

**IN THE UNITED STATES DISTRICT COURT FOR THE
MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION**

DONALD RAY LOVELL,)
)
 Plaintiff,)
)
 v.) **No.** _____)
)
 HOWMEDICA OSTEONICS)
 d/b/a STRYKER ORTHOPAEDICS,)
 STRYKER CORPORATION,)
 STRYKER SALES CORPORATION,)
 and STRYKER IRELAND LIMITED,)
)
 Defendants.) **JURY DEMAND**

COMPLAINT

COMES NOW Plaintiff DONALD RAY LOVELL (“Plaintiff”) by and through the undersigned counsel, and brings this Complaint against Defendants, HOWMEDICA OSTEONICS d/b/a STRYKER ORTHOPAEDICS, STRYKER CORPORATION, STRYKER SALES CORPORATION, and STRYKER IRELAND LIMITED (“Defendants”, “Stryker”, “Stryker Defendants”) 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 TMZF[®] Hip Stem” and “LFIT[™] Anatomic CoCR V40[™] femoral heads” sold under the name “LFIT Anatomic CoCR V40 femoral heads” (“Defective Devices”).

PARTIES, JURISDICTION AND VENUE

2. Plaintiff is a resident of Madison, Davidson County, Tennessee. Plaintiff was implanted with Defective Devices on or about March 6, 2014, at Centennial Medical Center, Nashville, Tennessee.

3. Defendant, Howmedica Osteonics Corporation, (“Howmedica”), d/b/a Stryker Orthopaedics, is a foreign corporation organized and existing under the laws of the State 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 State of Tennessee. Defendant Howmedica Osteonics d/b/a Stryker Orthopaedics is a wholly owned subsidiary of parent corporation, Stryker Corporation.

4. Defendant, Stryker Corporation (hereinafter “Stryker”) is a foreign corporation organized and existing under the laws of the State 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 State of Tennessee. Stryker holds itself out as “one of the world’s leading medical technologies companies and is dedicated to helping healthcare professionals perform their jobs more efficiently while enhancing patient care. Stryker provides innovative orthopaedic implants as well as state-of-the-art medical and surgical equipment to help people lead more active and more satisfying lives.” www.stryker.com.

5. Defendant Stryker Sales Corporation is a corporation organized and existing under the laws of the State of Michigan having its principal place of business located at 2825 Airview Boulevard, Kalamazoo, Michigan 49002 and conducts business throughout the United States, including the State of Tennessee. Stryker Sales Corporation is a wholly owned subsidiary of Stryker Corporation and it employs field representatives throughout the United States.

6. Defendant Stryker Ireland Limited is a foreign corporation that is also a wholly owned subsidiary of Stryker Corporation. Stryker Ireland Limited has three (3) facilities located in Ireland (two (2) in Cork and one (1) in Limerick) and employs approximately 1,200 people in total. These sites are held out at “centers of excellence” in R&D, Manufacturing and Customer

Service. Stryker Ireland Limited's product profile includes: Hip Replacement Systems, Knee Replacement Systems, Bone Cement and Precise Cutting Accessories including Micro Rotary instruments and Bone Saw Blades. Stryker develops minimally invasive surgical instruments which are used for cutting, drilling, burring and shaping of bone and soft tissue. Upon information and belief, these products are used during Orthopaedic, Ear Nose and Throat (ENT), Spine, Neuro and Plastic Surgeries. Much of the research and design and manufacturing of the Devices at issue in this litigation occurred at Stryker Ireland Limited before moving the operation to Howmedica Osteonics in Mahwah, New Jersey.

7. The Devices manufactured at Stryker Ireland were sold throughout the United States and in the State of Tennessee.

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

9. 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 the State of Tennessee and Defendants systematically and continually conduct business here and conduct business throughout the United States.

10. Venue of this case is appropriate in the United States District Court for the Middle District of Tennessee because Plaintiff resides in the District and Defendants conduct business and have places of business in the District.

THE PRODUCTS

11. At all times material hereto, Defendants Howmedica and Stryker (“Stryker Defendants”) developed, tested, assembled, manufactured, packaged, labeled, prepared, distributed, marketed, supplied, and/or sold the defective products under the names “The Accolade TMZF[®] Hip Stem” and “LFIT[™] Anatomic CoCR V40[™] femoral heads”, either directly or indirectly, to members of the general public within the State of Tennessee and elsewhere, including Plaintiff, Donald Ray Lovell.

12. Defendants’ Defective Devices were placed into the stream of interstate commerce and were implanted in Plaintiff Donald Ray Lovell on March 6, 2014.

13. As a direct and proximate result of Defendants placing the Defective Products into the stream of commerce, Plaintiff Donald Ray Lovell 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.

FACTUAL ALLEGATIONS

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

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

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

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

17. 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.

18. The Accolade TMZF[®] Hip Stem and LFIT Anatomic V40 Femoral Head are two (2) parts of a total hip replacement system.

19. On March 16, 2000, Stryker Defendants received FDA clearance to sell its Accolade prosthetic hip stem in the United States.

20. 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.

21. The Accolade TMZF Stem is hip replacement prosthesis. It is indicated for patients requiring primary total hip arthroplasty or replacement due to joint disease.

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

23. Stryker's L-FIT Anatomic V40 femoral head is one of the modular balls or heads designed to be used with the Accolade TMZF Stem. It is made of chromium/cobalt alloy.

24. The titanium stem is manufactured utilizing a proprietary titanium alloy consisting of titanium, molybdenum, zinc and iron. Howmedica's alloy was designed and patented by Defendant and is different than the titanium alloy employed in the manufacture of prosthetic hip implants. Defendants claim in their Accolade TMZF Stem promotional materials that TMZF 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 Defendants to resist the effects of corrosion and fretting.

25. At all times material hereto, the Accolade TMZF Stem and L-FIT Anatomic V40 femoral head implanted in Plaintiff was designed, manufactured, marketed, retailed, distributed, and/or supplied by Defendants.

26. After the implantation of the Defective Devices, Plaintiff Donald Ray Lovell began experiencing discomfort in the area of his Defective Devices.

27. Initial diagnostic workup of Plaintiff revealed a marked elevation of serum cobalt, chromium and titanium.

28. As a result, Plaintiff was forced to have the device surgically removed. Upon removal, it was apparent the device had failed causing gross deformation of the Accolade TMZF Stem together with severe and permanent tissue and muscle damage.

THE STRYKER ACCOLADE HISTORY

29. 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, and the Osteonics Omnifit AD-HA Hip Stem Series all cleared for market between the years of 1994 and 1997.

30. According to Stryker's materials, the Accolade TMZF Stem was developed to maximize a patient's hip range of motion, increase stability, and prevent dislocation. These materials also state that the Accolade TMZF 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 TMZF Stem is also designed with two neck angles, the standard 132 degrees and extended 127 degrees offset, to assist with joint stability and proper restoration of joint kinematics without lengthening the leg. The neck lengths are proportional relative to the patient's body geometry to accommodate a wider patient population using a standard femoral head.

31. The Accolade TMZF Stem combines the material characteristics of TMZF (Ti-12Mo-6Zr-2Fe) with plasma sprayed ingrowth/on growth coating of PureFix HA. The LFIT Anatomic V40 Femoral Head was commonly used with the Accolade TMZF Hip Stem. It is made from a chromium/cobalt alloy. Defendants claim that laboratory testing demonstrates the compatibility of these materials without concern for fretting and corrosion.

32. Despite Defendants' claims, this material combination has been reported to cause corrosion. For decades, scientists have reported the occurrence of accelerated fretting and corrosion issues when dissimilar metals are combined. In their marketing and sale of the device, Defendants represented and warranted that proprietary materials alleviate concerns for this problem.

33. 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 recalled devices were 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.

34. Patients in whom Stryker Rejuvenate and ABG II hip stems had been implanted were experiencing device failure, symptoms and diagnostic findings identical to Plaintiff, Donald Ray Lovell. Information disseminated by Stryker at or about the time of the recall cited this failure mechanism as the reason for the recall.

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

36. At or about the same time Stryker recalled the Rejuvenate and ABG II, it redesigned its Accolade TMZF Stem. Stryker abandoned use of TMZF titanium and, instead, its new Accolade II stem is manufactured from a different titanium alloy.

37. Upon information and belief, Stryker has abandoned the use of TMZF titanium through its product line.

38. In addition, Stryker has now recalled a large number of L-FIT Anatomic V40 chromium/cobalt heads. The recall cites gross trunnion failure, metal wear, adverse tissue reaction and the need for revision surgery as causes for recalling the heads. Plaintiff suffered each of the above and the combination resulted in the need to surgically remove his Accolade TMZF Stem and L-FIT Anatomic V40 head.

CAUSES OF ACTION

COUNT I - NEGLIGENCE

39. Plaintiff realleges and incorporates by reference the allegations set forth above.

40. Defendants designed, manufactured, marketed, detailed, and advertised both the Accolade TMZF Stem and L-FIT Anatomic V40 head to physicians and consumers.

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

42. Defendants 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) Defendants failed to adequately design and manufacture the devices to insure that when combined each 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) Use of the TMZF alloy that contains a modulus of elasticity with far inferior stiffness characteristics to other available titanium alloys;

(iii) Use of the TMZF alloy with a known corrosion/fretting profile inferior to other titanium alloys;

(iv) Poor design of the taper junction between femoral head and neck such that micro motion was predictable;

(v) Poor design of the Accolade neck such that the “softer” TMZF alloy would induce suffer from excessive bending and movement;

(vi) Poor manufacturing practices such that the taper junction between the femoral head and neck do not “fit” as deigned and intended;

(vii) TMZF Stem to ceramic heads only;

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

(ix) 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) Defendants failed to adequately test the Defective Devices and their combination to insure they would not fret, corrode, erode, deteriorate and induce severe metal toxicity in the patient;

(c) Prior to marketing the Defective Devices, Defendants failed to conduct anything other than simple, basic bench testing. At the time Defendants designed the Defective Devices, sufficient scientific art and knowledge existed to conduct testing that would have exposed the defects in the Accolade TMZF 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 (2) materials when used in this design;

(e) Defendants made affirmative representations that the Defective Devices would not fret or corrode in the human body. These representations were false and misleading to both physicians and the consumer;

(f) Defendants trained its sales force to detail the Defective Devices utilizing representations Defendants knew or should have known to be false, creating in the minds

of both surgeons and consumers the belief that the Defective Devices were safe for its intended use;

(g) Defendants specifically marketed the Defective Devices as a safe alternative to metal-on-metal bearing surface Defective Devices that had been widely publicized as capable of causing premature failure due to heavy metal toxicity;

(h) Defendants failed to manufacture the products to Defendants' 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) Defendants failed to adequately test the TMZF alloy's compatibility with chromium/cobalt components in an effort to prevent corrosion and fretting at the bearing surface junction of this stem;

(j) Defendants 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 well after it should have been recalled or redesigned; and

(k) Defendants chose these materials to be used in combination as a system at a time when safer alternative designs and materials were available.

43. The above conduct exhibits Defendants' 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.

44. As a direct and proximate result of Defendants' negligence, Plaintiff suffered severe physical pain and suffering, emotional distress, mental anguish, loss of the capacity for the enjoyment of life, medical and nursing expenses, surgical expenses, lost wages and loss of earning capacity. These damages have occurred in the past and will continue into the future.

COUNT II – BREACH OF EXPRESS WARRANTY

45. Plaintiff realleges and incorporates by reference the allegations set forth above as if set forth herein.

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

47. Through its public statements and descriptions of the L-FIT Anatomic V40 heads and its promises relating to the these heads, Defendants expressly warranted among other things that the L-FIT Anatomic V40 heads were efficacious and safe for their intended use and were designed and constructed of materials that would prevent fretting and corrosion and would provide superior component longevity to or over competing products.

48. These warranties came in the form of (i) publicly made written and verbal assurances of safety; (ii) press releases and dissemination via the media of uniform promotional information that was intended to create demand for the Accolade TMZF Stem and L-FIT Anatomic V40 heads, but which contained material misrepresentations and failed to warn of the risks of the Accolade TMZF Stem and L-FIT Anatomic V40 heads; (iii) verbal assurances made by Defendants' consumer relations personnel to the public about the safety of the Accolade TMZF Stem and L-FIT Anatomic V40 heads and the downplaying of the risks associated with the Accolade TMZF Stem and L-FIT Anatomic V40 heads; and (iv) false and misleading written information supplied by Defendants.

49. Plaintiff further alleges that all of the aforementioned written materials are known to Defendants and in its possession, and it is Plaintiff's reasonable belief that these materials shall be produced by Defendants and be made of record once Plaintiff is afforded the opportunity to conduct discovery.

50. When Defendants made these express warranties, Defendants knew the purpose for which Accolade TMZF Stem and L-FIT Anatomic V40 heads were to be used and warranted them to be in all respects safe and proper for such purpose including their use in combination.

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

52. The Accolade TMZF Stem and L-FIT Anatomic V40 heads do not conform to Defendants' representations in that their use in combination is not safe and produces serious side effects.

53. As such, the Accolade TMZF Stem and L-FIT Anatomic V40 heads did not conform to Defendants' promises, descriptions or affirmations of fact and were not adequately packaged, labeled, promoted or fit for the ordinary purposes for which such Defective Devices are used.

54. Defendants, therefore, breached their express warranties to Plaintiff in violation of both Tennessee statutory and common law by manufacturing, marketing and selling the Accolade TMZF Stem and L-FIT Anatomic V40 heads to Plaintiff causing damages as will be established at trial.

COUNT III – STRICT LIABILITY – FAILURE TO WARN

55. Plaintiff realleges and incorporates by reference the allegations set forth above as if set forth herein.

56. The Accolade TMZF 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.

57. The Accolade TMZF Stem implanted into Plaintiff contained no warnings that it should not be implanted with chromium/cobalt femoral heads which posed significant increased risk of fretting, corrosion and heavy metal toxicity in patients.

58. The warnings that accompanied the Accolade TMZF 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 Defendants. This made the product unreasonably dangerous.

59. The corollary is also true. The L-FIT Anatomic V40 head implanted into Plaintiff contained no warnings.

60. Had Plaintiff or his surgeon received a proper or adequate warning as to the risks associated with using the Accolade and L-FIT Anatomic V40 heads, the product would not have been used.

61. Reasonable and adequate alternatives to chromium/cobalt femoral heads existed at the time Plaintiff was implanted with his Accolade TMZF Stem and L-FIT Anatomic V40 heads.

62. Had Plaintiff's surgeon received a proper or adequate warning as to the risks associated with using the Accolade TMZF Stem and its combination with chromium/cobalt femoral heads, he would not have recommended the device; would have used an alternate device or at a minimum, provided Plaintiff with adequate warning and obtained his informed consent. As stated above, had Plaintiff received an adequate warning, Plaintiff would not have agreed to have the Accolade implanted or would have demanded that the Accolade be combined with a ceramic femoral head.

63. The failure to warn of the Accolade and L-FIT Anatomic V40 head's risks 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, the costs of medical care and expenses, loss of earnings and loss of the ability to earn money, all of which damages and losses will continue in the future.

COUNT IV - STRICT LIABILITY - DESIGN DEFECT

64. Plaintiff realleges and incorporates by reference the allegations set forth above as if set forth herein.

65. This is an action based upon design defect against Defendants.

66. Integral to the design of the Accolade TMZF Stem was its compatibility with Stryker's chromium/cobalt L-FIT Anatomic V40 femoral heads.

67. Defendants' Accolade TMZF Stem is designed in such a way that, when used as intended in combination with L-FIT Anatomic V40 chromium/cobalt femoral heads, it causes serious, permanent and devastating damage to patients in which it is implanted. The damage and mechanism of injury have been previously described.

68. When combined with L-FIT Anatomic V40 chromium/cobalt femoral heads, Defendants' Accolade TMZF Stems do not perform as safely as an ordinary consumer would expect when used as intended or in a manner reasonably foreseeable to Defendants.

69. The risks of using Defendants' Accolade TMZF Stems in combination with L-FIT Anatomic V40 heads chromium/cobalt femoral heads outweigh the benefits of using them.

70. The Accolade TMZF Stem and L-FIT Anatomic V40 head installed in Plaintiff's hip was defectively designed and unreasonably dangerous.

71. The design defect in Defendants' Accolade TMZF Stem and L-FIT Anatomic V40 head 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, the costs of medical care and expenses, loss of earnings and loss of the ability to earn money, all of which damage and losses will continue in the future.

COUNT V - STRICT LIABILITY - MANUFACTURING DEFECT

72. Plaintiff realleges and incorporates by reference the allegations set forth above as if set forth herein.

73. This is an action based on a manufacturing defect against Defendants.

74. The Accolade TMZF Stem and L-FIT Anatomic V40 heads are designed for implantation into the human body and to last fifteen (15) or more years. They are also designed to be compatible with human tissue and bone.

75. The Accolade TMZF Stem and L-FIT Anatomic V40 head implanted in Plaintiff prematurely failed as previously described.

76. The Accolade TMZF titanium stem was manufactured in a substandard manner such that either:

- (a) The tapers were poorly manufactured so that they 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 chromium/cobalt femoral head was manufactured such that it did not "fit;"

(e) The chromium/cobalt femoral head was fashioned in such a manner that it did not maintain structural integrity when implanted in the biologic environment; and

(f) The 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.

77. This combination was not compatible with human tissue and bone. Through a process of fretting and corrosion, it released heavy metals into Plaintiff's body causing severe and permanent destruction of bone and tissue. Defendants 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.

78. The Accolade TMZF Stem and L-FIT Anatomic V40 head installed in Plaintiff's hip contained a manufacturing defect and was unreasonably dangerous.

79. The manufacturing defect in the Accolade TMZF Stem and L-FIT Anatomic V40 head 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, the costs of medical care and expenses, loss of earnings and loss of the ability to earn money, all of which damage and losses will continue in the future.

80. As a direct and proximate result of Defendants placing the Defective Devices 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.

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

82. The Defect Devices reached Plaintiff without substantial change in its condition when it left the possession of Defendants and was used in the manner for which it was intended.

83. The Defective Devices were defective and unreasonably dangerous when Defendants placed them into the stream of commerce.

84. Plaintiff received a recall notice from Stryker on or about August 30, 2016, which stated, “Stryker has initiated a voluntary medical device recall for the following Femoral Heads” which included Plaintiff’s model names and numbers. Plaintiff’s action is filed well within the applicable statutory limitations period.

85. Defendants are and were under a continuing duty to monitor and disclose the true character, quality, and nature of its Defective Devices. 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.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment against Defendants as follows:

a. Awarding compensatory damages resulting from Defendants’ breach of warranty, negligence, and for strict liability;

b. Awarding actual damages to Plaintiff Donald Ray Lovell incidental to his purchase and use of the “The Accolade TMZF[®] Hip Stem” and “LFIT[™] Anatomic CoCR V40[™] femoral heads” in an amount to be determined at trial;

c. Awarding punitive damages to Plaintiff;

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

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

DONALD RAY LOVELL

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



DEFENDANTS

HOWMEDICA OSTEONICS d/b/a STRYKER ORTHOPAEDICS, STRYKER CORPORATION, et al.

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
- 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)

	PTF	DEF		PTF	DEF
Citizen of This State	<input checked="" type="checkbox"/> 1	<input type="checkbox"/> 1	Incorporated or Principal Place of Business In This State	<input type="checkbox"/> 4	<input type="checkbox"/> 4
Citizen of Another State	<input type="checkbox"/> 2	<input type="checkbox"/> 2	Incorporated and Principal Place of Business In Another State	<input type="checkbox"/> 5	<input checked="" type="checkbox"/> 5
Citizen or Subject of a Foreign Country	<input type="checkbox"/> 3	<input type="checkbox"/> 3	Foreign Nation	<input type="checkbox"/> 6	<input type="checkbox"/> 6

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

Click here for: [Nature of Suit Code Descriptions.](#)

CONTRACT	TORTS	FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES
<input type="checkbox"/> 110 Insurance <input type="checkbox"/> 120 Marine <input type="checkbox"/> 130 Miller Act <input type="checkbox"/> 140 Negotiable Instrument <input type="checkbox"/> 150 Recovery of Overpayment & Enforcement of Judgment <input type="checkbox"/> 151 Medicare Act <input type="checkbox"/> 152 Recovery of Defaulted Student Loans (Excludes Veterans) <input type="checkbox"/> 153 Recovery of Overpayment of Veteran's Benefits <input type="checkbox"/> 160 Stockholders' Suits <input type="checkbox"/> 190 Other Contract <input type="checkbox"/> 195 Contract Product Liability <input type="checkbox"/> 196 Franchise	PERSONAL INJURY <input type="checkbox"/> 310 Airplane <input type="checkbox"/> 315 Airplane Product Liability <input type="checkbox"/> 320 Assault, Libel & Slander <input type="checkbox"/> 330 Federal Employers' Liability <input type="checkbox"/> 340 Marine <input type="checkbox"/> 345 Marine Product Liability <input type="checkbox"/> 350 Motor Vehicle <input type="checkbox"/> 355 Motor Vehicle Product Liability <input type="checkbox"/> 360 Other Personal Injury <input type="checkbox"/> 362 Personal Injury - Medical Malpractice	<input type="checkbox"/> 365 Personal Injury - Product Liability <input checked="" type="checkbox"/> 367 Health Care/Pharmaceutical Personal Injury Product Liability <input type="checkbox"/> 368 Asbestos Personal Injury Product Liability PERSONAL PROPERTY <input type="checkbox"/> 370 Other Fraud <input type="checkbox"/> 371 Truth in Lending <input type="checkbox"/> 380 Other Personal Property Damage <input type="checkbox"/> 385 Property Damage Product Liability	<input type="checkbox"/> 422 Appeal 28 USC 158 <input type="checkbox"/> 423 Withdrawal 28 USC 157 PROPERTY RIGHTS <input type="checkbox"/> 820 Copyrights <input type="checkbox"/> 830 Patent <input type="checkbox"/> 835 Patent - Abbreviated New Drug Application <input type="checkbox"/> 840 Trademark SOCIAL SECURITY <input type="checkbox"/> 861 HIA (1395ff) <input type="checkbox"/> 862 Black Lung (923) <input type="checkbox"/> 863 DIWC/DIWW (405(g)) <input type="checkbox"/> 864 SSID Title XVI <input type="checkbox"/> 865 RSI (405(g))	<input type="checkbox"/> 375 False Claims Act <input type="checkbox"/> 376 Qui Tam (31 USC 3729(a)) <input type="checkbox"/> 400 State Reapportionment <input type="checkbox"/> 410 Antitrust <input type="checkbox"/> 430 Banks and Banking <input type="checkbox"/> 450 Commerce <input type="checkbox"/> 460 Deportation <input type="checkbox"/> 470 Racketeer Influenced and Corrupt Organizations <input type="checkbox"/> 480 Consumer Credit <input type="checkbox"/> 490 Cable/Sat TV <input type="checkbox"/> 850 Securities/Commodities/Exchange <input type="checkbox"/> 890 Other Statutory Actions <input type="checkbox"/> 891 Agricultural Acts <input type="checkbox"/> 893 Environmental Matters <input type="checkbox"/> 895 Freedom of Information Act <input type="checkbox"/> 896 Arbitration <input type="checkbox"/> 899 Administrative Procedure Act/Review or Appeal of Agency Decision <input type="checkbox"/> 950 Constitutionality of State Statutes
REAL PROPERTY	CIVIL RIGHTS	PRISONER PETITIONS	FEDERAL TAX SUITS	
<input type="checkbox"/> 210 Land Condemnation <input type="checkbox"/> 220 Foreclosure <input type="checkbox"/> 230 Rent Lease & Ejectment <input type="checkbox"/> 240 Torts to Land <input type="checkbox"/> 245 Tort Product Liability <input type="checkbox"/> 290 All Other Real Property	<input type="checkbox"/> 440 Other Civil Rights <input type="checkbox"/> 441 Voting <input type="checkbox"/> 442 Employment <input type="checkbox"/> 443 Housing/Accommodations <input type="checkbox"/> 445 Amer. w/Disabilities - Employment <input type="checkbox"/> 446 Amer. w/Disabilities - Other <input type="checkbox"/> 448 Education	Habeas Corpus: <input type="checkbox"/> 463 Alien Detainee <input type="checkbox"/> 510 Motions to Vacate Sentence <input type="checkbox"/> 530 General <input type="checkbox"/> 535 Death Penalty Other: <input type="checkbox"/> 540 Mandamus & Other <input type="checkbox"/> 550 Civil Rights <input type="checkbox"/> 555 Prison Condition <input type="checkbox"/> 560 Civil Detainee - Conditions of Confinement	<input type="checkbox"/> 870 Taxes (U.S. Plaintiff or Defendant) <input type="checkbox"/> 871 IRS—Third Party 26 USC 7609	
			LABOR	
			<input type="checkbox"/> 625 Drug Related Seizure of Property 21 USC 881 <input type="checkbox"/> 690 Other <input type="checkbox"/> 710 Fair Labor Standards Act <input type="checkbox"/> 720 Labor/Management Relations <input type="checkbox"/> 740 Railway Labor Act <input type="checkbox"/> 751 Family and Medical Leave Act <input type="checkbox"/> 790 Other Labor Litigation <input type="checkbox"/> 791 Employee Retirement Income Security Act	
			IMMIGRATION	
			<input type="checkbox"/> 462 Naturalization Application <input type="checkbox"/> 465 Other Immigration Actions	

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 USC Sec. 1332 (a) (1)

Brief description of cause:

Personal injuries as a result of failed prosthesis

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

08/17/2017

SIGNATURE OF ATTORNEY OF RECORD



FOR OFFICE USE ONLY

RECEIPT #

UNITED STATES DISTRICT COURT

for the

Middle District of Tennessee

DONALD RAY LOVELL

Plaintiff

v.

HOWMEDICA OSTEONICS d/b/a
STRYKER ORTHOPAEDICS, et al.

Defendant

Civil Action No. 3:17-cv-1168

SUMMONS IN A CIVIL ACTION

To: (Defendant's name and address) HOWMEDICA OSTEONICS CORP.
c/o C T Corporation System
800 S Gay Street, Suite 2021
Knoxville, TN 37929-9710

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:



If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

KEITH THROCKMORTON
CLERK OF COURT

Signature of Clerk or Deputy Clerk

Date: August 17, 2017

Civil Action No. _____

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* HOWMEDICA OSTEONICS CORP. (TN)
was received by me on *(date)* _____ .

I personally served the summons on the individual at *(place)* _____
_____ on *(date)* _____ ; or

I left the summons at the individual's residence or usual place of abode with *(name)* _____
_____, a person of suitable age and discretion who resides there,
on *(date)* _____, and mailed a copy to the individual's last known address; or

I served the summons on *(name of individual)* _____, who is
designated by law to accept service of process on behalf of *(name of organization)* _____
_____ on *(date)* _____ ; or

I returned the summons unexecuted because _____ ; or

Other *(specify)*: _____

My fees are \$ _____ for travel and \$ _____ for services, for a total of \$ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

Server's signature

Printed name and title

Server's address

Additional information regarding attempted service, etc:

UNITED STATES DISTRICT COURT

for the

Middle District of Tennessee

DONALD RAY LOVELL

Plaintiff

v.

HOWMEDICA OSTEONICS d/b/a
STRYKER ORTHOPAEDICS, et al.

Defendant

Civil Action No. 3:17-cv-1168

SUMMONS IN A CIVIL ACTION

To: (Defendant's name and address) HOWMEDICA OSTEONICS CORP.
325 CORPORATE DRIVE
MAHWAH, NJ 07430


A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:



If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

KEITH THROCKMORTON
CLERK OF COURT


Signature of Clerk or Deputy Clerk

Date: August 17, 2017

Civil Action No. _____

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* HOWMEDICA OSTEONICS CORP. (NJ)
was received by me on *(date)* _____.

I personally served the summons on the individual at *(place)* _____
_____ on *(date)* _____ ; or

I left the summons at the individual's residence or usual place of abode with *(name)* _____
_____, a person of suitable age and discretion who resides there,
on *(date)* _____, and mailed a copy to the individual's last known address; or

I served the summons on *(name of individual)* _____, who is
designated by law to accept service of process on behalf of *(name of organization)* _____
_____ on *(date)* _____ ; or

I returned the summons unexecuted because _____ ; or

Other *(specify)*: _____

My fees are \$ _____ for travel and \$ _____ for services, for a total of \$ 0.00.

I declare under penalty of perjury that this information is true.

Date: _____

Server's signature

Printed name and title

Server's address

Additional information regarding attempted service, etc:

UNITED STATES DISTRICT COURT

for the

Middle District of Tennessee

DONALD RAY LOVELL

Plaintiff

v.

HOWMEDICA OSTEONICS d/b/a
STRYKER ORTHOPAEDICS, et al.

Defendant

Civil Action No. 3:17-cv-1168

SUMMONS IN A CIVIL ACTION

To: (Defendant's name and address) STRYKER SALES CORPORATION
c/o C T Corporation System
800 S Gay Street, Suite 2021
Knoxville, TN 37929-9710

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:



If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

KEITH THROCKMORTON

CLERK OF COURT

Signature of Clerk or Deputy Clerk

Date: August 17, 2017

Civil Action No. _____

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* STRYKER SALES CORPORATION (TN)
was received by me on *(date)* _____ .

I personally served the summons on the individual at *(place)* _____
_____ on *(date)* _____ ; or

I left the summons at the individual's residence or usual place of abode with *(name)* _____
_____, a person of suitable age and discretion who resides there,
on *(date)* _____ , and mailed a copy to the individual's last known address; or

I served the summons on *(name of individual)* _____ , who is
designated by law to accept service of process on behalf of *(name of organization)* _____
_____ on *(date)* _____ ; or

I returned the summons unexecuted because _____ ; or

Other *(specify)*: _____ .

My fees are \$ _____ for travel and \$ _____ for services, for a total of \$ _____ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

Server's signature

Printed name and title

Server's address

Additional information regarding attempted service, etc:

UNITED STATES DISTRICT COURT

for the

Middle District of Tennessee

DONALD RAY LOVELL

Plaintiff

v.

HOWMEDICA OSTEONICS d/b/a
STRYKER ORTHOPAEDICS, et al.

Defendant

Civil Action No. 3:17-cv-1168

SUMMONS IN A CIVIL ACTION

To: (Defendant's name and address) STRYKER CORPORATION
2825 AIRVIEW BOULEVARD
KALAMAZOO, MI 49002

A lawsuit has been filed against you.


Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:



If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

KEITH THROCKMORTON

CLERK OF COURT


Signature of Clerk or Deputy Clerk

Date: August 17, 2017

Civil Action No. _____

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* STRYKER SALES CORPORATION (TN)
was received by me on *(date)* _____ .

I personally served the summons on the individual at *(place)* _____
_____ on *(date)* _____ ; or

I left the summons at the individual's residence or usual place of abode with *(name)* _____
_____, a person of suitable age and discretion who resides there,
on *(date)* _____ , and mailed a copy to the individual's last known address; or

I served the summons on *(name of individual)* _____ , who is
designated by law to accept service of process on behalf of *(name of organization)* _____
_____ on *(date)* _____ ; or

I returned the summons unexecuted because _____ ; or

Other *(specify)*: _____

My fees are \$ _____ for travel and \$ _____ for services, for a total of \$ _____ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

Server's signature

Printed name and title

Server's address

Additional information regarding attempted service, etc:

UNITED STATES DISTRICT COURT

for the

Middle District of Tennessee

DONALD RAY LOVELL

Plaintiff

v.

HOWMEDICA OSTEONICS d/b/a
STRYKER ORTHOPAEDICS, et al.

Defendant

Civil Action No. 3:17-cv-1168

SUMMONS IN A CIVIL ACTION

To: (Defendant's name and address) STRYKER IRELAND LIMITED
2825 AIRVIEW BOULEVARD
KALAMAZOO, MI 49002

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:



If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

KEITH THROCKMORTON
CLERK OF COURT

Date: August 17, 2017

Signature of Clerk or Deputy Clerk

Civil Action No. _____

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* STRYKER SALES CORPORATION (TN)
was received by me on *(date)* _____.

I personally served the summons on the individual at *(place)* _____
_____ on *(date)* _____ ; or

I left the summons at the individual's residence or usual place of abode with *(name)* _____
_____, a person of suitable age and discretion who resides there,
on *(date)* _____, and mailed a copy to the individual's last known address; or

I served the summons on *(name of individual)* _____, who is
designated by law to accept service of process on behalf of *(name of organization)* _____
_____ on *(date)* _____ ; or

I returned the summons unexecuted because _____ ; or

Other *(specify)*:

My fees are \$ _____ for travel and \$ _____ for services, for a total of \$ _____ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

Server's signature

Printed name and title

Server's address

Additional information regarding attempted service, etc: