosion.

155. 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.

URGENT SAFETY NOTICES AND RECALLS

156. On or about August 29, 2016, Defendants issued a voluntary worldwide recall of certain lots of the LFIT V40 Heads, citing a "higher than expected" incidence of taper lock failure. Defendants identified several "Potential Hazards" Associated with taper lock failure, including:

- Dislocation of the femoral head from the hip stem
- Fractured hip stem trunnions
- Excessive metallic debris
- Excessive wear debris

157. The recall notice further states that the problems caused by the LFIT V40 Head include "revision" surgery," "inflammatory response," "adverse local tissue reaction," "dislocation," and "periprosthetic fracture." However, despite these serious "hazards," the recall notice provides no information concerning the cause of the failures or steps surgeons should take to monitor patients.

158. In this notice, Defendants acknowledged that they had received reports of device failure due to heavy metal contamination. The Urgent Medical Device Recall Notification specifically referred to failures at the taper lock junction.

159. Nevertheless, the Stryker recall notification minimized the gravity and magnitude of the problem by noting that the reason for the voluntary recall was "Stryker has receive higher than expected complaints of taper lock failure for specific lots of the following certain sizes of the V40 LFIT Anatomic Cobalt Chrome femoral heads manufactured prior to 2011" thus conveying the message to surgeons that there was no concern for other sizes beyond those specifically recalled– certain 36, 40 and 44 mm head diameters with certain specific offsets.

160. Moreover, the recall notice failed to advise surgeons that they should notify their patients of the recall or that the surgeons should pursue any specific follow up of their at-risk patients. Instead, Stryker stated "implanted patients with LFIT Anatomic CoCr V40 femoral heads as described above should continue to be followed for the normal protocol established by his, her surgeon." Said statement provides no guidance whatsoever to the surgeons since many of these failures occurred a number of years after the implantation and most surgeons don't require follow-up of a patient beyond the first year or two following implant. Defendants knew that by providing ambiguous, and misleading "recommendation" that patients would not be notified of the recall, would not return to their surgeons and would not receive any testing to diagnose problems that if promptly detected could mitigate ongoing tissue damage or prevent catastrophic failure like disassociation of the femoral head from the stem.

161. In July of 2014 the American Association of Hip and Knee Surgeons, the American Academy of Orthopedic Surgeons and The Hip Society issued a Consensus Statement on Risk Stratification Algorithm for Management of Patients with Dual Modular Taper Total Hip Arthroplasty. While the statement was geared to dual

modularity devices, many of its recommendations were equally applicable to single modularity at the neck head junction such as the Devices in issue here. For example, it recommended magnetic resonance imaging (MRI) in detection of local adverse soft tissue reaction as "an important diagnostic tool in evaluating the presence of adverse tissue reactions to the modular taper fretting corrosion... Early application of MRI may be important tool that allows early detection of adverse soft tissue reactions due to modular taper fretting corrosion. This has been reported and THA patients with neck–stem modularity as well as head–neck modularity." Nevertheless, Stryker in its misleading recall notice did not suggest to surgeons that they call their patients for a visit to perform an MRI and determine if there was adverse tissue reaction.

162. The consensus statement also recommended frequent follow ups including patients at high-risk receiving six-month intervals and at moderate risk annual follow-up due to the risks of insidious tissue damage. The conclusion of the consensus statement is "there should be a low threshold to perform a systematic evaluation of patients with dual taper stem total hip arthroplasty as early recognition diagnosis will facilitate the initiation of appropriate treatment prior to significant adverse biological reactions." Nevertheless Stryker in its misleading recall notice did not suggest to surgeons that they call their patients to return for a visit to perform a systematic evaluation of patients with the LFIT V40 Heads and instead sought to minimize the problem and distinguish it from that of the notoriously disastrous recalled dual modular Rejuvenate and ABG II stems.

163. A simple, inexpensive blood test can be used to determine whether a patient is experiencing the corrosive process that lead to the 2016 recall. Specifically, the

presence of elevated levels of cobalt, chromium, or titanium in the blood is an important sign that the prosthetic hip is corroding. Despite the availability of this test, the Defendants' recall notice fails to instruct surgeons to contact patients with the Device to perform such tests.

164. Defendants, through their sales representatives who typically are present in the operating room for the implantation, have possession, custody or control over their sales representative records, which frequently keep track of which device was used by which surgeon in particular patients. Defendants could have provided those records to surgeons to assist them in identifying which of their patients were implanted with the LFIT V40 cobalt chromium heads. However, since Defendants' strategy to deal with this health disaster was the uninformative and misleading recall notice, Defendants failed to facilitate any surgeons' efforts to inform patients of the recall, and the need for periodic follow up to look for signs of failure of the head stem junction. Such follow up, could have led to earlier diagnosis of Device failure and surgical intervention.

165. Accordingly, Defendants failed to mitigate damages arising from their defective products and left patients uninformed of the recall, resulting in ongoing destruction of tissue, muscle and bone causing worsening and permanent impairment in many unknowing patients.

166. The Urgent Medical Device Recall Notification went on to describe symptoms and findings consistent with those experienced by Plaintiffs herein.

THE FEDERAL REQUIREMENTS

167. The Medical Device Amendments of 1976 ("MDA") to the Food Device Cosmetic Act ("FDCA") established the current regulatory framework for medical device approval.

168. The MDA contains a three-class classification system for medical devices. Class I devices pose the lowest risk to consumers' health, do not require FDA approval for marketing, and include devices such as tongue depressors. Class II devices pose intermediate risk and often include special controls including post-market surveillance and guidance documents. Finally, Class III devices pose the greatest risk of death or complications and include most implantable surgical devices such as cardiac pacemakers, coronary artery stents, automated external defibrillators, and several types of implantable orthopedic devices for spine and hip surgery. The LFIT V40 is a Class III devices.

169. Manufacturers such as Stryker that are seeking to market Class III devices, such as the LFIT V40, are required to submit a 510(k) Approval Application ("510(k)") that must be evaluated and approved by the FDA, if they can demonstrate to the FDA that the devices are shown to be "substantially equivalent" to a predicate device the manufacturer previously submitted for approval to the FDA. 21 U.S.C.§ 360e(b)(1)(B).

170. According to the U.S. Supreme Court in Buckman v. Plaintiffs' Legal Comm., 531 U.S. 341 (2001), the Supreme Court explained that demonstrating that a device qualifies for this , known as the " § 510(k) process," means that: "[s]ection 510(k) submissions must include the following: 'Proposed labels, labeling, and advertisements sufficient to describe the device, its intended use, and the directions for its use,' 21 CFR §

807.87(e) (2000); and must include "[a] statement indicating the device is similar to and/or different from other products of comparable type in commercial distribution, accompanied by data to support the statement," § 807.87(f); "[a] statement that the submitter believes, to the best of his or her knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted," § 807.87(k); and "any additional information regarding the device requested by the [FDA] Commissioner that is necessary for the Commissioner to make a finding as to whether or not the device is substantially equivalent to a device in commercial distribution," § 807.87(l). 531 U.S. 341, 345-46. Here, the LFIT™ CoCr V40™ Femoral Head was approved pursuant to this 510(k) process.

171. The FDCA requires Class III medical devices to be demonstrated to be safe and effective for each intended use[1]. Not only is the medical device itself part of the 510(k) approval process, but the labeling and packaging that comes with it.

172. A manufacturer is required to give adequate directions for the use of a medical device such that a "layman can use a device safely and for the purposes for which it is intended"[2], and conform to section 801.15 requirements governing the appearance of the label.

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[1] 21 U.S.C. §360e(c)(2)(A)(iv) (2015)
[2] 21 C.F.R. § 801.5 (2016)

173. The FDCA requires medical device manufacturers to disclose all material facts in advertising and labeling[3], and false and misleading labeling is considered 'misbranded"[4], which is prohibited[5].

174. The distribution of a "misbranded" medical device is prohibited pursuant to 21 U.S.C. §§ 331(a), (k) (2012) and 21 U.S.C. § 352(f) (2012).

175. The FDCA provides that a medical device is misbranded if, among other things, the labeling did not contain adequate directions for use, which includes critical information about adverse events. Adequate directions for use cannot be written including adverse events when the manufacturer has failed to disclose those adverse events to the FDA. Therefore, the labeling becomes inadequate and the product is misbranded.

176. Federal law requires a manufacturer to ensure that any warranty statements it voluntary makes are truthful, accurate, not misleading, and consistent with applicable federal and state law[6].

177. Under the FDCA, medical device manufacturers are prohibited from introducing the adulteration or misbranding of any medical device into interstate commerce[7].

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[3] 21 U.S.C.§ 321 (n) (2015)
[4] 21 U.S.C.§ 352 (a), (q) (2015)
[5] 21 U.S.C.§ 331(b) (2015)
[6] 21 U.S.C. § 331(b). It should be noted that the FDA approval letter for Infuse® specifically states that the FDA "...does not evaluate information related to contract liability warranties, however you should be aware that any such warranty statements must be truthful, accurate, and not misleading, and must be consistent with applicable Federal and State laws." See http://www.accessdata.fda.gov/cdrh_docs/pdf/P000058a.pdf

A. The FDA, By Its Regulations and 510(k) Process Prohibits Misleading or False Promotion and Marketing Activities

178. Under the FDCA and FDA's implementing regulations, labeling, promotional advertisements, and making claims about medical devices are deemed misleading if they fail to disclose certain information about the product's risks.

179. Generally, to comply with the FDCA and FDA's implementing regulations, and therefore the PMA, such promotional pieces:

a. cannot be false or misleading in any particular; and

b. must reveal material facts about the product being promoted, including facts about the consequences that can result from use of the product as suggested in the promotional piece[8]; and,

c. must be about only approved intended uses[9].

180. The FDA regulates the manufacture, sale, and distribution of medical devices in the United States under the authority of the FDCA. This authority includes oversight of labeling and advertising for all medical devices[10].

181. A medical device shall be deemed to be misbranded if its labeling is false or misleading in any particular. Labeling or advertising may be considered misleading if it fails to reveal material facts about the product being promoted, including facts about

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[7] 21 U.S.C. § 331(b) (effective 2013)
[8] 21 U.S.C. § 321(n) (2015); 21 C.F.R. §§ 1.21, 202.1(e)(5)(iii) (2016)
[9] 21 C.F.R. § 801.4 (2016)
[10] *See* 21 U.S.C.§352(a), (n), (q)(2015)

the consequences that can result from use of the product as suggested in a promotional piece[11].

182. "In the case of any restricted device distributed for sale in any State, if (1) its advertising is false or misleading in any particular, or (2) it is sold, distributed, or used in violation of regulations prescribed under section 520(e)."

183. Advertisements for restricted devices must include "a brief statement of the intended uses of the device and relevant warnings, precautions, side effects, and contraindications…"[12]

184. Restricted device advertisements must not be false or misleading and must reveal facts that are material about the product being advertised, including facts about the consequences that can result from use of the product as suggested in an ad.

185. The FDA regulates the manufacture, sale, and distribution of medical devices in the United States under the authority of the FDCA. This authority includes oversight of labeling and advertising for all medical devices.

186. A medical device shall be deemed to be misbranded if its labeling is false or misleading in any particular. Labeling or advertising may be considered misleading if it fails to reveal material facts about the product being promoted, including facts about the consequences that can result from use of the product as suggested in a promotional piece.

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[11] 21 U.S.C. § 321(n) (2012); 21 C.F.R.§§ 1.21, 202.1 (e)(5)(iii) (2016)
[12] 21 C.F.R. § 352 (r) (2015)

187. "In the case of any restricted device distributed for sale in any State, if (1) its advertising is false or misleading in any particular, or (2) it is sold, distributed, or used in violation of regulations prescribed under section 360j (e)." [13]

188. Advertisements for restricted devices must include "a brief statement of the intended uses of the device and relevant warnings, precautions, side effects, and contraindications…"[14]

189. Restricted device advertisements must not be false or misleading[15] and must reveal facts that are material about the product being advertised, including facts about the consequences that can result from use of the product as suggested in an ad[16].

B. After a Medical Device Is Cleared for Marketing, The Manufacturer Still Has Requirements, Including General reporting Requirements to the FDA Mandated by Federal Regulations.

190. A medical device manufacturer's obligations do not end with the 510(k) Clearance.

191. Even after approval, manufacturers are required to report to the FDA "no later than 30 calendar days after the day: the manufacturer receive[s] or otherwise become[s] aware of information, from any source, that reasonably suggests that a device" marketed by the manufacturer:

a. May have caused or contributed to death or serious injury; or

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[13] 21 C.F.R. § 352 (q) (2015)
[14] *See* 21 U.S.C. § 352 (r)(2015)
[15] 21 U.S.C. § 352 (q)(1) (2015)
[16] 21 U.S.C. § 321 (n) (2015)

b. Has malfunctioned and this device or a similar device [likewise marketed by the manufacturer] would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur[17].

192. These 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[18].

193. In addition, manufacturers are required to make periodic reports to the FDA regarding approved devices, such reports to include summaries of:

a. Unpublished reports of data from any clinical investigations or nonclinical laboratory studies involving the device or related devices and known to or that reasonably should be known to the applicant.

b. Reports in the scientific literature concerning the device and known to or that reasonably should be known to the applicant[19].

194. Under federal law, a medical device manufacturer has a continuing duty to monitor the product after premarket approval and to discover and report to the FDA any complaints about the product's performance and any adverse health consequences of which it became aware and that are or may be attributable to the product.

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[17] 21 C.F.R. § 803.50 (a) (2015)
[18] *Id.*
[19] 21 C.F.R.§ 814.84 (b)(2) (2015)

195. Following approval, a medical device manufacturer is required to report adverse events associated with the use of the product, i.e. those that may have caused serious injury or death or has malfunctioned and would likely cause or contribute to death or serious injury if recurred[20].

196. The medical device manufacturer is required to report any incidents or information that reasonably suggests that the device (1) "[m]ay have caused or contributed to a death or serious injury" or (2) "[h]as malfunctioned" in a manner that would likely "cause or contribute to a death or serious injury" if it recurred[21].

197. Another general reporting requirement for Class III medical devices after PMA approval is that the manufacturer is obligated to inform the FDA of new clinical investigations or scientific studies concerning the device about which the manufacturer knows or reasonably should know.[22]

198. Further, the FDCA subjects approved devices to reporting requirements[23]. For example, the manufacturer must update the FDA when it learns of investigations or scientific studies concerning its device[24], or incidents where the device used in any manner "[m]ay have caused or contributed to a death or serious injury," either due to malfunction or normal operation[25]. The FDA can revoke its approval based on these

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[20] 21 C.F.R. §803.50(a) (2015); 21 U.S.C. § 360i(a) (2015)
[21] 21 C.F.R. § 803.50(a) (2015); 21 C.F.R. §360i (a) (2015)
[22] 21 C.F.R. § 814.84 (b)(2) (2015)
[23] 21 U.S.C. §360i(2015)
[24] 21 C.F.R. § 814.84 (b)(2) (2015)
[25] *Id.*, § 803.50(a) (2015)

post-approval reports[26]. The manufacturer must establish internal procedures for reviewing complaints and event reports[27]. 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[28].

199. Medical device manufacturers are required by federal regulation to "establish and maintain" an adverse event database[29]. 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[30].

200. Pursuant to federal regulations, manufacturers must disclose 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[31].

201. Pursuant to federal regulations, device manufacturers must report promptly to FDA any device corrections and removals, and maintain records of device corrections and removals.

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[26] 21 U.S.C. §§ 360e(1), 360h(e) (2015)
[27] 21 C.F.R. § 820.198 (a) (2015)
[28] 21 U.S.C. § 360i (2015).
[29] 21 C.F.R. §803.1(a) (2015)
[30] 21 C.F.R. § 803.52 (2015)
[31] *See* 21 C.F.R.§ 806 (2015)

202. FDA regulations require submission of a written report within ten (10) 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[32]. Stryker failed to do so in timely manner.

203. 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.

204. Manufacturers must also meet quality standards in manufacture and production of the devices.

205. 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.

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[32] *See* 21 C.F.R. § 806 (2015)

206. Manufacturers are also required to review and evaluate all complaints and determine whether an investigation is necessary.

207. Manufacturers are also required to use statistical techniques, where necessary, to evaluate product performance.

C. Post Approval, The FDA, By Its Regulations And PMA Process, Requires A Manufacturer To Follow Good Manufacturing Practices

208. Under 21 C.F.R. § 820.1(a) (2012) of the Quality System (QS) Regulation for Medical Devices, current good manufacturing practice (CGMP) requirements are set forth in this quality system regulation. The requirements in this part govern the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, and servicing of all finished devices intended for human use. The requirements in this part are intended to ensure that finished devices will be safe and effective and otherwise in compliance with the Federal Food, Drug, and Cosmetic Act (FDCA). This part establishes basic requirements applicable to manufacturers of finished medical devices.

209. 21 C.F.R. § 820.5 (2015) "Quality Systems", the FDA regulations state, "Each manufacturer shall establish and maintain a quality system that is appropriate for the specific medical device(s) designed or manufactured, and that meets the requirements of this part."

210. 21 C.F.R. § 820.3(z)(2) (2015) Design validation means establishing by objective evidence that device specifications conform with user needs and intended use(s).

211. 21 C.F.R. § 820.22 (2015): "Quality Audit" states: "Each manufacturer shall establish procedures for quality audits and conduct such audits to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system."

212. 21 C.F.R. § 820.160(a) (2015): "Distribution" states: "Each manufacturer shall establish and maintain procedures for control and distribution of finished devices to ensure that only those devices approved for release are distributed and that purchase orders are reviewed to ensure that ambiguities and errors are resolved before devices are released for distribution."

213. 21 C.F.R. § 820.170(a) (2015): "Installation" states: "Each manufacturer of a device requiring installation shall establish and maintain adequate installation and inspection instructions, and where appropriate test procedures. Instructions and procedures shall include directions for ensuring proper installation so that the device will perform as intended after installation. The manufacturer shall distribute the instructions and procedures with the device or otherwise make them available to the person(s) installing the device."

214. 21 C.F.R. § 803 (2015), requires manufacturers to make Medical Device Reporting ("MDR") submissions, to include information that is reasonably known to the manufacturer, to define the procedures for implementing corrective and preventative actions, and to review sampling methods for adequacy of their intended use.

215. 21 C.F.R. § 820.100 (2015) "Corrective and Preventive Action" states: (a) [e]ach manufacturer shall establish and maintain procedures for implementing corrective and preventive action.

216. The procedures shall include requirements for:

a. Analyzing processes, work operations, concessions, quality audit reports, quality records, service records, complaints, returned product, and other sources of quality data to identify existing and potential causes of nonconforming product, or other quality problems. Appropriate statistical methodology shall be employed where necessary to detect recurring quality problems;

b. Investigating the cause of nonconformities relating to product, processes, and the quality system;

c. Identifying the action(s) needed to correct and prevent recurrence of nonconforming product and other quality problems;

d. Verifying or validating the corrective and preventive action to ensure that such action is effective and does not adversely affect the finished device; and

e. Implementing and recording changes in methods and procedures needed to correct and prevent identified quality problems.

D. Stryker's Conduct in Violation of the FDCA

217. Stryker violated these FDCA statutes and accompanying regulations by:

a. falsely and misleadingly promoting the LFIT™ CoCr V40™ Femoral Head;

b. failing to report to the FDA adverse events;

c. failing to timely conduct failure investigations and analysis;

d. failing to timely report any and all information concerning product failures and corrections;

e. failing to timely and fully inform FDA of unanticipated adverse effects, increases in the incidence of adverse effects, and device failures necessitating a labeling, manufacturing or device modification;

f. failing to conduct necessary design validation;,

g. selling and distributing a misbranded and adulterated product through interstate commerce; and,

h. failing to immediately disclose the metallosis risk from the fretting and corroding failure of these Devices after implantation in patients.

218. Stryker's violation of these FDCA statutes and accompany regulations, as discussed above, constitutes violation of the state law tort causes of action alleged in this Complaint, as set forth herein.

219. Stryker's violation of the FDCA statutes and accompany regulations, as discussed above, directly caused or significantly contributed to the use of the LFIT™ CoCr V40™ Femoral Head; and, generally, and directly caused or significantly

contributed to the use of these Defective Devices in Plaintiffs and Stryker's misconduct in this regard thus caused or contributed to Plaintiffs' injuries and damages.

The Recalls

220. 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."[33]

221. Recalls are classified by the FDA in to one of three categories. The designation or category "assigned by the Food and Drug Administration to a particular product recall… indicate[s] the relative degree of health hazard presented by the product being recalled."[34]

222. The FDA categorized the LFIT™ Anatomic CoCr V40™ Femoral Head recall as a "Class II" recall. "A Class II [recall] 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."[35] Classifying the LFIT™ Anatomic CoCr V40™ Femoral Head as a "Class II" recall confirms by definition that the devices in question were in violation of federal law and that initiation of legal action or seizure would be indicated for these devices.

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[33] *See* 21 C.F.R. § 7.3 (g) (2012)
[34] *See* 21 C.F.R. § 7.3 (m) (2015).
[35] *Id.*

CLAIMS FOR RELIEF

COUNT I - NEGLIGENCE

223. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein and further allege as follows:

224. Defendants negligently designed, manufactured, marketed, detailed, labeled and advertised, both to physicians and consumers, the LFIT CoCr V40 Femoral Head and its accompanying femoral stems.

225. As a result, Defendants 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 the devices would be implanted, including Plaintiffs. Defendants failed to reasonably execute these duties.

226. Defendants failed to use reasonable and due care for the safety and well-being of those in whom the LFIT™ CoCr V40™ Femoral Head and accompanying stems would be implanted, including Plaintiffs, and is therefore negligent in the following respects:

a. Defendants failed to adequately design and manufacture the LFIT™ CoCr V40™ Femoral Head and its accompanying stems to insure that neither would corrode, erode, deteriorate, fret, and induce severe metal toxicity in the patient. The flaws include, but are not limited to, the following:

i. The incompatibility of the chromium cobalt femoral heads with titanium components, TMZF® components, and other alloy components;

ii. Poor design of the femoral head such that micro motion was unavoidable:

iv. Poor manufacturing practices such that the LFIT V40 bore and neck trunnion did not "fit" the way in which they were intended to fit, resulting in taper lock failure, micro-motion, corrosion and fretting; failing to establish and maintain adequate procedures to ensure that the specified design requirements for LFIT V40 heads were met during the manufacturing process;

v. Allowing and promoting the use of large metal heads on Stryker's small and insufficient V40 trunnion which would predictably lead to excessive motion, fretting, mechanically assisted crevice corrosion and ultimately device failure;

vi. A combination of the above factors led to rapid, severe heavy metal cast off causing soft tissue and bony necrosis, pain and premature failure of the LFIT™ CoCr V40™ Femoral Head.

b. Defendants failed to adequately test the LFIT™ CoCr V40™ Femoral Head to insure that it would not corrode, erode, deteriorate and/or induce severe metal toxicity in the patient;

c. Defendants failed to conduct anything other than bench testing so that when manufactured and marketed, patients became in essence Defendants' first clinical trial;

d. Defendants made affirmative representations that the LFIT™ CoCr V40™ Femoral Head would not fret or corrode in the human body. These representations were false and misleading to both physicians and the consumer, including Plaintiffs;

e. Defendants trained its sales force to "detail" the LFIT™ CoCr V40™ Femoral Head utilizing representations that the Defendants knew or should have known were false, creating in the minds of both surgeons and consumers that the device would not cause metal toxicity;

f. Defendants marketed the LFIT™ CoCr V40™ Femoral Head as a prosthesis that reduced the risk of dislocation and were superior to other available hip implants, when in fact, the LFIT™ CoCr V40™ Femoral Head when combined with certain stems was so poorly designed, constructed and tested that they had to be recalled from the market. Defendants failed to manufacture the LFIT™ CoCr V40™ Femoral Head to FDA-cleared and/or Defendants' own internal specifications such that the taper lock junction prematurely failed causing metal debris cast-off and severe metal toxicity in patients;

g. Defendants failed to adequately test the chromium cobalt femoral heads compatibility with titanium components, TMZF components and other alloy components in an effort to prevent corrosion and fretting at the taper lock junction of this hip replacement device;

h. Defendants failed to promptly act upon reports of early failure such that the LFIT™ CoCr V40™ Femoral Head continued to be implanted in unknowing patients by surgeons well after it should have been recalled or sales suspended;

i. Defendants negligently and intentionally performed a recall that was inadequate in scope and gravity when they knew individuals with these devices would not learn of the recall from their surgeons and would not have necessary testing on a timely basis which could have mitigated the irreversible tissue damage patients have and are continuing to suffer.

j. Defendants had actual knowledge prior to marketing the LFIT™ CoCr V40™ Femoral Head that the chrome cobalt head performed poorly when mated with TMZF and other dissimilar alloy components. Defendants also had knowledge that when the LFIT™ CoCr V40™ Femoral Head was introduced to the market that the Stryker Accolade®, Rejuvenate® and ABG II® as well as other Stryker devices that were mated with TMZF alloy were experiencing corrosion, fretting, and failure issues. Nevertheless, Defendants

either suppressed or ignored the reports and marketed the LFIT™ CoCr V40™ Femoral Head anyway, knowing that these heads were performing poorly after implantation and were causing harm to patients when utilized in various hip implant devices.

k. Defendants failed to adequately warn physicians and patients of the risks of these products and further failed to advise physicians of the appropriate monitoring protocol for patients to timely diagnose fretting, corrosion and metallosis related injuries.

l. Use of the TMZF alloy that contains a modulus of elasticity with far inferior stiffness characteristics to other available titanium alloys;

m. A combination of the above factors leads to rapid, severe heavy metal cast off causing soft tissue and bony necrosis, pain and premature failure of the device.

227. Defendants, as manufacturers, suppliers and sellers of these medical devices had superior knowledge and owed a duty of care to their customers and to the patients themselves, in whom these Defective Devices were implanted.

228. Defendants breached their duty of care. The above conduct demonstrates Defendants' failure to exercise reasonable and appropriate care in the testing, designing, manufacturing, marketing, labelling, instructing and safety evaluations resulting in the products entering the market in a dangerous condition, and remaining on the market with improper warnings.

229. It was foreseeable that this wrongful conduct and omissions would lead to premature device failure as well as severe, permanent, debilitating injuries to patients, including Plaintiffs.

230. As a direct and proximate result of Defendants' negligence, Plaintiffs suffered all or some of the following: bodily injury; severe physical pain and suffering; emotional distress; disability; physical impairment; disfigurement; mental anguish; inconvenience; aggravation of a pre-existing condition; loss of the capacity for the enjoyment of life; the costs of medical care and expenses; loss of earnings; and loss of the ability to earn money, all of which damages and losses will continue in the future.

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

COUNT II – NEGLIGENCE PER SE

231. Plaintiffs reallege and incorporate by reference the allegations set above as if set forth herein.

232. Defendants had an obligation to not violate the law in the manufacture, design, testing, assembly, inspection, labeling, packaging, supplying marketing, selling, advertising, preparing for use, and warning of the risks and dangers of the Devices.

233. Defendants failed to comply with federal requirements. Specifically, it is believed that with respect to the Devices, Defendants failed to timely report adverse events; failed to timely conduct failure investigations and analyses; 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.

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

COUNT III

STRICT PRODUCTS LIABILITY-DEFECTIVE DESIGN UNDER COMMON LAW, STATE STATUTORY LAW AND THE NEW JERSEY PRODUCTS LIABILITY ACT

234. Plaintiffs reallege and incorporate by reference the allegations set forth above as if set forth herein.

235. This is an action for strict liability based upon design defect against Defendants.

236. Defendants' Devices are designed in such a way that, when used as intended, the Defective Device 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. Defendants acted unreasonably in its design of the Devices in that Defendants failed to adopt a safer design for the Devices that was practical, feasible, and otherwise a reasonable alternative design or formulation that would have prevented or substantially reduced the risk of harm without substantially impairing the usefulness, practicality, or desirability of the product.

237. Defendants' Devices do not perform as safely as an ordinary consumer would expect when used as intended or in a manner reasonably foreseeable to Defendants.

238. The risks of using Defendants' Devices outweigh the benefits of using the Devices.

239. There were numerous safer alternative designs to the Devices which in reasonable probability would have prevented or significantly reduced the risk of the personal injuries suffered by Plaintiffs herein without substantially impairing the product's utility and such safer alternative designs were economically and technologically feasible at the time the Devices left the control of Defendants by the application of existing or reasonably- achievable scientific knowledge.

240. The design defects in Defendants' Devices caused serious damage to Plaintiffs herein, including all or some of the following: bodily injury; severe physical pain and suffering; emotional distress; disability; physical impairment; disfigurement; mental anguish; inconvenience; aggravation of a pre-existing condition; loss of the capacity for the enjoyment of life; the costs of medical care and expenses; loss of earnings; and loss of the ability to earn money, all of which damages and losses will continue in the future.

WHEREFORE, Plaintiffs respectfully request that Plaintiffs be granted relief against Defendants, as contained in the Prayer for Relief.

COUNT IV

STRICT PRODUCTS LIABILITY- MANUFACTURING DEFECT UNDER COMMON LAW, STATE STATUTORY LAW AND THE NEW JERSEY PRODUCTS LIABILITY ACT

241. Plaintiffs reallege and incorporate by reference the allegations set forth above as if set forth herein.

242. This is an action for strict liability based on a manufacturing defect.

243. The Devices were designed for implantation into the human body and to last for fifteen or more years. The Devices was also designed to be compatible with human tissue and bone.

244. The Devices implanted in Plaintiffs herein failed and were removed (or will be required to be removed) prematurely.

245. The Devices installed in the hips of Plaintiffs herein were not compatible with human tissue and bone. Through a process of fretting and corrosion, the Devices released heavy metals into the bodies of Plaintiffs' herein causing severe and permanent destruction of bone and tissue. Defendants failed to manufacture the Devices in a manner that prevented fretting and corrosion, and, in fact, manufactured the product such that it caused fretting and corrosion.

246. The Devices implanted in the hips of Plaintiffs herein contained manufacturing defects, such that:

a. The bore within the LFIT V40 Head was poorly machined or fashioned so that it could not achieve the desired taper lock or coldweld with the trunnion of the Accolade TMZF Plus;

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

c. The bore within the LFIT V40 Head was fashioned in such a manner that it did not maintain structural integrity when mated with a titanium alloy trunnion; and/or

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

247. The manufacturing defects in the Devices implanted in the hips of Plaintiffs herein caused serious damage to Plaintiffs including all or some of the following: bodily injury; severe physical pain and suffering; emotional distress; disability; physical impairment; disfigurement; mental anguish; inconvenience; aggravation of a pre-existing condition; loss of the capacity for the enjoyment of life; the costs of medical care and expenses; loss of earnings; and loss of the ability to earn money, all of which damages and losses will continue in the future.

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

COUNT V

STRICT PRODUCTS LIABILITY - FAILURE TO WARN UNDER COMMON LAW, STATE STATUTORY LAW AND THE NEW JERSEY PRODUCTS LIABILITY ACT

248. Plaintiffs reallege and incorporate by reference the allegations set forth above as if set forth herein.

249. The Devices implanted into Plaintiffs herein contained no warnings or, in the alternative, inadequate warnings as to the risks that the product could cause fretting, corrosion, and significant heavy metal toxicity. Defendants acted unreasonably in failing to provide such warning or instruction prior to August 2016 and in the recall notice of August, 2016.

250. The warnings that accompanied the Devices failed to provide that level of information that an ordinary consumer, including Plaintiffs herein, would expect when using the implants in a manner reasonably foreseeable to the Defendants.

251. Moreover, the Devices left the Defendants' control without an adequate warning or instruction, and created an unreasonably dangerous condition in that Defendants, as the seller and manufacturer, knew or in the exercise of ordinary care should have known that the Defective Device posed a substantial risk of harm. Alternatively, after the Devices left the Defendants' control, Defendants became aware of, or in the exercise of ordinary care should have known, that the Devices posed a substantial risk of harm to patients, including Plaintiffs herein, yet Defendants failed to take reasonable steps to give adequate warning or instruction or to take other reasonable action under the circumstances.

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

COUNT VI

BREACH OF EXPRESS WARRANTY

252. Plaintiffs reallege and incorporate by reference the allegations set forth above as if set forth herein.

253. Through Defendants' public statements, descriptions of the Devices, and promises relating to the Devices, Defendants expressly warranted, among other things, that the Devices were efficacious and safe for their intended use; was designed and constructed of materials that would prevent fretting and corrosion; would last longer than competing hip implant devices; and were effective in reducing the risk of dislocation.

254. These warranties came in the form of (i) publicly-made written and verbal assurances of safety; (ii) press releases and dissemination via the media of uniform promotional information that was intended to create demand for the Devices (but which contained material misrepresentations and utterly failed to warn of the risks of the Devices); (iii) verbal assurances made by Defendants' consumer relations personnel to the public about the safety of the Devices that also downplayed the risks associated with implantation of the Devices; and (iv) false and misleading written information supplied by Defendants.

255. The most prominent representation made by Defendants was on websites where Defendants expressly warranted that the design, testing, and materials utilized in the Devices would prevent fretting and corrosion.

256. In its advertising, Stryker claimed that its proprietary TMZF alloy was "specifically tailored for high performance in orthopaedic applications" and that Stryker's testing "demonstrates improved wear resistance, reducing the potential for generation of particulate metallic wear debris." Stryker promised that in developing the TMZF alloy, it had "optimiz[ed] the material properties that are key elements in the comfort of your patients and the long-term clinical success of the implant."

257. All of these representations were untrue at the time Stryker made them and Stryker knew or should have known that they were untrue. For example, Stryker knew or should have known that the flexural rigidity of femoral necks made from the TMZF alloy was half that of a standard titanium alloy used in other orthopedic implants. Stryker also knew or should have known at the time these misrepresentations were made that the significant reduction in flexural rigidity predisposed the trunnion interface on femoral stems made out of the TMZF alloy to significantly greater micromotion, fretting, corrosion, and disassociation than trunnions on femoral stems made out of a standard titanium alloy.

258. Plaintiffs herein further allege that all of the aforementioned written materials are known to Defendants and in their possession, and it is Plaintiffs' reasonable belief that these materials shall be produced by Defendants and be made of record once Plaintiffs are afforded the opportunity to conduct discovery.

259. When Defendants made these express warranties, Defendants knew the purposes for which Devices were to be used and warranted the Devices to be in all respects safe and proper for such purposes.

260. Defendants drafted the documents and/or made the statements upon which these warranty claims are based and, in so doing, defined the terms of those warranties.

261. Defendants' representations and promises regarding the Devices had the natural tendency to induce those in need of prosthetic hip implants, including Plaintiffs herein, to purchase the Devices in reliance thereon.

262. The Devices do not conform to Defendants' representations in that the Devices are not safe and produce serious side effects.

263. As such, the Devices did not conform to Defendants' promises, descriptions, or affirmations of fact and were not adequately packaged, labeled, promoted, or fit for the ordinary purposes for which such devices are used.

264. Defendants therefore breached their express warranties to Plaintiffs herein in violation of applicable state statutes and common law, by manufacturing, marketing, and selling the Devices to Plaintiffs herein and causing damages as will be established at trial.

WHEREFORE, Plaintiffs respectfully request that Plaintiffs be granted relief against Defendants, as contained in the Prayer for Relief.

COUNT VII

BREACH OF WARRANTY AS TO MERCHANTABILITY

265. Plaintiffs reallege and incorporate by reference the allegations set forth above as if set forth herein.

266. At all times material, Defendants were merchants with respect to the Devices.

267. The Devices were defectively designed and manufactured, and were distributed and sold without the provision of reasonable instructions or warnings regarding the foreseeable risk of harm posed by the Devices to patients, including Plaintiffs herein.

268. The Devices were not fit for their ordinary purposes.

269. Plaintiffs herein were foreseeable users of the Devices.

270. The Devices were being used in the intended manner at the time of the injuries sustained by Plaintiffs herein.

271. Plaintiffs suffered harm as a direct and proximate result of the above said defects in the Devices.

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

COUNT VIII

BREACH OF IMPLIED WARRANTIES

272. Plaintiffs reallege and incorporate by reference the allegations set forth above as if set forth herein.

273. At all relevant and material times, Defendants manufactured, distributed, advertised, promoted, and sold the Devices.

274. At all relevant times, Defendants intended that the Devices be used in the manner that Plaintiffs herein in fact used the Devices, and Defendants impliedly warranted each of the Devices to be of merchantable quality; safe and fit for such use; and warranted that each of the Devices was adequately tested.

275. Defendants were aware that consumers, including Plaintiffs herein, would use the Devices as hip implants; which is to say that Plaintiffs herein were foreseeable users.

276. Plaintiffs were at all relevant times in privity with Defendants.

277. The Devices were expected to reach and did in fact reach consumers, including Plaintiffs herein, without substantial changes in the condition in which the Devices were manufactured and sold by Defendants.

278. Defendants breached various implied warranties with respect to the Devices in the following manner:

279. Defendants represented through their labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that the Devices were safe and fraudulently withheld and concealed information about the substantial risks of serious injury and/or death associated with using the Devices;

280. Defendants represented that the Devices were safe, and/or safer than other alternative hip implants and fraudulently concealed information which demonstrated that the Devices were not safer than alternatives available on the market; and

281. Defendants represented that the Devices were more efficacious than other alternative devices and fraudulently concealed information, regarding the true efficacy of the Devices.

282. In reliance upon Defendants' implied warranties, Plaintiffs herein used the Devices as prescribed and in the foreseeable manner normally intended, recommended, promoted, and marketed by Defendants.

283. Defendants breached their implied warranty to Plaintiffs in that the Devices were not of merchantable quality, safe and fit for their intended use, or adequately tested, in violation of the following statutes:

a. Ala. Code §§ 7-2-314, et seq.;

b. Alaska. Stat. §§ 45.02.314, et seq.;

c. Ariz. Rev. Stat. Ann. §§ 47-2314, et seq.;

d. Ark. Code Ann. §§ 4-2-314, et seq.;

e. Cal. Comm. Code §§ 2314, et seq.;

f. Colo. Rev. Stat. §§ 4-2-314, et seq.;

g. Conn. Gen. Stat. Ann. §§ 42a-2-314, et seq.;

h. Del. Code Ann. tit. 6, §§ 2-314, et seq.;

i. D.C. Code Ann. §§ 28:2-314, et seq.;

j. Fla. Stat. Ann. §§ 672.314, et seq.;

k. O.C.G.A. §§ 11-2-314, et seq.;

l. Haw. Rev. Stat. §§ 490:2-314, et seq.;

m. Id. Code §§ 28-2-314, et seq.;

n. Ill. Comp. Stat. Ann. Ch. 810, 5/2-314, et seq.;

o. Indiana Code Ann. §§ 26-1-2-314, et seq.;

p. Iowa Code Ann. §§ 554.2314, et seq.;

q. Kan. Stat. Ann. §§ 84-2-314, et seq.;

r. Ky. Rev. Stat. Ann. §§ 355.2-314, et seq.;

s. La. Civ. Code Ann. art. 2520, et seq. (and is liable for redhibition under this statute);

t. Me. Rev. Stat. Ann. tit. 11, §§ 2-314, et seq.;

u. Md. Code Ann., Com. Law §§ 2-314, et seq.;

v. Mass. Gen. Laws Ann. Ch. 106, §§ 2-314, et seq.;

w. Mich. Comp. Laws Ann. §§ 440.2314, et seq.;

x. Minn. Stat. Ann. §§ 336.2-314, et seq.;

y. Miss. Code Ann. §§ 75-2-314, et seq.;

z. Mo. Rev. Stat. Ann. §§ 400.2-314, et seq.;

aa. Mont. Code Ann. §§ 30-2-314, et seq.;

bb. Neb. Rev. Stat. §§ 2-314, et seq.;

cc. Nev. Rev. Stat. §§ 104.2314, et seq.;

dd. N.H. Rev. Stat. Ann. §§ 382-A:2-314, et seq.;

ee. N.J. Stat. Ann. §§ 12A:2-314, et seq.;

ff. N.M. Stat. Ann. § 55-2-314, et seq.;

gg. N.Y. U.C.C. Law §§ 2-314, et seq.;

hh. N.C. Gen. Stat. Ann. §§ 25-2-314, et seq.;

ii. N.D. Cent. Code §§ 41-02-31, et seq.;

jj. Ohio Rev. Code Ann. §§ 1302.27, et seq.;

kk. Okl. Stat. Tit. 12A, §§ 2-314 et seq.;

ll. Or. Rev. Stat. §§ 72.3140, et seq.;

mm. 13 Pa. Stat. Ann. §§ 2314 et seq.;

nn. R.I. Gen. Laws §§ 6A-2-314, et seq.;

oo. S.C. Code Ann. §§ 36-2-314, et seq.;

pp. S.D. Codified Laws §§ 57A-2-314, et seq.;

qq. Tenn. Code Ann. §§ 47-2-314, et seq.;

rr. Tex. Bus. & Com. Code Aim. §§ 2.314, et seq.;

ss. Utah Code Ann. §§ 70A-2-314, et seq.;

tt. Va. Code Ann. §§ 8.2-314, et seq.;

uu. Vt. Stat. Ann. §§ 9A-2-314, et seq.;

vv. Wash. Rev. Code §§ 62A.2-314, et seq.;

ww. W. Va. Code §§ 46-2-314, et seq.;

xx. Wis. Stat. Ann. §§ 402.314, et seq.; and,

yy. Wyo. Stat. Ann. §§ 34.1-2-314, et seq.

284. As a result of Defendants' foregoing acts and omissions, Plaintiffs herein were and/or still are caused to suffer and/or are at a greatly increased risk of serious and dangerous side effects.

285. As a direct and proximate result of the foregoing acts and omissions, Plaintiffs herein have required and will require health care and services, and have incurred medical, health care, incidental, and related expenses. Plaintiffs are informed and believe and further allege that Plaintiffs will in the future be required to obtain further medical care and/or hospital care and medical services.

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

COUNT IX

CONSUMER FRAUD AND/OR UNFAIR AND DECEPTIVE TRADE PRACTICES UNDER STATE LAW

286. Plaintiffs reallege and incorporate by reference the allegations set forth above as if set forth herein.

287. Certain Plaintiffs herein will bring a cause of action for consumer fraud and/or unfair and deceptive trade practice under applicable state law.

288. Defendants are on notice that such claims may be asserted by individual Plaintiffs herein.

289. Plaintiffs purchased and used the Devices for personal use and thereby suffered ascertainable losses as a result of Defendants' actions in violation of the consumer protection laws.

290. Had Defendants not engaged in the deceptive conduct described herein, Plaintiffs, their physicians and hospitals and medical centers would not have purchased and/or paid for the Devices, and would not have incurred related medical costs and injuries.

291. Defendants engaged in wrongful conduct while at the same time obtaining, under false pretenses, moneys from Plaintiffs, their physicians and hospitals for the

Devices that would not have been paid had Defendants not engaged in unfair and deceptive conduct.

292. Unfair methods of competition or deceptive acts or practices that were proscribed by law, including the following:

293. Representing that goods or services have characteristics, ingredients, uses benefits or quantities that they do not have;

294. Advertising goods or services with the intent not to sell them as advertised; and,

295. Engaging in fraudulent or deceptive conduct that creates a likelihood of confusion or misunderstanding.

296. Plaintiffs were injured by the cumulative and indivisible nature of Defendants' conduct. The cumulative effect of Defendants' conduct directed at patients, physicians and consumers was to create demand for and sell the Devices. Each aspect of Defendants' conduct combined to artificially create sales of the Devices.

297. Defendants have a statutory duty to refrain from unfair or deceptive acts or trade practices in the design, development, manufacture, promotion, and sale of the Devices.

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

299. Defendants' deceptive, unconscionable, or fraudulent representations and material omissions to patients, physicians and consumers, including Plaintiffs, constituted

unfair and deceptive acts and trade practices in violation of the state consumer protection statutes listed.

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

301. Defendants have engaged in unfair competition or unfair or deceptive acts or trade practices or have made false representations in violation of:

a. Ala. Code §§ 8-19-1 et seq.;

b. Alaska Stat. §§ 45.50.471 et seq.;

c. Ariz. Rev. Stat. Ann. §§ 44-1522 et seq.;

d. Ark. Code Ann. §§ 4-88-101 et seq.;

e. Cal. Civ. Code §§ 1770 et seq. and Cal. Bus. & Prof. Code §§ 17200 et seq.;

f. Colo. Rev. Stat. §§ 6-1-105 et seq.;

g. Conn. Gen. Stat. §§ 42-110a et seq.;

h. Del. Code Ann. tit. 6, §§ 2511 et seq. and §§ 2531 et seq.;

i. D.C. Code Ann. §§ 28-3901 et seq.;

j. Fla. Stat. Ann. §§ 501.201 et seq.;

k. O.C.G.A. §§ 10-1-372 et seq.;

l. Haw. Rev. Stat. §§ 480-1 et seq.;

m. Id. Code Ann. §§ 48-601 et seq.;

n. Ill. Comp. Stat. Ann ch. 815, 505/1 et seq.;

o. Ind. Code Ann. §§ 24-5-0.5-1 et seq.;

p. Iowa Code Ann. §§ 714.16 et seq.;

q. Kan. Stat. Ann. §§ 50-623 et seq.;

r. Ky. Rev. Stat. Ann. §§ 367.170 et seq.;

s. La. Rev. Stat. Ann. §§ 51:1401 et seq.;

t. Me. Rev. Stat. Ann. tit. 5, §§ 205A et seq.;

u. Md. Code Ann., Com. Law §§ 13-101 et seq.;

v. Mass. Gen. Laws Ann. Ch. 93A et seq.;

w. Mich. Comp. Laws §§ 445.901 et seq.;

x. Minn. Stat. §§ 325D.43 et seq. and §§ 325F.67 et seq.;

y. Miss. Code Ann. §§ 75-24-1 et seq.;

z. Mo. Ann. Stat. §§ 407.010 et seq.;

aa. Mont. Code Ann. §§ 30-14-101 et seq.;

bb. Neb. Rev. Stat. §§ 59-1601 et seq.;

cc. Nev. Rev. Stat. §§ 598.0903 et seq.;

dd. N.H. Rev. Stat. Ann. §§ 358-A:1 et seq.;

ee. N.M. Stat. Ann. §§ 57-12-1 et seq.;

ff. N.Y. Gen. Bus. Law §§ 349 et seq. and §§ 350-e et seq.;

gg. N.C. Gen. Stat. §§ 75-1.1 et seq.;

hh. N.D. Cent. Code §§ 51-12-01 et seq. and §§ 51-15-01 et seq.;

ii. Ohio Rev. Code Ann. §§ 1345.01 et seq.;

jj. Okla. Stat. tit. 15 §§ 751 et seq.;

kk. Or. Rev. Stat. §§ 646.605 et seq.;

ll. 73 Pa. Stat. §§ 201-1 et seq.;

mm. R.I. Gen. Laws. §§ 6-13.1-1 et seq.;

nn. S.C. Code Ann. §§ 39-5-10 et seq.;

oo. S.D. Codified Laws §§ 37-24-1 et seq.;

pp. Tenn. Code Ann. §§ 47-18-101 et seq.;

qq. Tex. Bus. & Com. Code Ann. §§17.41 et seq.;

rr. Utah Code Ann. §§ 13-11-1 et seq.;

ss. Vt. Stat. Ann. tit. 9, §§ 2451 et seq.;

tt. Va. Code Ann. §§ 59.1-196 et seq.;

uu. Wash. Rev. Code. §§ 19.86.010 et seq.;

vv. W. Va. Code §§ 46A-6-101 et seq.;

ww. Wis. Stat. Ann. §§ 100.20 et seq.; and

xx. Wyo. Stat. Ann. §§ 40-12-101 et seq.

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

303. Defendants violated the statutes that were enacted in these states to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising, by knowingly and falsely representing that the Devices

were fit to be used for the purpose for which they were intended, when in fact the Devices were defective and dangerous, and by other acts alleged herein. These representations were made in uniform promotional materials.

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

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

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

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

308. By reason of the unlawful acts engaged in by Defendants, and as a direct and proximate result thereof, Plaintiffs have suffered ascertainable losses and damages.

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

WHEREFORE, Plaintiffs respectfully request that Plaintiffs be granted relief against Defendants, as contained in the Prayer For Relief and as permitted by the applicable state laws.

COUNT X

NEGLIGENT MISREPRESENTATION

310. Plaintiffs incorporate by reference all previous and subsequent paragraphs of this Complaint as if fully set forth here and further allege as follows:

311. Specific defects in the LFIT™ CoCr V40™ Femoral Head as specified above in this Complaint rendered it defective and unreasonably dangerous.

312. At all relevant times, Defendants were engaged in the business of selling LFIT™ CoCr V40™ Femoral Head for resale or use, and in fact did sell the Devices used by Plaintiffs' implanting surgeons. In the course of marketing LFIT™ CoCr V40™ Femoral Head, Stryker made untrue representations of material facts and omitted material information to Plaintiffs, Plaintiffs' physicians, and the public at large. Stryker made these misrepresentations and omissions to guide physicians in their purchase and use of LFIT™ CoCr V40™ Femoral Head.

313. Plaintiffs and Plaintiffs' physicians would not have purchased and implanted the Device or Devices in the hip implant surgery had they known of the true safety risks related to LFIT™ CoCr V40™ Femoral Head.

314. Defendants were negligent in making the untrue misrepresentations and omitting material information because Defendants knew, or had reason to know, of the actual, unreasonable dangers and defects in their Devices.

315. Plaintiffs and Plaintiffs' physicians would reasonably be expected to use LFIT™ CoCr V40™ Femoral Head. Defendants intended to induce Plaintiff and Plaintiff's physicians to rely on their misrepresentations and omissions to use either or both of these devices in hip implant operations in lieu of using safer, alternative hip stems and hip systems.

316. Plaintiffs and Plaintiffs' physicians were justified in relying, and did rely, on the misrepresentations and omissions about the safety risks related to LFIT™ CoCr V40™ Femoral Head in deciding to implant these Devices as femoral heads.

317. As the direct, producing, proximate and legal result of the Defendants' misrepresentations, Plaintiffs have suffered severe physical pain, medical and hospital expenses, lost wages, pain and suffering, and pecuniary loss.

318. Plaintiffs have been injured and suffer injuries to the body and mind, the exact nature of which are not completely known to date.

319. Plaintiffs have sustained economic losses, including loss of earnings and diminution of the loss of earning capacity, the exact amount of which is presently unknown.

320. Plaintiffs will be required to incur additional medical expenses in the future to care for themselves and each of them as a result of the injury and damages each has suffered.

321. Plaintiffs are therefore entitled to damages in an amount to be proven at trial, together with interest thereon and costs.

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

COUNT XI

LOSS OF CONSORTIUM

322. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein and further allege as follows:

323. At all times material, certain Plaintiffs were married to spouses. As a result of the injuries and damages sustained by certain Plaintiffs, Plaintiffs' spouses have suffered the loss of care, comfort, society and affections from Plaintiffs.

WHEREFORE, Plaintiffs respectfully request that Plaintiffs be granted relief against Defendants, as contained in the Prayer for Relief.

COUNT XII

UNJUST ENRICHMENT

324. Plaintiffs repeat and re-allege each of the allegations contained in the foregoing paragraphs.

325. Stryker enjoys enormous revenues from sales of the Defective Devices during the period the Devices were on the market in the U.S.

326. It is unjust to allow Stryker to earn revenues and retain the benefits and profits from these Defective Devices while Plaintiffs suffered injuries and damages as specified herein.

WHEREFORE, Plaintiffs respectfully request that Plaintiffs be granted relief against Defendants, as contained in the Prayer for Relief.

COUNT XIII

WRONGFUL DEATH

327. Plaintiff re-alleges the allegations contained in the foregoing paragraphs;

328. Plaintiff alleges, on information and belief, that Decedent's sudden, premature, and untimely death was the result of the defective LFIT™ CoCr V40™ Femoral Head.

329. As alleged throughout this Complaint and as reincorporated herein, Plaintiff alleges that Decedent would not have received the LFIT™ CoCr V40™ Femoral Head hip implant but for the intentionally and negligently tortious conduct of Defendants; similarly, as alleged throughout this Complaint and as incorporated herein, Plaintiff alleges the Defendants are strictly liable for the Decedent's death and all injuries and damages flowing from Decedent's death, for the reasons alleged in this Complaint;

330. Plaintiff seeks to recover damages for all legally compensable injuries relating to Decedent's wrongful death.

WHEREFORE, Plaintiffs respectfully request that Plaintiffs be granted relief against Defendants, as contained in the Prayer for Relief.

COUNT XIV

PUNITIVE DAMAGES

331. Plaintiff incorporates by reference the paragraphs above, as though fully set forth herein.

332. At all times material hereto, the Defendants knew or should have known that the LFIT V40 Cobalt Chromium femoral heads and its compatible femoral stems were inherently more dangerous than the alternative hip replacement stems on the market with respect to the risk of fretting and corrosion, shorter life span, and an increased need for additional surgeries.

333. At all times material hereto, Defendants attempted to misrepresent, and did misrepresent, facts concerning the safety of, the LFIT V40 Cobalt Chromium femoral head and the compatible stems, and use of these products together.

334. Defendants' misrepresentations included knowingly withholding material information from the medical community and the public, including the Plaintiff herein, concerning the safety and efficacy of the subject products. This misrepresentation continued even when Defendants finally issued a partial recall of the LFIT V40 Cobalt Chromium femoral heads, they misleadingly narrowed the scope of the recall and misled doctors into lack of follow up needed for the safety of their patients.

335. At all times material hereto, the Defendants knew and recklessly disregarded the fact that the LFIT V40 Cobalt Chromium femoral heads and compatible

stems were subject to causing fretting and corrosion in persons implanted with the devices with far greater frequency than alternative hip replacement stems.

336. Notwithstanding the foregoing, Defendants continued to aggressively market the subject products without disclosing the aforesaid side effects when there were safer alternative methods available.

337. The Defendants knew of the subject products' defective and unreasonably dangerous nature, as set forth herein, but continued to design, develop, manufacture, market, distribute and sell the LFIT V40 Cobalt Chromium femoral heads and compatible stems so as to maximize sales and profits at the expense of the health and safety of the public, including the Plaintiff herein, in conscious and/or negligent disregard of the foreseeable harm.

338. The Defendants' intentional and/or reckless, fraudulent and malicious failure to disclose information deprived the Plaintiff and his surgeon of necessary information to enable them to weigh the true risks of using the subject product against its benefits.

339. Defendants knew or ought to have known that this conduct would result in injury or damage, but continued to mislead both the medical community and the public at large, including Plaintiff, by making false representations about the safety and efficacy of the LFIT V40 Cobalt Chromium femoral heads and compatible stems.

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

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

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

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

PRAYER FOR RELIEF

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

1. Awarding compensatory damages;
2. Awarding pre-judgment and post-judgment interest to Plaintiffs;
3. Awarding all statutory damages and relief;
4. Awarding the costs and the expenses of this litigation to Plaintiffs;
5. Awarding reasonable attorneys' fees and costs to Plaintiffs as provided by law;
6. Awarding punitive damages, where appropriate, to the Plaintiffs;
7. Granting Plaintiffs equitable relief in the nature of disgorgement;

Restitution to remedy Stryker's unjust enrichment; and,

8. Granting all such other relief as the Court deems necessary, just and proper.

DEMAND FOR JURY TRIAL

Demand is hereby made for a trial by jury.

Plaintiffs' Lead/Liaison Counsel

WEITZ & LUXENBERG
A New York Professional Corporation
Attorneys for Plaintiff

Dated:

Ellen Relkin
220 Lake Drive East, Suite 210
Cherry Hill, NJ 08002
Tel #: (856) 755-1115
Fax #: (856) 755-1995

CERTIFICATION PURSUANT TO RULE 4:5-1

The undersigned attorney for Plaintiffs certifies as follows:

1. The matter in controversy is not the subject of any other action pending in any Court or of a pending arbitration proceeding;
2. No other action or arbitration proceeding is contemplated; and
3. There are no known parties who may be liable to any party on the basis of the transaction or events which form the subject matter of their action that should be joined pursuant to R. 4:28.
4. I certify that the foregoing statements made by me are true to the best of my knowledge, information and belief. I am aware that if any of the foregoing statements made by me are willfully false, I am subject to punishment.

Respectfully submitted,

Plaintiffs' Lead/Liaison Counsel

WEITZ & LUXENBERG
A New York Professional Corporation
Attorneys for Plaintiff

Dated:

Ellen Relkin
220 Lake Drive East, Suite 210
Cherry Hill, NJ 08002
Tel #: (856) 755-1115
Fax #: (856) 755-1995

EXHIBIT 2

IN RE: STRYKER LFIT CoCr V40 FEMORAL HEADS HIP IMPLANT LITIGATION **[INSERT NAME],** **Plaintiff(s)** **vs.** **HOWMEDICA OSTEONICS CORPORATION, a New Jersey Corporation, d/b/a STRYKER ORTHOPAEDICS, JILL DOE MANUFACTURERS (1-10), JACK DOE WHOLESALERS (1-10), JAKE DOE SELLERS (1-10), JANE DOE DISTRIBUTORS and MARKETERS (1-10), JIM DOE HEALTH CARE PROVIDERS (1-10), and JEAN DOE (1-10),** **Defendants**	**SUPERIOR COURT OF NEW JERSEY** **LAW DIVISION: BERGEN COUNTY** **MASTER DOCKET NO. BER-L-** 7859-17 **CASE NO. 624** **[INSERT INDIVIDUAL DOCKET NO.]** **SHORT FORM COMPLAINT AND JURY TRIAL DEMAND**

1. Plaintiff(s), [NAME(S)], state(s) and bring(s) this civil action as a related action in the matter entitled In Re Stryker LFIT CoCr V40 Femoral Heads Hip Implant Litigation, Case No. 624. Plaintiff(s) is/are filing this Short Form Complaint as permitted by Case Management Order #3 and Implementing Order dated _____ of this Court.

PARTIES, JURISDICTION AND VENUE

2. Plaintiff, _____, is a resident and citizen of the State of _____ and claims damages as set forth below.
3. Plaintiff's Spouse, _____, is a resident and citizen of the State of _____ and claims damages as set forth below. *Cross out Spousal Claim if not applicable.*
4. Plaintiff brings this action *[check the applicable designation]*:

☐ On behalf of himself/herself;

☐ In a representative capacity as the _____ of the _____ having been duly appointed as the _____ by the _____Court of _____. A copy of the Letters of Administration for a wrongful death claim is annexed hereto if such letters are required for the commencement of such a claim by the Probate, Surrogate or other appropriate court of the jurisdiction of the decedent. *Cross out if not applicable.*

FACTUAL ALLEGATIONS

Allegations as to **Right-Side** Implant/Explant Surgery(ies): *(Cross out if not applicable)*

5. Plaintiff was implanted with an LFIT Anatomic CoCr V40 Femoral Head on his/her right hip on or about _____ (date), at the _____ (medical center and address), in _____, by Dr. _____. *Cross out if not applicable.*
6. Plaintiff was implanted with the following femoral stem during the ____ (date) surgery:

   _____ Accolade TMZF

   _____ Accolade II

   _____ Other _____(Femoral Stem)
7. Plaintiff had the right femoral head at issue explanted on _____, at _____ (medical center and address) by Dr. _____. *Cross out if not applicable.*
8. Plaintiff will have the right femoral head at issue explanted on or about _____, at _____ (medical center and address) by Dr. _____. *Cross out if not applicable.*
9. Plaintiff has not yet scheduled a surgery for explantation of the right femoral head at issue. *Cross out if not applicable.*

Allegations as to **Left-Side** Implant/Explant Surgery(ies): *(Cross out if not applicable)*

10. Plaintiff was implanted with an LFIT Anatomic CoCr V40 Femoral Head on his/her left hip on or about _____ (date), at the _____ (medical center and address), in _____ by Dr. _____. *Cross out if not applicable.*

11. Plaintiff was implanted with the following femoral stem during the ____ (date) surgery:

    _____ Accolade TMZF

    _____ Accolade II

    _____ Other _____(Femoral Stem)

12. Plaintiff had the left femoral head at issue explanted on _____, at _____ (medical center and address) by Dr. _____. *Cross out if not applicable.*

13. Plaintiff will have the left femoral head at issue explanted on or about _____, at _____ (medical center and address) by Dr. _____. *Cross out if not applicable.*

14. Plaintiff has not yet scheduled a surgery for explantation of the left femoral head at issue. *Cross out if not applicable.*

ALLEGATIONS AS TO INJURIES

15. (a) Plaintiff claims damages as a result of (check all that are applicable):

    _____ injury to herself/himself

    _____ injury to the person represented

    _____ wrongful death

    _____ survivorship action

    _____ economic loss

    (b) Plaintiff's spouse claims damages as a result of (check all that are applicable):

Cross out if not applicable.

_____ loss of services

_____ loss of consortium

16. Plaintiff has suffered injuries as a result of implantation of the Device(s) at issue manufactured by the Defendants as shall be fully set forth in Plaintiff's Fact Sheet and other responsive documents provided to the Defendants and are incorporated by reference herein.

17. Plaintiff has suffered injuries as a result of the explantation of the Device(s) at issue manufactured by the Defendants as shall be fully set forth in Plaintiff's Fact Sheet and other responsive documents provided to the Defendants and are incorporated by reference herein. *Cross out if not applicable.*

18. Defendants, by their actions or inactions, proximately caused the injuries to Plaintiff(s).

19. Plaintiff(s) could not have known that the injuries he/she suffered were as a result of a defect in the Device(s) at issue until after the date the Device was recalled from the market and the Plaintiff(s) came to learn of the recall.

20. In addition, Plaintiff could not have known that he/she was injured by excessive levels of chromium and cobalt until after the date he/she had his/her blood drawn and he/she was advised of the results of said blood-work and the fact that those blood work abnormalities were attributable to a defect in the Device(s) at issue.

CASE-SPECIFIC ALLEGATIONS AND THEORIES OF RECOVERY

21. The following claims and allegations are asserted by Plaintiff(s) and are herein adopted by reference (check all that are applicable):

_____ FIRST CAUSE OF ACTION – NEGLIGENCE;

_____ SECOND CAUSE OF ACTION – NEGLIGENCE PER SE;

_____ THIRD CAUSE OF ACTION – STRICT PRODUCTS LIABILITY – DEFECTIVE DESIGN, NJPLA;

_____ FOURTH CAUSE OF ACTION – STRICT PRODUCTS LIABILITY – MANUFACTURING DEFECT, NJPLA;

_____ FIFTH CAUSE OF ACTION – STRICT PRODUCTS LIABILITY – FAILURE TO WARN, NJPLA;

_____ SIXTH CAUSE OF ACTION – BREACH OF EXPRESS WARRANTY;

_____ SEVENTH CAUSE OF ACTION – BREACH OF WARRANTY AS TO MERCHANTABILITY;

_____ EIGHTH CAUSE OF ACTION – BREACH OF IMPLIED WARRANTIES;

_____ NINTH CAUSE OF ACTION – VIOLATION OF CONSUMER FRAUD AND/OR UNFAIR AND DECEPTIVE TRADE PRACTICES UNDER STATE LAW;

_____ TENTH CAUSE OF ACTION – NEGLIGENT MISREPRESENTATION;

_____ ELEVENTH CAUSE OF ACTION – LOSS OF CONSORTIUM

_____ TWELFTH CAUSE OF ACTION – UNJUST ENRICHMENT

_____ THIRTEENTH CAUSE OF ACTION – WRONGFUL DEATH

_____ FOURTEENTH CAUSE OF ACTION – PUNITIVE DAMAGES

In addition to the above, Plaintiff(s) assert the following additional causes of action under applicable state law:

_____

_____

_____

_____

PRAYER FOR RELIEF

WHEREFORE, Plaintiff(s) pray for judgment against Defendant as follows:

1. For compensatory damages requested and according to proof;
2. For all applicable statutory damages of the state whose laws will govern this action;
3. For an award of attorneys' fees and costs;
4. For prejudgment interest and costs of suit;
5. For restitution and disgorgement of profits; and,
6. For such other and further relief as this Court may deem just and proper.

JURY DEMAND

Plaintiff(s) hereby demand(s) a trial by jury as to all claims in this action.

Respectfully submitted,

_____

Date: _____

CERTIFICATION PURSUANT TO RULE 4:5-1

The undersigned attorney for Plaintiffs certifies as follows:

1. The matter in controversy is not the subject of any other action pending in any Court or of a pending arbitration proceeding;

2. No other action or arbitration proceeding is contemplated; and

3. There are no known parties who may be liable to any party on the basis of the transaction or events which form the subject matter of their action that should be joined pursuant to R. 4:28.

4. I certify that the foregoing statements made by me are true to the best of my knowledge, information and belief. I am aware that if any of the foregoing statements made by me are willfully false, I am subject to punishment.

Respectfully submitted,

_____

Date: _____

DESIGNATION OF TRIAL COUNSEL

Pursuant to R. 4:25-4, _____ is hereby designated as trial counsel in their matter.

_____

Date: _____

EXHIBIT 3

SUPERIOR COURT OF NEW JERSEY
LAW DIVISION: BERGEN COUNTY

CASE NO. 624
MASTER DOCKET NO. BER-L-7859-17
CIVIL ACTION

IN RE STRYKER LFIT CoCr V40 FEMORAL HEADS HIP IMPLANT LITIGATION

This Document Relates to all Cases

STIPULATION

IT IS HEREBY STIPULATED BY AND BETWEEN THE PARTIES that Plaintiffs will name as defendant in the Master Complaint only Howmedica Osteonics Corp. based upon the agreement that Defendant Howmedica Osteonics Corp.:

1. Agreed that in the event additional information is learned from discovery that would reasonably support naming Stryker Corporation and/or Stryker Ireland Limited, then assuming timely amendment by Plaintiffs' counsel, such entities will not raise a statute of limitations defense that did not exist at the time Plaintiff's original complaint was filed and acknowledge that the amended complaint against said parties can relate back to the original filing of each individual Plaintiff's original complaint.[1] The Court's allowance of an amended complaint shall constitute the threshold reasonable support required above;

2. Agrees not to withhold from production relevant and responsive documents on the **sole** basis that such documents are in the possession, custody or control of Stryker Ireland Limited or other foreign affiliates. This agreement does not prevent Howmedica Osteonics Corp. from raising other defenses to production of said documents;

3. Will not attribute blame at trial, also known as asserting the "empty chair defense," to Stryker Corporation or Stryker Ireland Limited;

[1] The rights of Howmedica Osteonics Corp., Stryker Corporation, and Stryker Ireland Limited to move for dismissal of some or all of Plaintiffs' claims and/or seek dismissal based on lack of jurisdiction, improper venue, the doctrine of *forum non conveniens*, or any other applicable grounds are expressly not waived or in any way limited by this Stipulation.

4. In the event that Howmedica Osteonics Corp. is not able to satisfy any potential liability in this litigation, Stryker Corporation or another designated Stryker-related entity shall assume financial responsibility; and

5. Allow its counsel to accept service of complaints on behalf of Howmedica Osteonics Corp. only pursuant to the specific terms set forth in the New Jersey Multicounty Litigation Master Pleading Implementation Order.

APPROVED AS TO FORM AND SUBSTANCE

Ellen Relkin
WEITZ AND LUXENBERG
220 Lake Drive East, Suite 210
Cherry Hill, NJ 08002
Tel: 856-755-1115
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Attorney ID No: 006691985

Plaintiffs' Liaison/Lead Counsel

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Defendant Howmedica Osteonics Corp.'s Liaison/Lead Counsel