Ashleigh Raso
Meshbesher & Spence
1616 Park Avenue
Minneapolis, MN 55401
(612) 339-9121
(612) 339-9188
araso@meshbesher.com
Attorney for Plaintiffs Patton and Annie Witt

UNITED STATES DISTRICT COURT
DISTRICT OF ALASKA

Patton Witt and Annie Witt,

Plaintiffs,

v.

Howmedica Osteonics Corp.,

Defendant.

Case No. 4:17-cv-00001-HRH

COMPLAINT AND JURY TRIAL DEMAND

Plaintiffs Patton Witt and Annie Witt, for their cause of action against the above-named Defendant, allege and state upon information and belief as follows:

PARTIES, JURISDICTION & VENUE

1. Plaintiffs Patton Witt and Annie Witt are residents of the town of Fairbanks, Borough of Fairbanks North Star, State of Alaska. Plaintiffs are, and at all times relevant to this Complaint were, husband and wife.

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

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

4. This action is properly before the Court because complete diversity of citizenship exists between Plaintiffs and Defendant. In addition, the amount in controversy claimed by Plaintiffs exceeds $75,000.00. As a result, this Court has jurisdiction over this matter pursuant to 28 U.S.C. § 1332(a).

5. Defendant is subject to the *in personam* jurisdiction of this Court, and venue is therefore proper herein pursuant to 28 U.S.C. § 1391, because Defendant did (and does) business within the State of Alaska and has had continuous and systematic contacts with the State of Alaska, has consented to jurisdiction in the State of Alaska and/or committed a tort in whole or in part in the State of Alaska against Plaintiffs as more fully set-forth herein. Upon information and belief,

Defendant also advertised in this district, made material omissions and representations in this district, and breached warranties in this district.

FACTUAL ALLEGATIONS

A. Total Hip Arthroplasty Procedure

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

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

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

8. On March 16, 2000, Defendant received FDA clearance to sell its TMZF® Fit Hip Stem ("TMZF") in the United States.

9. The Accolade TMZF Hip Stem was the latest evolution in Defendant'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 approved for market between the years 1994 and 1997.

10. The accolade TMZF Hip Stem in a monoblock, single piece artificial hip replacement device that is designed to be implanted into the patient's femur. The Accolade TMZF Hip 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.

11. The Accolade TMZF Hip Stem is manufactured utilizing a proprietary titanium alloy consisting of titanium, molybdenum, zinc and iron ("TMZF"). Defendant's alloy was designed and patented by Defendant and is unlike any titanium alloy employed in the manufacture of other prosthetic hip implants. Defendant claims in its promotional materials for the Accolade TMZF

Hip Stem that its alloy is both stronger and less rigid than other titanium alloys. It also claims that the particular titanium alloy has been tested and proven by Defendant to resist the effects of corrosion and fretting.

12. According to Defendant's materials, the Accolade TMZF Hip Stem was developed to maximize a patient's hip range of motion, increase stability, and resist dislocation. The Accolade TMZF Hip Stem is designed to be used with a number of femoral head options, including cobalt chromium and ceramic options. The Accolade TMZF Hip Stem is also designed with two neck angles, the standard 132 degrees and extended 127 degrees offset, to assist with joint stability and proper restoration of joint kinematics without lengthening the leg. The neck lengths are proportional relative to the patient's body geometry to accommodate a wider patient population using a standard femoral head.

13. The Accolade TMZF Hip Stem combines the material characteristics of TMZF (Ti-12Mo-6Zr-2Fe) with a plasma sprayed coating, PureFix HA. The femoral head that is commonly used with the Accolade TMZF Hip Stem is the V40 LFIT Anatomic Femoral Head, which is made from cobalt and chromium. Defendant claims laboratory testing demonstrated the compatibility of these materials without concern for fretting and corrosion.

14. Despite Defendant's claims, this material combination of an Accolade TMZF Hip Stem with V40 LFIT Anatomic Femoral Head made of cobalt and chromium has been reported to cause fretting and corrosion. Scientists have reported the occurrence of significant fretting and corrosion issues when dissimilar metals are combined. In its marketing and sale of the device, Defendant represented and warranted its proprietary materials alleviate this problem.

15. The Accolade TMZF is designed to be used with a variety of femoral heads, including femoral heads manufactured from either cobalt/chromium or ceramic.

16. The material combination of a titanium alloy stem, with a cobalt chromium femoral head, has been reported to cause fretting and corrosion. Scientists have reported the occurrence of significant fretting and corrosion caused by the combination of dissimilar metals and/or micro-motion at the junction between the stem trunnion and head bore dating back to the Reagan Administration.

17. 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.

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

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

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

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

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

Head is placed onto the tapered trunnion (male portion) of the Accolade TMZF stem and impacted by the surgeon using a Stem Head Impactor tool. The stresses created by compression of the wall of the bore by the trunnion results in a cold-welding or locking of the head/stem taper interface (i.e. taper lock).

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

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

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

26. On or about August 29, 2016, Stryker issued a voluntary recall of certain sizes and lots of LFIT V40 Heads manufactured prior to 2011 citing a "higher than expected" incidence of taper lock failure. Stryker identified various

"potential hazards" associated with LFIT V40 Head taper lock failure, including "excessive metallic debris" which could result in an "inflammatory response" and "adverse local tissue reaction" ("ALTR") and require additional surgery to revise or replace the product.

C. Plaintiff Allegations

27. On March 24, 2008, Plaintiff underwent left total hip arthroplasty as a result of advanced right hip arthritis. At that time, Plaintiff's surgeon implanted an Accolade® TMZF femoral stem with an LFIT V40 Head.

28. Diagnostic workup revealed an increased serum cobalt level of 3.9 ng/mL, and an MRI demonstrated a large soft tissue mass. Based upon these findings, Plaintiff's orthopedic surgeon's impression was ALTR resulting from corrosion at the junction between the Accolade TMZF and the LFIT V40 head, and he recommended revision surgery.

29. Plaintiff underwent revision surgery on January 13, 2015, at which time Plaintiff's surgeon encountered chronic inflammatory changes, ALTR, trunnionosis and corrosion. Upon disassembly of the LFIT V40 Head from the trunnion of the Accolade TMZF stem the surgeon noted, "one could clearly see

extensive corrosion present at this site. There appeared to be some deterioration at the trunnion with loss of the passified layer".

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

THE FEDERAL REQUIREMENTS

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

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

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

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

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

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

37. Pursuant to federal law, manufacturers are required to comply with FDA regulation of medical devices, including FDA requirements for records and

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

38. Pursuant to FDA regulation, adverse events associated with a medical device must be reported to FDA within 30 days after the manufacturer becomes aware that (a) a device may have caused or contributed to death or serious injury, or (b) that a device has malfunctioned and would be likely to cause or contribute to death or serious injury if the malfunction was to recur. Such reports must contain all information reasonably known to the manufacturer, including any information that can be obtained by analysis, testing, or other evaluation of the device, and any information in the

manufacturer's possession. In addition, manufacturers are responsible for conducting an investigation of each adverse event, and must evaluate the cause of the adverse event. *See* 21 CFR § 803.50.

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

40. Pursuant to federal regulations, manufacturers must report any reportable MDR event or events, including a trend analysis that necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health, to the FDA within 5 business days after becoming aware of such event or events. *See* 21 CFR § 803.53.

41. Pursuant to federal regulation, device manufacturers must report promptly to FDA any device corrections and removals, and maintain records of device corrections and removals. FDA regulations require submission of a written report within ten working days of any correction or removal of a device initiated by the manufacturer to reduce a risk to health posed by the device, or to

remedy a violation of the Act caused by the device, which may present a risk to health. The written submission must contain, among other things, a description of the event giving rise to the information reported, the corrective or removal actions taken, and any illness or injuries that have occurred with use of the device, including reference to any device report numbers. Manufacturers must also indicate the total number of devices manufactured or distributed which are subject to the correction or removal, and provide a copy of all communications regarding the correction or removal. *See* 21 CFR § 806.

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

necessary. Manufacturers are also required to use statistical techniques, where necessary, to evaluate product performance. *See* 21 CFR § 820.

43. Pursuant to federal regulations, a manufacturer must report to the FDA any new indications for use of a device, labeling changes, or changes in the performance or design specifications, circuits, components, ingredients, principle of operation or physical layout of the device. Federal regulations require that: "A PMA supplement must be submitted when unanticipated adverse effects, increases in the incidence of anticipated adverse effects, or device failures necessitate a labeling, manufacturing, or device modification." *See* 21 CFR § 814.

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

CLAIMS FOR RELIEF

COUNT 1
NEGLIGENCE

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

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

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

48. Defendant failed to use reasonable and due care for the safety and well-being of those in whom Accolade TMZF stems and LFIT V40 Heads would be implanted, including Plaintiff, and is therefore negligent in the following respects:

a. Defendant failed to adequately design and manufacture these devices to insure that they would not corrode, fret, deteriorate and induce metallosis and ALTR in patients. Defendant's failures include, but are not limited to, the following:

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

ii. Poor design of the bore of the LFIT V40 Heads such that it resulted in taper lock failure, micro-motion of the Accolade TMZF trunnion within the LFIT V40 bore, corrosion and fretting;

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

iv. 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. Failing to limit the type of femoral head components it recommended for use with the Accolade TMZF stem to

those that would not promote micro-motion, taper lock failure, corrosion and fretting; and

vi. A combination of the above factors which resulted in metallosis, ALTR, soft tissue and bony necrosis, pain and premature failure of the device.

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

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

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

cobalt/chromium head. Defendant also had knowledge at the time the Accolade TMZF was introduced to the market that other HOC devices made of titanium alloy were experiencing corrosion, fretting, and failure at the trunnion-bore interface. Nevertheless, Defendant either suppressed or ignored such knowledge, and marketed the LFIT V40 Heads as compatible with the Accolade TMZF, knowing full-well that these two dissimilar metals historically performed poorly after implantation and were causing harm to patients when utilized in various hip implant devices.

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

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

51. It was foreseeable that this wrongful conduct and these omissions would lead to premature failure of the Accolade TMZF/LFIT V40 Head

combination, and cause severe, permanent, debilitating injuries to patients, including Plaintiff.

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

COUNT 2
STRICT PRODUCTS LIABILITY- DEFECTIVE DESIGN

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

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

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

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

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

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

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

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

COUNT 3
STRICT PRODUCTS LIABILITY – MANUFACTURING DEFECT

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

61. The Accolade TMZF/LFIT V40 Head combination was designed for implantation into the human body and anticipated to function for fifteen or more years. The Accolade TMZF/LFIT V40 Head combination was also designed to be compatible with human tissue and bone.

62. The Accolade TMZF/LFIT V40 Head combination implanted in Plaintiff, however, failed and was explanted in *less than three years*.

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

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

b. The bore within the LFIT V40 Head was 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.

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

COUNT 4
STRICT PRODUCTS LIABILITY – FAILURE TO WARN

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

66. Defendant knew or should have known that the LIFT V40 Heads it manufactured and distributed contained a manufacturing defect in the Head's bore which would prevent the Accolade TMZF trunnion from achieving the desired taper lock and result in taper lock failure and micro-motion. Defendant also knew or should have known that the titanium alloy used in the Accolade TMZF stem was incompatible with the cobalt-chromium in the LFIT V40 Heads which, in the presence of taper lock failure and micro-motion, would lead to galvanic and crevice corrosion and fretting, and cause metallosis and ALTR in patients.

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

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

69. If Defendant had warned orthopedic surgeons about the risk of taper lock failure with its LFIT V40 Heads, and that the resulting micro-motion would increase the risk of corrosion and fretting at the trunnion-bore interface, and that such corrosion and fretting could lead to metallosis and ALTR in their patients, orthopedic surgeons (including Plaintiff's surgeon) would not have implanted the Accolade TMZF stem with an LFIT V40 Head, and Plaintiff would not have developed metallosis and ALTR, and would not have had to undergo a revision surgery less than three years after his index surgery.

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

COUNT 5
LOSS OF CONSORTIUM

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

72. As a further direct result of Defendant's acts, omission, and/or breach of duties as described and alleged above, Plaintiff Deborah Denne has lost, and will in the future lose, her husband's companionship, aid, comfort, society, services, protection and consortium, all to her damage in an amount greater than $75,000.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs seek judgment in their favor as follows:

1. Awarding actual damages to Plaintiff incidental to the purchase and use of the Accolade TMZF/LFIT V40 Head system in an amount to be determined at trial;

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

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

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

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

6. Awarding, if the Court allows an amended complaint on Plaintiff's motion, for punitive damages;

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

8. Awarding reasonable attorneys' fees and costs to Plaintiff as provided by law; and

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

DEMAND FOR JURY TRIAL

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

Dated: January 12, 2017 MESHBESHER & SPENCE, LTD.

By: /s/ Ashleigh E. Raso
Ashleigh E. Raso (#0393353) (Oath forthcoming)
Anthony J. Nemo (#221351) (*Pro Hac Vice* forthcoming)
Andrew L. Davick (#332719) (*Pro Hac Vice* forthcoming)
Genevieve Zimmerman (330292) (*Pro Hac Vice* forthcoming)
1616 Park Avenue
Minneapolis, MN 55404
Telephone: (612) 339-9121
Facsimile: (612) 339-9188
araso@meshbesher.com
tnemo@meshbesher.com
adavick@meshbesher.com
gzimmerman@meshbesher.com

Attorneys for Plaintiffs

JS 44 (Rev. 11/15)

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
Patton Witt and Annie Witt

(b) County of Residence of First Listed Plaintiff Fairbanks North Star
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Ashleigh E. Raso, Tony Nemo, Genevieve Zimmerman, Andrew Davick, Meshbesher & Spence, 1616 Park Avenue, Minneapolis, MN 55404 (612) 339-9121

DEFENDANTS
Howmedica Osteonics Corp.,

County of Residence of First Listed Defendant
(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
- ☐ 2 U.S. Government Defendant
- ☐ 3 Federal Question *(U.S. Government Not a Party)*
- ☒ 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)*

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
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- ☐ 160 Stockholders' Suits
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PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
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- ☐ 350 Motor Vehicle
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- ☐ 360 Other Personal Injury
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- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit
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- ☐ 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

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

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

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

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

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

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

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

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. 1332

Brief description of cause:
Defective hip implant resulting in personal injury

VII. REQUESTED IN COMPLAINT:

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

DEMAND $ 75,000.00

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

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE _____ DOCKET NUMBER _____

DATE 01/12/2017

SIGNATURE OF ATTORNEY OF RECORD /s/Ashleigh Raso

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

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