IN THE UNITED STATES DISTRICT COURT MIDDLE DISTRICT OF FLORIDA TAMPA DIVISION

FRANCIS T. HASSETT and KAY HASSETT, his wife,	
Plaintiffs,	Civil Action No
VS.	
HOWMEDICA OSTEONICS CORP., d/b/a STRYKER ORTHOPAEDICS,	JURY TRIAL DEMANDED
Defendant.	
/	

COMPLAINT

COME NOW, FRANCIS T. HASSETT and KAY HASSETT, Plaintiffs, by their undersigned counsel, and bring this complaint against the Defendant, HOWMEDICA OSTEONICS CORP., and allege:

1. This is an action for damages relating to Defendant's development, testing, assembling, manufacture, packaging, labeling, preparing, distribution, marketing, supplying, and/or selling the defective product 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. This Court has jurisdiction over this action pursuant to 28 U.S.C.§1332, because the amount in controversy exceeds \$75,000.00, exclusive of interest and costs, and because Defendants are all incorporated and have their principal places of business in states other than the state in which Plaintiffs reside.
- 3. Venue is proper in this Court pursuant to 28 USC §1391 because Defendant engaged in marketing, promoting, labeling, distributing, and sale of their product in each of the

fifty States in the United States, and specifically including Plaintiff's state of citizenship and the state or states in which Plaintiff used the Accolade Devices.

The Parties

- At times relevant hereto, Plaintiffs were and are citizens and residents of Bradenton,
 Manatee County, Florida, and are married and live together as husband and wife.
- 5. The Plaintiff, Francis T. Hassett, used Accolade Devices in his bilateral hips in both Massachusetts and Florida as hip replacements from approximately 2009 to 2016. This was an intended and foreseeable use of the Accolade Devices based on the advertising, marketing, and labeling of the Device.
- 6. Defendant, Howmedica Osteonics Corp., (hereinafter "Howmedica"), d/b/a STRYKER ORTHOPAEDICS is a corporation organized and existing under the laws of New Jersey, with its principal place of business located at 325 Corporate Drive, Mahwah, NJ 07430 and conducts business throughout the United States including in the States of New Jersey, Massachusetts, and Florida.
- 7. Howmedica Osteonics Corp. may be served with process by serving its registered agent, C.T. Corporation System, 1200 South Pine Island Road, Plantation, Florida 33324.
- 8. Venue in this District is proper because Plaintiff sustained injury in Massachusetts and Manatee County, Florida and Defendant conducts substantial business within this district and the State of Florida.

The Product

9. At all times material hereto, Defendant Stryker/Howmedica (hereinafter referred to collectively as "Defendant") developed, tested, assembled, manufactured, packaged, labeled, prepared, distributed, marketed, supplied, and/or sold the defective product sold under the name

"The Accolade TMZF Hip Stem and LFIT Anatomic V40 Femoral Head" (hereinafter "Accolade Stem" or "Defective Device"), either directly or indirectly, to members of the general public within the States of New Jersey, Massachusetts, and Florida, including Plaintiff, Francis T. Hassett.

- 10. On or about June 10, 2009, Plaintiff, Francis T. Hassett, underwent a right total hip replacement for osteoarthritis in that hip and was implanted with a 62mm Trident PSL acetabular shell, Ref. 542-11-62H, Lot 1EP04L; a 44mm Trident X3 poly liner, Ref. 623-00-44H, Lot MHE9TL; a 44mm LFIT V40 femoral head, Ref. 6260-9-444, Lot MDJMAD; a size 6 Accolade TMZF Plus femoral stem, Ref. 6021-0637, lot 28613401, and two 6.5mm cancellous bone screws.
- 11. On or about January 4, 2011, Plaintiff, Francis T. Hassett, underwent a left total hip replacement for osteoarthritis in that hip and was implanted with a 62mm Trident cluster hole acetabular shell, Ref. 502-03-62G, Lot MJPL1D; a 44mm Trident X3 poly liner, Ref. 623-00-44G, Lot MJN4DM; a 44mm LFIT V40 femoral head, Ref. 6260-9-244, Lot MJA8VJ; a size 6 Accolade TMZF Plus femoral stem, Ref. 6021-0637, lot 34326302; and two 6.5mm cancellous bone screws.
- 12. Both hip replacement components were manufactured, tested, packaged, marketed, distributed and sold by the Defendant.
- 13. After the implantation of the Defective Device, Plaintiff, Francis T. Hassett, began to experience discomfort in his bilateral hips, groin and buttock areas.
- 14. Initial diagnostic workup revealed the absence of device loosening, infection, malposition or any other explanation for the Plaintiff's symptoms.

- 15. As symptoms persisted, additional diagnostic workup revealed the presence of elevated metal ions in the patient's blood, and peritrochanteric fluid collections in both hips, suggestive of adverse local tissue reaction.
- 16. As a result, the Plaintiff was required to undergo bilateral hip revision surgeries on January 13, 2016 (right hip) and June 16, 2016 (left hip) at New England Baptist Hospital in Boston, Massachusetts. During both revision surgeries, adverse local tissue reaction (ALTR), corrosion, and metallosis were found.
- 17. As a direct and proximate result of Defendant placing the Defective Product into the stream of commerce, Plaintiff, Francis T. Hassett, 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 STRYKER ACCOLADE HISTORY

- 18. On March 16, 2000 Defendant received FDA clearance to sell its Accolade prosthetic hip system in the United States.
- 19. The Accolade system 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.
- 20. 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.

- 21. The titanium stem is manufactured utilizing a proprietary titanium allow consisting of titanium, molybdenum, zinc and iron. Howmedica's alloy was designed and patented by Defendant and is unlike any titanium alloy employed in the manufacture of other prosthetic hip implants. The Defendant claims in its promotional materials for the Accolade 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.
- 22. In March 2000, Stryker released its 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 approved for market between the years of 1994 and 1997.
- 23. According to Stryker's materials, the Accolade Stem was developed to maximize a patient's hip range of motion, increase stability, and prevent dislocation. These materials also state that the Accolade TMZF Hip Stem is designed to be used with V40 Femoral Heads, which are offered in both forged Vitallium alloy (CoCrMo) and zirconia ceramic. 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 proportional relative to the patient's body geometry to accommodate a wider patient population using a standard femoral head.
- 24. The stem is comprised of a femoral stem and neck component and offers a variety of femoral head options intraoperatively.
- 25. The Accolade Stem combines the material characteristics of TMZF (Ti-12Mo-6Zr-2Fe) with a plasma sprayed coating of PureFix HA for the stem and neck. One femoral head

commonly used with the Accolade TMZF Hip Stem is the LFIT Anatomic V40 Femoral Head, which is made from a cobalt/chromium alloy. Stryker claims that laboratory testing demonstrates the compatibility of these materials without concern for fretting and corrosion.

- 26. Despite Stryker's claims, this material combination has been reported to cause corrosion. For decades, scientists have reported the occurrence of significant fretting and corrosion issues when dissimilar metals are combined. In its marketing and sale of the device, Stryker represented and warranted that its proprietary materials alleviate this problem.
- 27. In 2012, Stryker recalled its Rejuvenate and ABG II modular hip systems. These two systems employed the same TMZF titanium metal in the femoral stem. The modular neck of both devices was manufactured from chromium/cobalt. These devices were recalled after reports surfaced indicating excessive device failure due to fretting and corrosion at the taper junction where these dissimilar metals were joined.
- 28. Patients in whom Stryker Rejuvenate and ABG II hip stems had been implanted were experiencing device failure, symptoms and diagnostic findings identical to Plaintiff, Francis T. Hassett. Information disseminated by Stryker at or about the time of the recall cited this failure mechanism as the reason for the recall.
- 29. Since the recall, revision rates for the Rejuvenate have been reported to exceed 50% in a very short period of time.
- 30. At or about the same Stryker recalled the Rejuvenate and ABG II, it redesigned its Accolade stem. Stryker abandoned use of TMZF titanium and instead manufactures its new Accolade II stem using a different titanium alloy.
- 31. Upon information and belief, Stryker has abandoned the use of TMZF titanium throughout its product line.

COUNT I Common Law Negligence

- 32. Plaintiffs reallege and incorporate by reference the allegations set forth in Paragraphs 1 through 31 above.
- 33. At all relevant times, Defendant designed, manufactured, marketed, detailed, and advertised the Accolade stem to both physicians and consumers.
- 34. 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 the devices would be implanted.
- 35. Defendant failed to use reasonable and due care for the safety and well-being of those in whom the device would be implanted and is therefore negligent in the following respects:
 - a. Defendant failed to adequately design and manufacture the device to insure that it would not fret, 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 chromium/cobalt heads;
 - ii. Poor design of the taper junction between femoral head and neck such that micro motion was predictable;
 - iii. Poor manufacturing practices such that the taper junction between the femoral head and neck do not "fit" as deigned and intended;
 - iv. Not restricting authorized or recommended use of the Accolade stem to ceramic heads only;
 - 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 device.
 - b. Defendant failed to adequately test the device to insure that it would not fret, corrode, erode, deteriorate and induce severe metal toxicity in the patient;

- c. Prior to marketing the Accolade, Defendant failed to conduct anything other than simple, basic bench testing. At the time Defendant designed the Accolade stem, sufficient scientific art and knowledge existed to conduct testing that would have exposed the defects in the Accolade stem when implanted in patients with the chromium/cobalt head;
- d. In fact, Stryker has likely conducted testing that reveals the incompatibility of these two materials when used in this design;
- e. Defendant 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 consumer;
- f. Defendant trained its sales force to detail the device utilizing representations that the Defendant knew or should have known were false, creating in the minds of both surgeons and consumers the belief that the device was safe for its intended use;
- g. Defendant specifically marketed the device as a safe alternative to metal on metal bearing surface devices that had been widely publicized as capable of causing premature failure due to heavy metal toxicity;
- h. Defendant failed to manufacture the product to Defendant's own internal specifications such that the taper junction between the neck and stem prematurely failed causing metal debris cast-off and severe metal toxicity in patients;
- i. Defendant failed to adequately test the TMZF alloy's compatibility with chrome cobalt components in an effort to prevent corrosion and fretting at the bearing surface junction of this stem;
- j. Defendant failed to promptly act upon reports of failure or warn surgeons such that the device continued to be implanted in combination with chromium/cobalt femoral heads or sleeves in patients by surgeons well after it should have been recalled or redesigned;
- 36. The above conduct exhibits Defendant's failure to exercise reasonable care. It was foreseeable that such negligence would lead to premature device failure as well as severe, debilitating injury that is permanent.
- 37. As a direct and proximate result of the Defendant's negligence, Plaintiff, Francis T. Hassett, was implanted with bilateral Stryker hip systems with Accolade hip stems coupled with

LFIT Anatomic V40 Femoral Heads and suffered severe physical pain and suffering, emotional distress, mental anguish, loss of the capacity for the enjoyment of life, and has incurred medical, surgical and nursing expenses. These damages have occurred in the past and will continue into the future.

COUNT II Strict Liability - Failure to Warn

- 38. Plaintiffs reallege and incorporate by reference the allegations set forth in Paragraphs 1 through 31 above.
- 39. The Accolade Stem implanted into Plaintiff contained no warnings or in the alternative, inadequate warnings as to the risk that the product could cause significant heavy metal toxicity.
- 40. The Accolade Stem implanted into Plaintiff contained no warnings that it should not be implanted with chromium/cobalt femoral heads or sleeves which posed a significantly increased risk of fretting, corrosion and heavy metal toxicity in patients.
- 41. The warnings that accompanied the Accolade Stem failed to provide that level of information that an ordinary consumer would expect when using the Accolade implant in a manner reasonably foreseeable to the Defendant.
- 42. Had Plaintiff, Francis T. Hassett, or his surgeon, received a proper or adequate warning as to the risks associated with using the Accolade implant, Plaintiff would not have agreed to be implanted with the product.
- 43. Reasonable and adequate alternatives to chromium/cobalt femoral heads existed at the time Plaintiff was implanted with his Accolade stem.
- 44. 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, he would not have recommended the device; or would have used an alternate device; or at a minimum, provided Plaintiff with adequate warning and obtained his informed consent.

45. As the result of Defendant's failure to provide adequate warning as to the Accolade's unreasonable risk of serious injury and damage, Plaintiff was implanted with bilateral Stryker hips with Accolade stems coupled with LFIT Anatomic V40 Femoral Heads, and suffered bodily injury, pain and suffering, disability, physical impairment, disfigurement, mental anguish, inconvenience, loss of the capacity for the enjoyment of life, and costs of medical care and expenses, all of which damage and losses will continue in the future.

WHEREFORE, Plaintiff, Francis T. Hassett, respectfully requests that he be granted relief against Defendant, as contained in the Prayer For Relief.

COUNT III Strict Liability -Design Defect

- 46. Plaintiffs reallege and incorporate by reference the allegations set forth in Paragraphs 1 through 31 above.
 - 47. This is an action based upon design defect against Defendant.
- 48. Integral to the design of the Accolade stem was its compatibility with Stryker's chromium/cobalt femoral head.
- 49. Defendant's Accolade Stem is designed in such a way that, when used as intended in combination with a chromium/cobalt femoral head, it causes serious, permanent and devastating damage to patients in which it is implanted. The damage and mechanism of injury have been previously described.
- 50. When combined with a chromium/cobalt femoral head, Defendant's Accolade Stem does not perform as safely as an ordinary consumer would expect when used as intended or in a manner reasonably foreseeable to Defendant.

- 51. The risks of using Defendant's Accolade Stems in combination with chromium/cobalt femoral heads outweigh the benefits of using them.
- 52. The Accolade Stems that were implanted into Plaintiff's hips were defectively designed.
- 53. As the result of the defective design of Defendant's Accolade Stem, Plaintiff, Francis T. Hassett, was implanted with bilateral Stryker hip systems with Accolade stems coupled with LFIT Anatomic V40 Femoral Heads and suffered bodily injury, pain and suffering, disability, physical impairment, disfigurement, mental anguish, inconvenience, aggravation of a preexisting condition, loss of the capacity for the enjoyment of life, and costs of medical care and expenses, all of which damage and losses will continue in the future.

WHEREFORE, Plaintiff, Francis T. Hassett, respectfully requests that he be granted relief against Defendant, as contained in the Prayer For Relief.

COUNT IV Strict Liability - Manufacturing Defect

- 54. Plaintiffs reallege and incorporate by reference the allegations set forth in Paragraphs 1 through 31 above.
 - 55. This is an action based on a manufacturing defect against both Defendants.
- 56. The Accolade Stem is designed for implantation into the human body and to last fifteen or more years. It is also designed to be compatible with human tissue and bone.
- 57. The Accolade Stem implanted in the Plaintiff failed prematurely as previously described.
- 58. The Accolade Stems installed in Plaintiff's hips were combined with Stryker's chromium/cobalt femoral heads.
 - 59. The Accolade TMZF titanium stem was manufactured in a substandard manner

such that either:

- a. The taper was poorly fashioned so that it did not "fit;"
- b. The TMZF titanium material was fashioned in such a manner that it did not maintain structural integrity when implanted in the biologic environment:
- c. 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;
- d. The LFIT Anatomic V40 chromium/cobalt femoral head was manufactured such that it did not "fit";
- e. The LFIT Anatomic V40 chromium/cobalt femoral head was fashioned in such a manner that it did not maintain structural integrity when implanted in the biologic environment;
- f. The LFIT Anatomic V40 chromium/cobalt femoral head was fashioned in such a manner that it did not maintain structural integrity when mated with a chromium/cobalt femoral head.
- 60. This combination was not compatible with human tissue and bone. Through a process of fretting and corrosion it released heavy metals into the Plaintiff's body causing severe and permanent destruction of bone and tissue. Defendant failed to manufacture the product in a manner that prevented fretting and corrosion and, in fact, manufactured the product such that it caused fretting and corrosion.
- 61. The Accolade Stems coupled with LFIT Anatomic V40 Femoral Heads installed in Plaintiff's bilateral hips contained manufacturing defects.
- 62. The manufacturing defect in the Accolade Stems caused serious damage to Plaintiff including bodily injury, pain and suffering, disability, physical impairment, disfigurement, mental anguish, inconvenience, aggravation of a preexisting condition, loss of the capacity for the enjoyment of life, and costs of medical care and expenses, all of which damage and losses will continue in the future.

WHEREFORE, Plaintiff, Francis T. Hassett, respectfully requests that he be granted relief against Defendant, as contained in the Prayer For Relief.

PUNITIVE DAMAGES UNDER COMMON LAW,

- 63. Plaintiff incorporates by reference all of the paragraphs above, as though fully set forth herein.
- 64. At all times material hereto, the Defendant knew or should have known that the Accolade Stem product was inherently more dangerous with respect to the risk of fretting and corrosion and a shorter life span and need for additional surgeries than the alternative hip replacement stems on the market.
- 65. At all times material hereto, the Defendant attempted to misrepresent and did misrepresent facts concerning the safety of the subject product.
- 66. Defendant's 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 product.
- 67. At all times material hereto, the Defendant knew and recklessly disregarded the fact that the Accolade Stem was subject to causing fretting and corrosion in persons implanted with the device with far greater frequency than safer alternative hip replacement stems.
- 68. Notwithstanding the foregoing, the Defendant continued to aggressively market the subject product without disclosing the aforesaid side effects when there were safer alternative methods.
- 69. The Defendant knew of the subject product's defective and unreasonably dangerous nature, as set forth herein, but continued to design, develop, manufacture, market, distribute and

sell it 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.

- 70. The Defendant's intentional and/or reckless, fraudulent and malicious failure to disclose information deprived the Plaintiff, Francis T. Hassett, and his surgeon of necessary information to enable them to weigh the true risks against the benefits of using the subject product.
- 71. As a direct and proximate result of the Defendant's conscious and deliberate disregard for the rights and safety of consumers such as the Plaintiff, Francis T. Hassett, was implanted with bilateral Stryker hip systems with chromium/cobalt femoral head and Accolade stems, and suffered severe and permanent physical injuries as set forth above.
- 72. The aforesaid conduct of Defendant was committed with knowing, conscious, and deliberate disregard for the rights and safety of consumers, including the Plaintiff herein, thereby entitling the Plaintiff to punitive damages in an amount appropriate to punish the Defendant and deter it from similar conduct in the future.
- 73. Defendant's 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, Plaintiffs demand judgment against Defendant 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, the Plaintiff prays for judgment against the Defendant as follows:

- a. Awarding compensatory damages resulting from Defendant's negligence and for strict liability.
 - c. Awarding actual damages to the Plaintiff incidental to Francis T. Hassett's purchase and use of the Accolade Stem in an amount to be determined at trial;
 - d. Awarding punitive damages to the Plaintiff;
 - e. Awarding pre-judgment and post-judgment interest to the Plaintiff;
 - f. Awarding the costs and the expenses of their litigation to the Plaintiff;
 - g. Awarding reasonable attorneys' fees and costs to the Plaintiff as provided by law; and
 - h. 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.

Dated: 1/23/17

Respectfullysubmitted

Joseph H. Saunders

SAUNDERS & WALKER, P.A.

3491 Gandy Blvd. North, Ste. 200

Pinellas Park, FL 33781

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Counsel for Plaintiffs

JS 44 (Rev. 12/12)

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.)

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I. (a) PLAINTIFFS				DEFENDANTS				
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(b) County of Residence of First Listed Plaintiff Manatee (EXCEPT IN U.S. PLAINTIFF CASES) (c) Attorneys (Firm Name, Address, and Telephone Number) Joseph H. Saunders, Saunders & Walker, P.A., 3491 Gandy Blvd Ste. 200, Pinellas Park, FL 33781, (727) 579-4500				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) North,				
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IV. NATURE OF SUIT			l Rd	DEFITIOE/PENALTY	T BAN	INDIIDTOV	OTHED STATISTES	
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	moved from 3 ate Court Cite the U.S. Civil Sta 28 USC 1332 Brief description of ca Action for damag	Appellate Court stute under which you ar ause:	Reoper filing (i	istated or 5 Transfer Anothe (specify) Do not cite jurisdictional start to defective hip prosessments.	r District hutes unless di ethesis.			
COMPLAINT: VIII. RELATED CASI	UNDER RULE 2					URY DEMAND:	• .	
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