U.S. DISTRICT COURT

DISTRICT OF MASSACHUSETTS

LINDA REGAN, Plaintiff, v. HOWMEDICA OSTEONICS CORP., a New Jersey Corporation, d/b/a STRYKER ORTHOPAEDICS, and STRYKER CORP., a Michigan Corporation, Defendants.	**Civil Case No.:** _____

COMPLAINT AND DEMAND FOR JURY TRIAL

COME NOW Plaintiff, LINDA REGAN, by and through the undersigned counsel, and brings this complaint against Defendants, Howmedica Osteonics Corp., d/b/a Stryker Orthopedics; and Stryker Corp. and alleges as follows:

1. This is an action for damages relating to Defendants' development, testing, assembling, manufacture, packaging, labeling, preparing, distribution, marketing, supplying, and/or selling the Accolade Hip Stem and the LFIT V40 Femoral Head sold under the name "The Accolade TMZF® Hip Stem and LFIT Anatomic V40 Femoral Head" (hereinafter "Accolade" or "Defective Device").

PARTIES, JURISDICTION AND VENUE

2. Plaintiff, LINDA REGAN is a resident of Beverly, Essex County, Massachusetts. Plaintiff was implanted with a Defective Device on or about July 30, 2007 at Baystate Medical Center, Springfield, Massachusetts.

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

4. Defendant, Stryker Corp. (hereinafter "STRYKER") is a foreign corporation organized and existing under the laws of Michigan having its principal place of business located at 2825 Airview Boulevard, Kalamazoo, Michigan 49002. STRYKER conducts business throughout the United States including the Commonwealth of Massachusetts.

5. At all times material hereto, Defendants HOWMEDICA and STRYKER (hereinafter collectively referred to as "STRYKER DEFENDANTS") developed, tested, assembled, manufactured, packaged, labeled, prepared, distributed, marketed, supplied, and/or sold the Accolade, either directly or indirectly, to members of the general public within the Commonwealth of Massachusetts and elsewhere, including Plaintiff, LINDA REGAN.

6. This Court has diversity subject matter jurisdiction over this action pursuant to 28 U.S.C. §1332(a): "The district courts shall have original jurisdiction of all civil actions where the matter in controversy exceeds the sum or value of $75,000, exclusive of interests and costs, and is between (1) citizens of different states." Damages to Plaintiff exceed the sum or value of $75,000, exclusive of interest and costs. The Court also has personal jurisdiction over the parties because Plaintiff is a resident of Massachusetts and Defendants systematically and continually conduct business here and conduct business throughout the United States.

7. Venue of this case is appropriate in the United States District Court for the District of Massachusetts because Plaintiff resides in the District and Defendants conduct

business and have places of business in the District.

FACTUAL ALLEGATIONS

The Accolade TMZF® Hip Stem and LFIT Anatomic V40 Femoral Head

8. STRYKER DEFENDANTS manufacture medical devices worldwide, including total hip replacement systems and products.

9. The Accolade systems include several variations of neck, stem and head components.

10. The components can, for example, vary in size and material used in the manufacture of the product.

11. These interchangeable systems were designed to give surgeons more flexibility by providing more anatomically correct implant components that can be custom-fit to the patient.

12. The Accolade TMZF® Hip Stem and LFIT Anatomic V40 Femoral Head are two parts of a total hip replacement system.

13. On March 16, 2000, STRYKER DEFENDANTS received FDA clearance to sell its Accolade prosthetic hip stem in the United States.

14. This clearance (not approval) was obtained through the 510(k) process, which is a method used by manufacturers of medical devices to obtain faster and less costly permission to market a new device.

15. Through the 510(k) clearance process, a product will be cleared if the manufacturer establishes that the new device is substantially equivalent to a predicate device; one that is already on the market.

16. The Accolade stem is a hip replacement prosthesis. It is indicated for patients requiring primary total hip arthroplasty or replacement due to painful disabling joint disease of the hip resulting from non-inflammatory degenerative arthritis.

17. The Accolade stem is a monoblock, single piece artificial hip replacement device that is designed to be implanted into the patient's femur. The Accolade stem is designed to be used with any number of bearing surface components comprised of the modular ball or artificial femoral head and an acetabular cup or socket.

18. The stem is manufactured utilizing a proprietary titanium alloy consisting of titanium, molybdenum, zinc and iron.

19. STRYKER DEFENDANTS' alloy was designed and patented by HOWMEDICA and is unlike any titanium alloy employed in the manufacture of other prosthetic hip implants.

20. STRYKER DEFENDANTS claim in their promotional materials for the Accolade stem that their alloy is both stronger and less rigid than other titanium alloys. They also claim that the particular titanium alloy has been tested and proven by STRYKER DEFENDANTS to resist the effects of corrosion and fretting.

21. On November 16, 1999, and again on April 11, 2001, STRYKER DEFENDANTS received clearance from FDA to market the LFIT Anatomic V40 Cobalt Chromium Femoral Head.

22. Upon receiving clearance in March 2000, STRYKER DEFENDANTS released their Accolade TMZF Hip Stem, the latest evolution in the Company's Meridian Titanium Femoral Stem, the Howmedica Asymmetric Stem Femoral Component, the Osteonics Omnifit AD-HA Hip Stem Series, and the Biomet Taperlock Hip Stem, which were all previously

cleared for market between the years of 1994 and 1997.

23. According to STRYKER DEFENDANTS' marketing materials, the Accolade Stem was developed to maximize a patient's hip range of motion, increase stability, and resist dislocation. These materials also state that the Accolade TMZF Hip Stem is designed to be used with V40 Femoral Heads, which are offered in both forged Vitallium alloy (CoCrMo) and zirconia ceramic.

24. The Accolade Stem is also designed with two neck angles, the standard 132 degrees and extended 127 degrees offset, to assist with joint stability and proper restoration of joint kinematics without lengthening the leg. The neck lengths are proportionally relative to the patient's body geometry to accommodate a wider patient population using a standard femoral head.

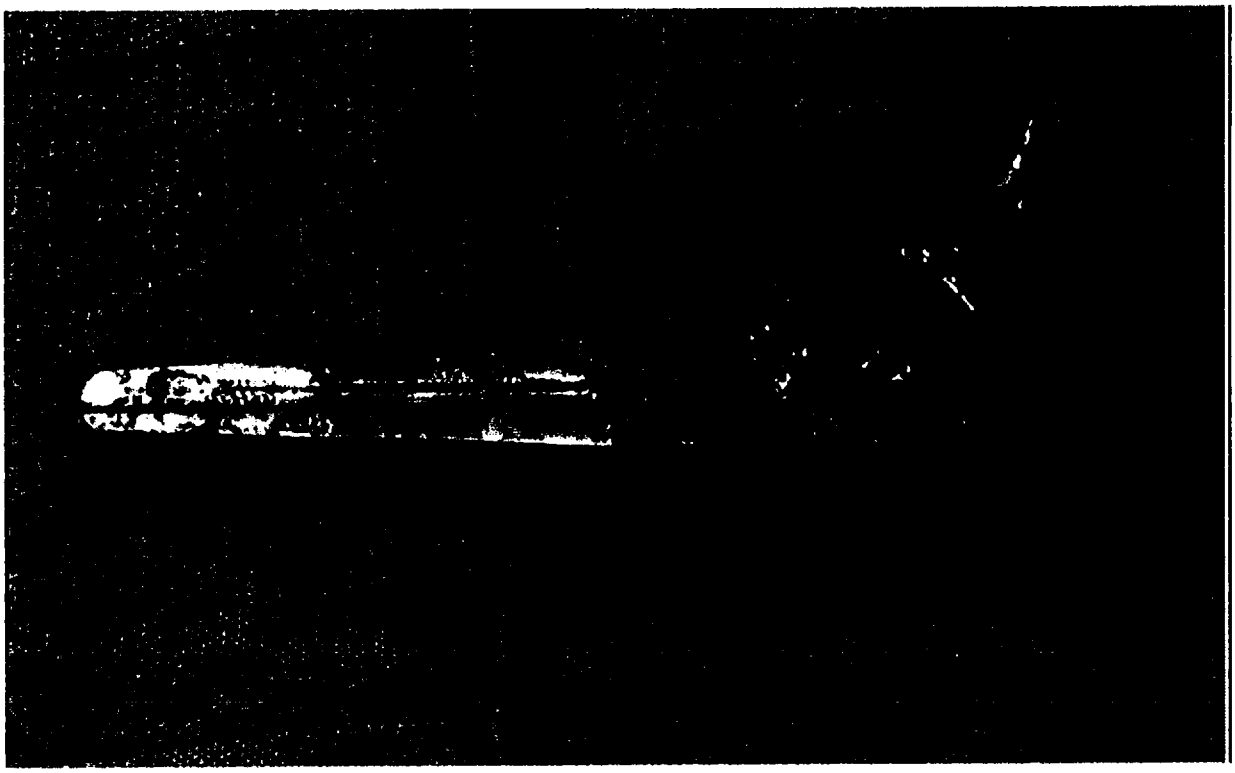
25. The Accolade Stem combines the material characteristics of TMZF (Ti-12Mo-6Zr-2Fe) with a plasma sprayed coating PureFix HA for the stem and neck. The femoral head that is commonly used with the Accolade TMZF Hip Stem is the LFIT Anatomic V40 Femoral Head, which is made from CoCr.

26. STRYKER DEFENDANTS claim that laboratory testing demonstrates the compatibility of these materials without concern for fretting and corrosion.

The Accolade and V40 Recall

27. In August 2016, an investigative report was published in the Journal of Bone and Joint Surgery. In this report, the authors noted 5 instances in which patients implanted with Accolade Stem/LFIT V40 head combinations suffered catastrophic failure when their Accolade stems fractured. Specifically, it was reported that there was extensive corrosion in the V40 head and Accolade stem that was so significant the stem actually fractured at the stem/head juncture.

It was also reported that in many of the patients, the corrosion caused the release of significant amounts of metallic debris that significantly damaged the soft tissues surrounding the patient's hips. Below is a picture of a stem that experienced corrosion to the point where it disassociated from the head. This is a catastrophic failure that results in significant injury to the patient's hip.



28. Following this report, the STRYKER DEFENDANTS issued a recall in the United States, Australia, and Canada. (See Exhibit A.) The recall notice states that Stryker is recalling certain lots of LFIT V40 Heads as a result of several "Potential Hazards." The hazards identified include:

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

29. 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 can take to monitor patients.

30. A simple, inexpensive blood test can be used to determine whether a patient is experiencing the corrosive process that lead to the 2017 recall. Specifically, the presence of elevated levels of cobalt, chromium, or titanium in the blood is a definitive sign that a prosthetic hip is corroding. Despite the availability of this test, the STRYKER DEFENDANTS' recall notice fails to instruct surgeons to contact patients with V40 heads to perform such tests. In fact, the recall notice does not even tell surgeons that the cause of the "hazards" identified in the notice is excessive corrosion at the head/neck juncture. As a result, there are potentially several hundred thousand individuals with defective V40 heads whose hips are currently leaching toxic levels of cobalt and chromium into their bodies who are completely unaware that their hips are corroding.

31. Plaintiff is informed and believes, and thereon alleges, that the problems with the V40 head/Accolade Stem combinations are much larger than those referenced in the STRYKER DEFENDANTS' recall notice and are caused by the metallurgical formula used to manufacture the TMZF Accolade Stem and/or the geometry of the Cobalt/Chromium V40 Head. Plaintiff alleges that all V40 heads sold by defendants are defective and should be recalled. Instead, the STRYKER DEFENDANTS have intentionally downplayed the risk of harm and limited the scope of its recall in an effort to hide from surgeons, patients, and the FDA the true extent of the problems with their defective hips.

LINDA REGAN Receives the Accolade/V40 hip/head combination

32. STRYKER DEFENDANTS' Defective Device was placed into the stream of interstate commerce and was implanted in Plaintiff, LINDA REGAN, on July 30, 2007.

33. After the implantation of the Defective Device, Plaintiff, began experiencing discomfort in the area of her Defective Device.

34. Diagnostic workup revealed the absence of device loosening, infection, malposition or any other explanation for the Plaintiff's symptoms.

35. Further diagnostic workup revealed the presence of markedly increased levels of metal ions in the patient's blood.

36. Based upon this finding and, in light of the Plaintiff's worsening symptoms, she was taken back for revision surgery on her hip on July 21, 2014. During this surgery, it was discovered that, in fact, there was significant metallosis and trunnionosis in the Plaintiff's hip resulting in soft tissue damage. Her surgeon also noted the presence of corrosion at the taper junction between the Accolade stem and Stryker's L-Fit V40 Chromium Cobalt femoral head.

37. Plaintiff has endured extensive rehabilitation in Massachusetts since undergoing revision of her right hip prosthesis.

38. As a direct and proximate result of STRYKER DEFENDANTS placing the Defective Device into the stream of commerce, Plaintiff has suffered and continues to suffer both injuries and damages, including but not limited to: past, present and future physical and mental pain and suffering; and past, present and future medical, hospital, rehabilitative and pharmaceutical expenses, and other related damages.

39. At all times material hereto, the Accolade Stem implanted in the Plaintiff was designed, manufactured, marketed, retailed, distributed, and/or supplied by the STRYKER

DEFENDANTS.

40. The Defect Device reached the Plaintiff without substantial change in its condition when it left the possession of STRYKER DEFENDANTS and was used in the manner for which it was intended.

41. The Defective Device was defective and unreasonably dangerous when STRYKER DEFENDANTS placed it into the stream of commerce.

42. Prior to seeing information about the Defective Device on the internet, Plaintiff did not have knowledge or sufficient notice of the cause of the corrosion that occurred with her hip. Even though he had some knowledge of symptoms, he was not aware of the Defendants' wrongful conduct until August 2016 when he learned that the defendants had recalled certain lots of its V40 heads. Under the facts of this case, Plaintiff's suit was filed well within the applicable statutory limitations period.

43. Plaintiff exercised reasonable diligence in investigating potential causes of her injury by discussing her injuries with healthcare providers. None of Plaintiff's conversations with her healthcare providers gave Plaintiff a reason to suspect, or reasonably should have given Plaintiff a reason to suspect, that the hip implanted within her was defective. The reason for this is that Defendants' fraudulently concealed relevant facts from plaintiff and the medical community about the true risks of harm associated with its V40/Accolade Stem combinations and fraudulently advised the medical community that instances of corrosion were no non-existent and/or extremely rare. As a result, Plaintiff and her physicians were deprived of vital information essential to the pursuit of these claims, without any fault or lack of diligence on their part. Plaintiff relied on Defendants' misrepresentations and omissions and therefore could not reasonably have known or become aware of facts that would lead a reasonable, prudent person to

make an inquiry to discover Defendants' tortious conduct. Plaintiff diligently filed suit once he discovered the actual facts that would lead a reasonable, prudent person to make an inquiry to discover Defendants' tortious conduct. Defendants' misconduct and fraudulent concealment of the relevant facts, as described *infra*, tolls any relevant statute of limitations. Regardless, Plaintiff's suit is filed well within the applicable statutory limitations period.

44. Defendants are and were under a continuing duty to monitor and disclose the true character, quality, and nature of its Defective Device. Because of Defendants' misconduct and fraudulent concealment of the true character, quality, and nature of its device, Defendants are estopped from relying on any statute of limitations defense.

CAUSES OF ACTION

COUNT I - NEGLIGENCE (STRYKER DEFENDANTS)

45. Plaintiff re-alleges the above paragraphs, and incorporate by reference the allegations set forth above.

46. STRYKER DEFENDANTS developed, tested, assembled, designed, manufactured, packaged, labeled, prepared, distributed, marketed, supplied, and/or sold the Accolade Hip Stem and the LFIT V40 Femoral Head to physicians and consumers.

47. As a result, STRYKER 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.

48. STRYKER DEFENDANTS failed to use reasonable and due care for the safety and well-being of those in whom the devices would be implanted and are, therefore, negligent in the following respects:

a. STRYKER DEFENDANTS failed to adequately design and manufacture the

devices to ensure that it would not corrode, erode, deteriorate and induce severe metal toxicity in patients. The flaws include but are not limited to:

i. The incompatibility of the TMZF titanium with other device components like the cobalt chromium LFIT V40 Femoral Head;

ii. Poor design of the taper junction between stem and femoral head such that micro motion was predictable;

iii. Poor manufacturing practices such that the taper junction between the stem and head do not "fit" the way they were intended;

iv. Failing to limit the femoral head components that were recommended for use with the Accolade stem to those that would not promote fretting and corrosion;

v. 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 devices.

b. STRYKER DEFENDANTS failed to adequately test the devices to ensure that they would not corrode, erode, deteriorate and induce severe metal toxicity in the patient;

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

d. STRYKER DEFENDANTS failed to properly and adequately market its product and made affirmative representations that the device would not fret or corrode in the human body. These representations were false and misleading to both physicians and the consumers;

e. STRYKER DEFENDANTS negligently trained their sales force to detail the device utilizing representations that the STRYKER 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. STRYKER DEFENDANTS failed to manufacture the Accolade Stem and the LFIT V40 Femoral Head to STRYKER DEFENDANTS' own internal specifications such that the taper junction between the stem and head prematurely failed causing metal debris cast-off and severe metal toxicity in patients;

g. STRYKER DEFENDANTS failed to exercise reasonable care in the manufacture of the Accolade Stem and the LFIT V40 Femoral Head in that either:

i. The taper was poorly fashioned so that it did not "fit;"

ii. The TMZF titanium material was fashioned in such a manner that it did not maintain structural integrity when implanted in the biologic environment;

iii. The TMZF titanium material was fashioned in such a manner that it did not maintain structural integrity when mated with a Chromium Cobalt femoral head;

iv. The Chromium Cobalt femoral head was manufactured such that it did not "fit";

v. The Chromium Cobalt femoral head was fashioned in such a manner that it did not maintain structural integrity when implanted in the biologic environment; or

vi. The Chromium Cobalt femoral head was fashioned in such a manner that it did not maintain structural integrity when mated with a titanium stem.

h. STRYKER DEFENDANTS failed to adequately test the TMZF alloy's compatibility with chrome cobalt components, such as the LFIT V40 Femoral Head, in an effort to prevent corrosion and fretting at the neck/stem taper neck junction of this modular device;

i. STRYKER DEFENDANTS failed to promptly act upon reports of failure such that these devices continued to be implanted in unknowing patients by surgeons well after they should have been recalled; and

j. STRYKER DEFENDANTS failed to adequately warn implanting physicians as well as the patients that the Accolade Stem and LFIT V40 Femoral Head were defective and could lead to patient injury.

49. The above conduct exhibits STRYKER DEFENDANTS' failure to exercise reasonable care. It was foreseeable that such negligence would lead to premature device failure as well as severe, debilitating injuries that were permanent.

50. As a direct and proximate result of the STRYKER DEFENDANTS' negligence, Plaintiff suffered failure of the Accolade Stem and LFIT V40 Femoral Head, severe physical pain and suffering, emotional distress, mental anguish, loss of the capacity for the enjoyment of life, medical and nursing expenses, and surgical expenses. These damages have occurred in the past and will continue into the future.

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

COUNT II - BREACH OF WARRANTY (STRYKER DEFENDANTS)

51. Plaintiff re-alleges the above paragraphs and incorporate by reference as if set forth herein.

52. At all times material hereto, the STRYKER DEFENDANTS engaged in the business of designing, manufacturing, testing, selling, detailing, distributing, marketing, and/or promoting the Accolade Stem and the LFIT V40 Femoral Head, which was unreasonably dangerous, and therefore defective.

53. The Accolade Hip Stem and the LFIT V40 Femoral Head were defective and used in the manner intended by STRYKER DEFENDANTS.

54. It was foreseeable that Plaintiff would receive the Accolade Stem and LFIT V40 Femoral Head as part of a hip replacement procedure.

55. At all times material hereto, the Accolade Hip Stem and the LFIT V40 Femoral Head reached Plaintiff without substantial change in the condition in which it left the possession of the STRYKER DEFENDANTS and was used in manner which had been contemplated and labeled.

56. The Accolade Hip Stem and LFIT V40 Femoral Heads were defective and unreasonably dangerous when they entered the stream of commerce and were received by Plaintiff because:

a. When they entered the stream of commerce, the Accolade Hip Stem and LFIT V40 Femoral Heads contained unreasonably dangerous design defects and were not reasonably safe as intended to be used, subjecting users and consumers like Plaintiff to risks which exceeded the benefits of the products;

b. When they entered the stream of commerce, the Accolade Hip Stem and LFIT V40 Femoral Heads were defective in design and formulation, making the use of the products more dangerous than an ordinary consumer would expect and more dangerous than other risks associated with hip replacement surgery;

c. The Accolade Hip Stem and LFIT V40 Femoral Heads were insufficiently and inadequately tested;

d. The Accolade Hip Stem and LFIT V40 Femoral Heads were not manufactured to STRYKER DEFENDANTS' specifications;

e. The Accolade Hip Stem and LFIT V40 Femoral Heads are unreasonably dangerous and defective when used as intended especially in light of the fact that

there existed a safer design of the product formulations;

f. When they entered the stream of commerce, the Accolade Hip Stem and LFIT V40 Femoral Heads were defective and unreasonably dangerous in that they were not constructed of materials that would prevent fretting and corrosion, and would not last longer than competing hip replacement devices;

g. The Accolade Hip Stem and LFIT V40 Femoral Heads were marketed and promoted for use as safe products in total hip replacement, when they were not safe for their intended use;

h. The Accolade Hip Stem implanted into the Plaintiff contained no warning against the use of Chromium Cobalt heads like the LFIT V40 Femoral Head;

i. Reasonable and adequate alternatives to Chromium Cobalt femoral heads, like the LFIT V40 Femoral Heads, existed at the time Plaintiff was implanted with her Accolade stem and LFIT V40 Femoral Head;

j. The warnings that accompanied the Accolade Stem and the LFIT V40 Femoral Heads failed to provide the level of information that an ordinary consumer would expect when using the Accolade Stem and LFIT V40 Femoral Heads in a manner reasonably foreseeable to the Defendants;

k. Had Plaintiff's surgeon received a proper or adequate warning as to the risks associated with using the Accolade Stem and its combination with Chromium Cobalt femoral heads, like the LFIT V40 Femoral Head, he would not have recommended the device; would have used an alternate device or at a minimum, provided Plaintiff with adequate warning and obtained her informed consent. As stated above, had Plaintiff received an adequate warning, he would not have agreed to have the Accolade Stem and LFIT V40 Femoral Head implanted in him; and

l. The intended use of the Accolade Hip Stem and the LFIT V40 Femoral Head caused harmful side effects that outweighed any potential utility.

57. Accolade Stem and LFIT V40 Femoral Heads were not fit for the ordinary purposes for which such goods are used.

58. As a direct and proximate result of the actions and inactions of the STRYKER DEFENDANTS as set forth above, Plaintiff sustained injuries. Plaintiff is entitled to damages as enumerated herein. Plaintiff's damages were not caused by an inherent characteristic of hip replacement surgery that cannot be eliminated, but instead were caused by the product being dangerously defective as outlined above.

59. STRYKER DEFENDANTS' actions and inactions as set forth above were intentional and deliberate, and resulted in injuries to the Plaintiff who suffered failure of the Accolade Stem and LFIT V40 Femoral Head, severe physical pain and suffering, emotional distress, mental anguish, loss of the capacity for the enjoyment of life, medical and nursing expenses, and surgical expenses. These damages have occurred in the past and will continue into the future.

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

PRAYER FOR RELIEF

WHEREFORE, the Plaintiff prays for judgment against the STRYKER DEFENDANTS as follows:

a. Awarding compensatory damages resulting from STRYKER DEFENDANTS' violation of Massachusetts law;
b. Awarding compensatory damages resulting from STRYKER DEFENDANTS' breach of warranty and negligence, as alleged above;
c. Awarding actual damages to the Plaintiff incidental to Plaintiff's purchase and use of The Accolade Hip Stem in an amount to be determined at trial;
d. Awarding pre-judgment and post-judgment interest to the Plaintiff as provided by law;
e. Awarding the costs and expenses of their litigation to the Plaintiff;
f. Awarding reasonable attorneys' fees and costs to the Plaintiff as provided by law; and
g. Granting all such other relief as the Court deems necessary, just and proper.

DEMAND FOR JURY TRIAL

Plaintiff hereby requests a trial by jury of all issues triable by jury.

Respectfully submitted,
PLAINTIFF
By their attorney,
Kelley Bernheim Dolinsky, LLC

/s/ Walter Kelley

Walter Kelley, Esquire
BBO# 670525
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Plymouth, MA 02360
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Dated: 2/22/17

JS 44 (Rev. 08/16)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS

Linda Regan

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

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Walter Kelley, Esq. of Kelley Bernheim Dolinsky LLC
4 Court Street, Plymouth, MA 02360
(508) 747-8854

DEFENDANTS

Howmedica Osteonics Corp., a New Jersey Corporation, d/b/a Stryker Orthopaedics, and Stryker Corp., a Michigan Corporation

County of Residence of First Listed Defendant Bergen County, NJ
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ☐ 1 U.S. Government Plaintiff
- ☐ 3 Federal Question *(U.S. Government Not a Party)*
- ☐ 2 U.S. Government Defendant
- ☒ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*

(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☒ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☒ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

Click here for: Nature of Suit Code Descriptions.

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Personal Injury - Medical Malpractice

PERSONAL INJURY
- ☐ 365 Personal Injury - Product Liability
- ☒ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

CIVIL RIGHTS
- ☐ 440 Other Civil Rights
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 445 Amer. w/Disabilities - Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 448 Education

PRISONER PETITIONS

Habeas Corpus:
- ☐ 463 Alien Detainee
- ☐ 510 Motions to Vacate Sentence
- ☐ 530 General
- ☐ 535 Death Penalty

Other:
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition
- ☐ 560 Civil Detainee - Conditions of Confinement

FORFEITURE/PENALTY
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Management Relations
- ☐ 740 Railway Labor Act
- ☐ 751 Family and Medical Leave Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Employee Retirement Income Security Act

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 465 Other Immigration Actions

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 840 Trademark

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ☐ 375 False Claims Act
- ☐ 376 Qui Tam (31 USC 3729(a))
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit
- ☐ 490 Cable/Sat TV
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 895 Freedom of Information Act
- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes

V. ORIGIN *(Place an "X" in One Box Only)*

☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from Another District *(specify)* ☐ 6 Multidistrict Litigation - Transfer ☐ 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing *(Do not cite jurisdictional statutes unless diversity)*:
28 U.S.C. section 1332 (a)

Brief description of cause:
Products Liability Litigation Involving the Accolade TMZF® Hip Stem and LFIT Anatomic V40 Femoral Head

VII. REQUESTED IN COMPLAINT:

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

DEMAND $

CHECK YES only if demanded in complaint:
JURY DEMAND: ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE Indira Talwani DOCKET NUMBER 1:16-cv-11510-IT

DATE
02/22/2017

SIGNATURE OF ATTORNEY OF RECORD
/s/ Walter Kelley

FOR OFFICE USE ONLY

RECEIPT # AMOUNT APPLYING IFP JUDGE MAG. JUDGE

INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

I.(a) **Plaintiffs-Defendants.** Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.

(b) **County of Residence.** For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)

(c) **Attorneys.** Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".

II. **Jurisdiction.** The basis of jurisdiction is set forth under Rule 8(a), F.R.Cv.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.
United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.
United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.
Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.
Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below; **NOTE: federal question actions take precedence over diversity cases.**)

III. **Residence (citizenship) of Principal Parties.** This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.

IV. Nature of Suit. Place an "X" in the appropriate box. If there are multiple nature of suit codes associated with the case, pick the nature of suit code that is most applicable. Click here for: Nature of Suit Code Descriptions.

V. **Origin.** Place an "X" in one of the seven boxes.
Original Proceedings. (1) Cases which originate in the United States district courts.
Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441. When the petition for removal is granted, check this box.
Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.
Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.
Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.
Multidistrict Litigation – Transfer. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407.
Multidistrict Litigation – Direct File. (8) Check this box when a multidistrict case is filed in the same district as the Master MDL docket.
PLEASE NOTE THAT THERE IS NOT AN ORIGIN CODE 7. Origin Code 7 was used for historical records and is no longer relevant due to changes in statue.

VI. **Cause of Action.** Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity.** Example: U.S. Civil Statute: 47 USC 553 Brief Description: Unauthorized reception of cable service

VII. **Requested in Complaint.** Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.
Demand. In this space enter the actual dollar amount being demanded or indicate other demand, such as a preliminary injunction.
Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.

VIII. **Related Cases.** This section of the JS 44 is used to reference related pending cases, if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.

Date and Attorney Signature. Date and sign the civil cover sheet.

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

1. **Title of case (name of first party on each side only)** Linda Regan v. Howmedica Osteonics Corp. et al

2. **Category in which the case belongs based upon the numbered nature of suit code listed on the civil cover sheet. (See local rule 40.1(a)(1)).**

☐ I. 410, 441, 470, 535, 830*, 891, 893, 895, R.23, REGARDLESS OF NATURE OF SUIT.

☐ II. 110, 130, 140, 160, 190, 196, 230, 240, 290,320,362, 370, 371, 380, 430, 440, 442, 443, 445, 446, 448, 710, 720, 740, 790, 820*, 840*, 850, 870, 871.

☑ III. 120, 150, 151, 152, 153, 195, 210, 220, 245, 310, 315, 330, 340, 345, 350, 355, 360, 365, 367, 368, 375, 376, 385, 400, 422, 423, 450, 460, 462, 463, 465, 480, 490, 510, 530, 540, 550, 555, 625, 690, 751, 791, 861-865, 890, 896, 899, 950.

*Also complete AO 120 or AO 121. for patent, trademark or copyright cases.

3. **Title and number, if any, of related cases. (See local rule 40.1(g)). If more than one prior related case has been filed in this district please indicate the title and number of the first filed case in this court.**

Robert O'Hare et al v. Howmedica Osteonics Corp. et al

4. **Has a prior action between the same parties and based on the same claim ever been filed in this court?**

YES ☐ NO ☑

5. **Does the complaint in this case question the constitutionality of an act of congress affecting the public interest? (See 28 USC §2403)**

YES ☐ NO ☑

If so, is the U.S.A. or an officer, agent or employee of the U.S. a party?

YES ☐ NO ☑

6. **Is this case required to be heard and determined by a district court of three judges pursuant to title 28 USC §2284?**

YES ☐ NO ☑

7. **Do all of the parties in this action, excluding governmental agencies of the United States and the Commonwealth of Massachusetts ("governmental agencies"), residing in Massachusetts reside in the same division? - (See Local Rule 40.1(d)).**

YES ☑ NO ☐

A. **If yes, in which division do all of the non-governmental parties reside?**

Eastern Division ☑ Central Division ☐ Western Division ☐

B. **If no, in which division do the majority of the plaintiffs or the only parties, excluding governmental agencies, residing in Massachusetts reside?**

Eastern Division ☐ Central Division ☐ Western Division ☐

8. **If filing a Notice of Removal - are there any motions pending in the state court requiring the attention of this Court? (If yes, submit a separate sheet identifying the motions)**

YES ☐ NO ☐

(PLEASE TYPE OR PRINT)

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