Attorneys for Plaintiffs Mern Direnzo and Robert Direnzo

MERN DIRENZO and ROBERT DIRENZO	SUPERIOR COURT OF NEW JERSEY LAW DIVISION: BERGEN COUNTY
Plaintiffs,	DOCKET NO.: L-4096-14
vs.	
HOWMEDICA OSTEONICS CORPORATION, a New Jersey corporation d/b/a STRYKER ORTHOPAEDICS	
Defendant,	

SUPERIOR COURT BERGEN COUNTY
FILED
MAY 20 2014
Laura A. Simoldoni
DEPUTY CLERK

DATE FILED 5-20-14
BATCH # 1430169
PAYMENT # 1430169
CA CK CC MO GG
PAYOR
AMOUNT $200
OVER

COMPLAINT

COME NOW, Plaintiffs, Mern Direnzo and Daniel Direnzo ("Plaintiffs") , by and through the undersigned counsel, and bring this complaint against Defendant, Howmedica Osteonics Corporation, and allege as follows:

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. Plaintiffs are citizens and residents, of the City of Jupiter, Florida.

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

4. Defendant, Howmedica Osteonics Corporation, (hereinafter "HOWMEDICA"), d/b/a STRYKER ORTHOPAEDICS is a corporation organized and existing under the laws of

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New Jersey having 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 and Florida.

THE PRODUCT

5. 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 State of New Jersey and the State of Florida, including Plaintiff Mern Direnzo.

6. Defendant's Defective Device was placed into the stream of interstate commerce and was implanted in Plaintiff Mern Direnzo on October 12, 2009.

7. As a direct and proximate result of Defendant placing the Defective Product into the stream of commerce, Plaintiff Mern Direnzo 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.

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

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

10. 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.

11. 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.

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

13. After the implantation of the Defective Device, Plaintiff Mern Direnzo began experiencing discomfort in the area of her Defective Device.

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 markedly increased levels of metal ions in the patient's blood and/or urine.

16. As a result, the Plaintiff was forced to have the device surgically removed.

THE STRYKER ACCOLADE HISTORY

17. 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.

18. 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.

19. The stem is comprised of a femoral stem and neck component and offers a variety of femoral head options intraoperatively.

20. 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.

21. 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.

22. 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.

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

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

25. 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 its new Accolade II stem is manufactured from a different titanium alloy.

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

CAUSES OF ACTION
COUNT I
COMMON LAW NEGLIGENCE

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

28. Defendant designed, manufactured, marketed, detailed, and advertised both to physicians and consumers the Accolade Stem.

29. 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.

30. 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;

31. 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.

32. As a direct and proximate result of the Defendant's 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 UNDER NEW JERSEY AND FLORIDA LAW

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

34. Through their public statements, their descriptions of the Accolade Stem and their promises relating to the Accolade Stem, Defendant expressly warranted among other things that the Accolade 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.

35. 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 Stem, but which contained material misrepresentations and utterly failed to warn of the risks of the Accolade Stem; (iii) verbal assurances made by Defendant's consumer relations personnel to the public about the

safety of the Accolade Stem and the downplaying of the risks associated with the Accolade Stem; (iv) false and misleading written information supplied by Defendant.

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

37. When Defendant made these express warranties, Defendant knew the purpose for which Accolade Stem was to be used and warranted it to be in all respects safe and proper for such purpose including its combination with chromium/cobalt femoral heads.

38. Defendant 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.

39. The Accolade Stem does not conform to Defendant's representations in that it is not safe and produces serious side effects when combined with chromium/cobalt heads.

40. As such, the Accolade Stem did not conform to Defendant's promises, descriptions or affirmations of fact and was not adequately packaged, labeled, promoted or fit for the ordinary purposes for which such devices are used.

41. Defendant therefore breached its express warranties to Plaintiff in violation of both Florida statutory and common law as well as N.J.S.A. 12A:2-313, codifying the Uniform Commercial Code, by manufacturing, marketing and selling the Accolade Stem to Plaintiff causing damages as will be established at trial.

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

COUNT III
STRICT LIABILITY
FAILURE TO WARN UNDER FLORIDA COMMON LAW AND NJ PLA

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

43. 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.

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

45. 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.

46. Had Plaintiff or her surgeon received a proper or adequate warning as to the risks associated with using the Accolade implant, the product would not have used.

47. Reasonable and adequate alternatives to chromium/cobalt femoral heads existed at the time Plaintiff was implanted with her Accolade stem.

48. 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; would have used an alternate device or at a minimum, provided Plaintiff with adequate warning and obtained her informed consent. As stated above, had Plaintiff received an adequate warning, Plaintiff would not have agreed to have the Accolade implanted.

49. The failure to warn of the Accolade'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 damage and losses will continue in the future.

COUNT IV
STRICT LIABILITY
DESIGN DEFECT UNDER FLORIDA COMMON LAW AND NJ PLA

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

51. This is an action based upon design defect against Defendant.

52. Integral to the design of the Accolade stem was its compatibility Stryker's chromium/cobalt femoral head.

53. Defendant's Accolade Stem is designed in such a way that, when used as intended in combination with 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.

54. When combined with chromium/cobalt femoral heads, Defendant's Accolade Stems do not perform as safely as an ordinary consumer would expect when used as intended or in a manner reasonably foreseeable to Defendant.

55. The risks of using Defendant's Accolade Stems in combination with chromium/cobalt femoral heads outweigh the benefits of using them.

56. The Accolade Stem installed in Plaintiff's hip was defectively designed.

57. The design defect in Defendant's Accolade Stem 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 UNDER FLORIDA COMMON LAW AND NJ PLA

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

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

60. 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.

61. The Accolade Stem implanted in the Plaintiff prematurely as previously described.

62. The Accolade Stem installed in Plaintiff's hip was combined with Stryker's chromium/cobalt femoral head.

63. 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 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;

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.

64. 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.

65. The Accolade Stem installed in Plaintiff's hip contained a manufacturing defect.

66. The manufacturing defect in the Accolade Stem 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 VI
LOSS OF CONSORTIUM
DANIEL DIRENZO

67. Plaintiffs reallege and incorporate by reference the paragraphs above, as though fully set forth herein.

68. At all times relevant to this Complaint, Plaintiffs Mern Direnzo and Daniel Direnzo were, and are, legally married as husband and wife.

69. As a direct and proximate result of the aforementioned conduct of the Defendants, and as a result of the injuries and damages to Plaintiff Mern Direnzo, Plaintiff Daniel Direnzo has been deprived of the love, companionship, comfort, affection, society, solace or moral support, protection, loss of enjoyment of sexual relations, and loss of physical assistance in the operation and maintenance of the home, of his wife, Mern Direnzo, and has thereby sustained, and will continue to sustain damages.

PUNITIVE DAMAGES UNDER COMMON LAW, PUNITIVE DAMAGES ACT (N.J.S.A. 2A:15-5.9, *et seq.*) and PRODUCT LIABILITY ACT (N.J.S.A. 2A:58C-1 *et seq)*

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

71. 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.

72. At all times material hereto, the Defendant attempted to misrepresent and did misrepresent facts concerning the safety of the subject product.

73. 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.

74. 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.

75. Notwithstanding the foregoing, the Defendant continued to aggressively market the subject product without disclosing the aforesaid side effects when there were safer alternative methods.

76. 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.

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

78. 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, the Plaintiff suffered severe and permanent physical injuries as set forth above.

79. 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.

80. 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.

81. Plaintiff alleges this cause of action for punitive damages, despite the holding of *McDarby v. Merck*, stating that the issue has not been heard by the New Jersey Supreme Court, or in the event a choice of law analysis is conducted and the Plaintiff's home state law is determined to govern.

WHEREFORE, Plaintiff demands 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 violation of the PLA and/or Florida.

b. Awarding compensatory damages resulting from Defendant's breach of warranty, negligence and for strict liability.

c. Awarding loss of consortium damages.

d. Awarding actual damages to the Plaintiff Mern Direnzo incidental to Robert Direnzo's purchase and use of the Accolade Stem in an amount to be determined at trial;

e. Awarding punitive damages to the Plaintiff;

f. Awarding pre-judgment and post-judgment interest to the Plaintiff;

g. Awarding the costs and the expenses of their litigation to the Plaintiff;

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

f. 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.

Respectfully submitted

SEARCY DENNEY SCAROLA BARNHART & SHIPLEY
Attorneys for Plaintiff

Dated: May 19, 2014

William B. King
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CERTIFICATION PURSUANT TO RULE 4:5-1

The undersigned attorney for Plaintiff certifies as follows:

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

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

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

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

SEARCY DENNEY SCAROLA BARNHART & SHIPLEY
Attorneys for Plaintiff

Dated: May 19, 2014

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DESIGNATION OF TRIAL COUNSEL

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

SEARCY DENNEY SCAROLA BARNHART & SHIPLEY
Attorneys for Plaintiff

Dated: May 19, 2014

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