UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF ARKANSAS
HOT SPRINGS DIVISION

ANGELA OWEN,	§	
	§	
Plaintiff,	§	CIVIL ACTION NO. 19-6026
	§	
v.	§	
	§	
ARTHREX, INC.	§	**JURY TRIAL DEMANDED**
	§	
Defendant.	§	
	§	
	§	

COMPLAINT FOR DAMAGES AND JURY DEMAND

Plaintiff, Angela Owen, by and through their undersigned counsel, brings this action for damages against the Defendant, Arthrex, Inc., and allege as follows:

1. At all times relevant to this Complaint, Plaintiff Angela Owen, (hereinafter "Plaintiff") was domiciled in Hot Springs, Garland County, Arkansas and was a citizen of Arkansas.

2. At all times relevant hereto, Defendant Arthrex, Inc. (hereinafter "Arthrex") was a corporation organized and existing under the laws of the State of Delaware with its principal place of business in the State of Florida and is conducting, and has regularly conducted, business in the State of Arkansas.

3. At all times material hereto, Arthrex, Inc. was believed to be a public entity or corporation, organized and existing under the laws of the State of Delaware with a principal place of business at 1370 Creekside Boulevard in the City of Naples, Florida, County of Collier.

JURISDICTION AND VENUE

4. This Court has diversity jurisdiction over the parties pursuant to 28 U.S.C. § 1332(a)(1). The amount in controversy exceeds the sum or value of $75,000.00, exclusive of interest and costs, and Plaintiff is not a citizen of the same state as Defendant.

5. Venue is proper in this Court under 28 U.S.C. § 1391 because Defendant conducts business in Arkansas within this district, and its commercial activities therein include, but are not limited to, the marketing and sale of knee replacement systems, including the Arthrex iBalance. Venue is also proper in this district because a substantial part of the events or omissions giving rise to Plaintiff's claims occurred within the Western District of Arkansas, where Plaintiff was a citizen at the time of her injury.

6. Arthrex, Inc. is subject to this Court's jurisdiction because, at all times relevant hereto, Arthrex, Inc. regularly and continuously conducted business in the State of Arkansas by manufacturing, selling and distributing reconstructive orthopedic implants, including, but not limited to, knee replacements, and orthopedic surgical products used by orthopedic surgeons in the State of Arkansas.

FACTUAL ALLEGATIONS

7. On November 6, 2015, Plaintiff Angela Owen was admitted to the Arkansas Surgical Hospital in Hot Springs, Arkansas for a total left knee replacement. The knee device implanted in Plaintiff Angela Owen's left knee by Dr. James Rudder was an Arthrex iBalance knee system ("Defective Device", "Arthrex iBalance" or "iBalance"), and the Arthrex iBalance device was implanted by Dr. James Rudder.

8. Following the knee replacement procedure, Plaintiff Angela Owen experienced and has continued to experience severe pain, swelling and numbness in and around the left knee.

As a result, on or about April 5, 2016 Dr. Rudder decided to perform a revision surgery to remove the Arthrex iBalance device.

9. Arthrex issued a recall of the Arthrex iBalance TKA Tibial Tray. Included in that Arthrex recall was the Arthrex iBalance TKA Tibial Tray device implanted in Angela Owen on November 6, 2015 and bearing Catalog #AR-503-TTTD.

10. On April 18, 2016, Plaintiff Angela Owen was admitted to National Park Medical Center in Hot Springs, Arkansas for a revision of her Arthrex iBalance knee device by Dr. Rudder. During that surgery to remove the defective device, Dr. Rudder noted that the tibial tray was extremely loose. It was not until after the revision surgery that Plaintiff Angela Owen possessed sufficient facts to put her on notice of a potential legal claim.

TOLLING OF STATUTES OF LIMITATIONS

11. Plaintiff filed this lawsuit within the applicable limitations period of first suspecting that the Arthrex iBalance had caused her injuries. Plaintiff could not by the exercise of reasonable diligence have discovered the wrongful cause of her injuries induced by the defective nature of the Arthrex iBalance at an earlier time because at the time of these injuries, the cause was unknown to the Plaintiff.

12. The statute of limitations has been further tolled by reason of Defendant's fraudulent concealment. Through its affirmative misrepresentations and omissions about the quality and performance of the Arthrex iBalance, Defendant actively concealed from Plaintiff and her implanting surgeon the risks associated with the Defective Device.

13. As a result of Arthrex's actions, Plaintiff was unaware and could not have reasonably known or have learned through reasonable diligence that she had been exposed to the defects and that those defects and risks were the direct and proximate cause of her injuries.

14. Through Defendant's misrepresentations and omissions pertaining to the safety and efficacy of the Arthrex iBalance, Plaintiff was prevented from discovering this information sooner because Defendant misrepresented the defective nature of the Arthrex iBalance. Therefore, any and all statutes of limitations otherwise applicable to the allegations have been tolled.

FIRST CAUSE OF ACTION
PRODUCTS LIABILITY - MANUFACTURING DEFECT

15. Plaintiff incorporates the preceding paragraphs as if fully rewritten herein.

16. The Arthrex iBalance knee implant was defectively manufactured in that it failed to withstand the normal and reasonable use of Plaintiff Angela Owen, and otherwise failed to perform adequately and safely when used in an intended and reasonably foreseeable manner, so as to proximately cause injuries to the Plaintiff.

17. The Arthrex iBalance implanted in Angela Owen failed due to loosening of the tibial tray. The tibial tray was defective in its manufacture in that the under surface of the tibial tray lacked the proper roughness and texture necessary to aid in adhesion to the bone. As a result of this defect in manufacturing, the Arthrex iBalance implanted in Angela Owen was recalled.

18. The defects existed at the time the Arthrex iBalance left the control of the Defendant and was introduced into the stream of commerce by Defendant Arthrex, Inc. Specifically, Defendant researched, tested, manufactured, prepared, designed, developed, distributed, advertised, marketed, inspected, configured, supplied and/or sold the iBalance knee implant and knew or should have known that the iBalance would be used by users without any knowledge of Arthrex's product defects and inherent dangers and without any inspection for dangers and defects.

19. Defendant knew, or in the exercise of reasonable diligence, should have known of the risk of injury to Plaintiff Angela Owen and others like her, from the use of the iBalance

knee implant and its defects in manufacturing as discussed in this section.

20. When used in an intended and reasonably foreseeable manner, the Arthrex iBalance is more dangerous than an ordinary consumer or user would expect. Defendant researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold and otherwise released the Defective Device into the stream of commerce in a condition which rendered it unreasonably dangerous due to its propensity to result in early failure of the device. The Arthrex iBalance was unreasonably dangerous in construction and/or composition.

21. Defendant expected the Arthrex iBalance to reach, and it did in fact reach, implanting orthopedic surgeons, health care professionals and consumers, including Angela Owen and her implanting surgeon, without any substantial change in the condition of the product from when it was initially distributed by Defendant.

22. The Arthrex iBalance, as manufactured and/or supplied by Defendant, was defective due to its high early failure rate. Defendant knew or should have known that the product created significant risks of serious bodily harm to consumers, as alleged herein, and it failed to adequately warn consumers and/or their health care professionals of such risks.

23. The Arthrex iBalance was defective and unsafe such that it was unreasonably dangerous when it left the Defendant's possession and/or control, was distributed by Defendant, and implanted by Angela Owen's surgeon.

24. The Arthrex iBalance used in Plaintiff Angela Owen's knee replacement surgery was supplied in a defective condition in its manufacture as discussed above.

25. The Arthrex iBalance design created an unreasonable risk of failure and resulting painful revision surgery.

26. The defect caused serious injury to Plaintiff and will continue to in the future, who used the Arthrex iBalance for its intended purpose and in a reasonably anticipated manner.

27. At all times herein mentioned, Defendant had a duty to properly test, develop, design, manufacture, inspect, package, label, market, promote, sell, distribute, supply, warn, and take such other steps as necessary to ensure the Defective Device did not cause users to suffer from unreasonable and dangerous risks.

28. Defendant negligently and recklessly manufactured, designed, distributed, and promoted the Defective Device.

29. Defendant, as designer, manufacturer, seller, and/or distributor of medical device, is held to the knowledge of an expert in the field.

30. Plaintiff could not have discovered any defects in the Arthrex iBalance through the exercise of reasonable care and relied upon the skill, superior knowledge, and judgment of Defendant.

31. The Defective Device, as manufactured and/or supplied by Defendant, was unreasonably dangerous when used by consumers, including Plaintiff Angela Owen, in a reasonably intended manner without knowledge of the risk of serious bodily harm.

32. The benefits of the Arthrex iBalance do not outweigh the risks inherent in the design and configuration of the Arthrex iBalance.

33. As a direct and proximate result of Defendant's defective product, Plaintiff has suffered severe pain, mental anguish, and the loss of enjoyment of life and also incurred lost wages, loss of earning capacity and incurred medical, hospital rehabilitative, drug and other related expenses.

SECOND CAUSE OF ACTION
PRODUCTS LIABILITY – FAILURE TO WARN

34. Plaintiff incorporates by reference all of the above paragraphs as if set forth in full herein.

35. Defendant is liable to Plaintiff for the negligent and/or willful failure to provide adequate warnings and other clinically relevant information and data regarding the appropriate use and the risks of the Arthrex iBalance to Plaintiff Angela Owen and her surgeons.

36. Defendant, as a duly licensed corporation, designed, manufactured, sold and/or otherwise introduced into the stream of commerce the iBalance knee implant which was being used by Plaintiff when the events above occurred.

37. Defendant knew, or in the exercise of reasonable care should have known, about the risk of injury to Plaintiff, and others like her, from the use of Defendant's iBalance knee implant.

38. Defendant, as the manufacturer of the Arthrex iBalance, is held to the level of knowledge of an expert in the field, and further, Defendant knew or should have known that warnings and other clinically relevant information and data which Defendant distributed regarding the safety of the device were inadequate.

39. Defendant failed to provide warnings and/or instructions to surgeons and/or patients at the time of its marketing and when it left the control of Defendant that a manufacturer, exercising reasonable care, would have provided concerning the risk to Plaintiff in light of the likelihood that the product would cause harm of the type for which Plaintiff seeks compensation in light of the seriousness of that harm.

40. The Arthrex iBalance used in Plaintiff's knee replacement surgery was supplied in a defective condition, because the Defendant failed to provide an adequate warning to consumers,

implanting surgeons and the public, including Plaintiff and her implanting surgeon, Dr. Rudder, regarding the hazards associated with the reasonable and foreseeable use of the Arthrex iBalance, including loosening of the tibial tray that could lead to early failure of the device and revision. This failure to warn rendered the device unreasonably dangerous and caused Plaintiff's injuries.

41. Plaintiff Angela Owen and her surgeon did not have the same knowledge as Defendant, and no adequate warning or other clinically relevant information and data was communicated to her or to her physicians.

42. Defendant had a continuing duty to provide consumers, including Angela Owen and her physicians, with warnings and other clinically relevant information and data regarding the risks and dangers associated with the Arthrex iBalance as it became or could have become available to Defendant.

43. Defendants manufactured, marketed, promoted, distributed, and sold an unreasonably dangerous and defective medical device, the Arthrex iBalance, in the stream of commerce, to health care providers empowered to implant the device to consumers, including, Plaintiff Angela Owen, without adequate warnings and other clinically relevant information and data.

44. Despite the fact that Defendant knew or should have known that the Arthrex iBalance caused unreasonable and dangerous side effects, including failure of the device entirely, Defendant continued to manufacture, market, promote, distribute, and sell the Defective Device.

45. Defendant knew or should have known that consumers, including Plaintiff Angela Owen, would foreseeably and needlessly suffer injury as a result of the failure of Defendant's product.

46. Defendant had an obligation to provide Plaintiff Angela Owen and her

surgeon with adequate and clinically relevant information, and data and warnings regarding the adverse health risks associated with the Defective Device, and/or that there existed safer and more or equally effective alternatives.

47. By failing to do so, Defendant breached its duty of reasonable care and safety.

48. As a direct and proximate result of the actions and inactions of Defendants as set forth above, Plaintiff suffered and continues to suffer the injuries and damages set out herein

THIRD CAUSE OF ACTION
PRODUCTS LIABILITY – DESIGN DEFECT

49. Plaintiff incorporates the preceding paragraphs as if fully rewritten herein.

50. The iBalance knee implant was defectively designed and/or manufactured in that the iBalance knee implant failed to withstand normal and reasonable use by Plaintiff, and otherwise failed to perform adequately and safely when used in an intended and reasonably foreseeable manner, in that the under surface of the tibial tray lacked the proper roughness and texture causing the tibial tray to fail to adhere to the bone once implanted. This caused Plaintiff's iBalance device to loosen at the tibial tray area resulting in pain and a subsequent revision surgery and medical treatment.

51. These defects existed at the time the iBalance knee implant left the control of the Defendant and was introduced into the stream of commerce by Defendant Arthrex, Inc. Specifically, Plaintiff states that the Defendant researched, tested, manufactured, prepared, designed, developed, distributed, advertised, marketed, inspected, configured, supplied and/or sold the iBalance knee implant and knew or should have known that the iBalance would be used by users without any knowledge of their product defects and inherent dangers and without any inspection for dangers and defects.

52. Defendant knew, or in the exercise of reasonably diligence, should have known

of the risk of injury to Plaintiff and others like her, from the use of the iBalance knee implant.

53. When used in an intended and reasonably foreseeable manner, the iBalance knee implant is more dangerous than an ordinary consumer or user would expect.

54. The benefits of the iBalance knee implant do not outweigh the risks inherent in the design and configuration of the iBalance knee implant.

55. As a direct and proximate result of Defendant's defective product, Plaintiff has suffered severe pain, mental anguish, and the loss of enjoyment of life and also incurred lost wages, loss of earning capacity and incurred medical, hospital rehabilitative, drug and other related expenses.

FOURTH CAUSE OF ACTION
NEGLIGENCE

56. Plaintiff incorporates the preceding paragraphs as if fully rewritten herein.

57. Plaintiff states that Defendant Arthrex, Inc. owed a duty to use reasonable care in the research, testing, manufacture, preparation, design, development, distribution, advertising, marketing, inspecting, configuring, suppling and/or selling of the Arthrex iBalance knee devices implanted in Plaintiff Angela Owen and was obligated to protect her against the foreseeable risk of harm posed by the Arthrex iBalance knee implant.

58. Defendant Arthrex, Inc. breached its duty of care owed to Plaintiff, to protect them from an unreasonable risk of harm in that they negligently researched, tested, manufactured, prepared, designed, developed, distributed, advertised, marketed, inspected, configured, supplied, and/or sold the iBalance knee implant for subsequent use by Plaintiff Angela Owen.

59. Defendant Arthrex, Inc. was negligent because they knew, or reasonably should have known, that the Arthrex iBalance device was unreasonably dangerous and harmful

to persons when used for its foreseeable and intended purpose because the Arthrex iBalance lacked the proper surface roughness on the tibial baseplate that was necessary for proper fixation.

60. Defendant failed to exercise due care under the circumstances, and its negligence and recklessness includes the following acts and omissions:

a. Failing to properly and thoroughly test and inspect the defective Arthrex iBalance device before releasing the device to market;

b. Designing, manufacturing, marketing, advertising, distributing, and selling the Defective Device to consumers, including to Plaintiff, without an adequate warning of the dangerous risks of the Arthrex iBalance;

c. Failing to adequately prevent, identify, mitigate, and fix defective designs and hazards associated with the Arthrex iBalance in accordance with good design practices;

d. Failing to notify and warn the public including Plaintiff and Plaintiff Angela Owen's implanting surgeon of reported incidents involving injury, and the negative health effects attendant to the use of the Arthrex iBalance, thus misrepresenting the safety of the product;

e. Failing to provide warnings, instructions or other information that accurately reflected the risks of failure of the Arthrex iBalance;

f. Failing to exercise due care when advertising and promoting Arthrex iBalance;

g. Disseminated information that was inaccurate, false, and misleading, and which failed to communicate accurately or adequately the early failure rate associated with the implantation of the Arthrex iBalance;

h. Continued to aggressively promote the Arthrex iBalance even after Defendant knew or should have known of the unreasonable risks from implantation;

i. Downplayed, or otherwise suppressed, through aggressive marketing and promotion the risks associated with the implantation of the Arthrex iBalance;

j. Failing to make timely and adequate corrections to the manufacture and design of the Arthrex iBalance so as to prevent and/or minimize the loosening of the tibial baseplate and failure of the Arthrex iBalance;

k. Continuing to negligently manufacture, market, advertise, and distribute the Arthrex iBalance after the Defendant knew or should have known of its adverse effects and/or the increased early onset failure rates, and

l. Being otherwise careless, reckless and negligent.

61. Defendant knew and/or should have known that it was foreseeable that consumers such as Plaintiff would suffer injuries as a result of Defendant's failure to exercise ordinary care in the manufacture, design, testing, assembly, inspection, labeling, packaging, supplying, marketing, selling, advertising, preparing for use, warning of the risks and dangers of the Arthrex iBalance, and otherwise distributing the Arthrex iBalance.

62. As a direct and proximate result of Defendant Arthrex, Inc's. negligence, Plaintiff has suffered severe and permanent injuries. These injuries have caused Plaintiff Angela Owen to incur physical and mental pain and suffering, lost wages, loss of earning capacity, as well as medical, hospital, rehabilitative and drug expenses. Due to the nature of her injuries, Plaintiff expects to incur these expenses into the future including future medical expenses, loss of earning capacity, as well as medical, hospital, rehabilitative and drug expenses.

63. Had Defendant properly disclosed the risks associated with the loosening and failure of the Arthrex iBalance, Plaintiff Angela Owen would have avoided the risk of implantation of the Arthrex iBalance.

FIFTH CAUSE OF ACTION
BREACH OF IMPLIED WARRANTY

64. Plaintiff incorporates the preceding paragraphs as if fully rewritten herein.

65. Defendant's implied warranty was that the iBalance knee implant was of good and merchantable quality, fit and safe for its ordinary and intended use without endangering human life or safety and free from design or manufacturing defects.

66. Defendant breached these implied warranties of merchantability, safety, and fitness for a particular purpose in that the iBalance knee implant was defective, defectively designed, defectively manufactured, and dangerous to reasonably foreseeable users like Plaintiff.

67. Plaintiff and her surgeon relied upon the implied warranties and representations of Defendants regarding their product and, as a result, utilized the iBalance knee implant.

68. As a direct and proximate result of Defendant's breaches of implied warranties, Plaintiff suffered severe and permanent injuries as discussed herein.

SIXTH CAUSE OF ACTION
BREACH OF EXPRESS WARRANTY

69. Plaintiff incorporates the preceding paragraphs as if fully rewritten herein.

70. Defendant expressly warranted that the iBalance knee implant was reasonably fit for its intended use without endangering human safety and free from design or manufacturing defects.

71. Defendant breached this express warranty because the iBalance knee implant was dangerous and defective for its reasonably foreseeable use.

72. Plaintiff and her surgeon relied on the expressed warranties and representations of Defendant regarding the fitness, safety, and durability of the iBalance knee implant and as a result Plaintiff used said iBalance knee implant.

73. As a direct and proximate result of Defendant's breach of express warranties, Plaintiff suffered severe and permanent injuries.

SEVENTH CAUSE OF ACTION
INTENTIONAL MISREPRESENTATION/FRAUD

74. Plaintiff incorporates by reference all of the allegations in the previous Complaint as if set forth fully at length herein.

75. At the time Defendant designed, manufactured, marketed distributed and sold the Arthrex iBalance to the public and to the Plaintiff, Angela Owen, Defendant knew of the dangerous nature of the device and the risks the device posed to patients such as Plaintiff. Specifically, Defendant knew that the tibial tray posed a potential danger to knee replacement recipients due to its potential for early failure due to a defect in surface roughness of the tibial tray.

76. The dangers and risk associated with the Arthrex iBalance were and are material facts which patients, such as Angela Owen, would consider and evaluate when deciding whether or not to use the Arthrex iBalance in knee replacement surgery.

77. Defendant knowingly, intentionally and/or with reckless disregard, made false representations and omissions of material facts to Plaintiff, Angela Owen, regarding the safety and effectiveness of the Arthrex iBalance device. Specifically, Defendant, independently and through consultants, represented that the Arthrex iBalance device was safe and effective when in reality they knew that the device was prone to early failure and was dangerous as described herein.

78. Defendant's misrepresentations and omissions of known facts regarding the Arthrex iBalance device were intended to induce reliance on the part of the Plaintiff and her surgeons, and to persuade her to agree to use the device.

79. Plaintiff Angela Owen relied on Defendant's misrepresentations and omissions of known material facts regarding the Arthrex iBalance device, and this reliance resulted in Angela Owen receiving a defective Arthrex iBalance devices which failed resulting in significant injuries.

80. Had Plaintiff Angela Owen been made aware of the known dangers and risks associated with the Arthrex iBalance device, she would not have agreed to use that device in her knee replacement surgeries.

81. As a direct and proximate result of the intentional misrepresentations of Defendant, and the detrimental reliance thereupon of Plaintiff, Angela Owen, she has suffered and will continue to suffer injuries.

PUNITIVE DAMAGES

82. Plaintiff incorporates the preceding paragraphs as if fully rewritten herein.

83. At all times material hereto, the Defendant knew or should have known that the Defective Device was inherently more dangerous, had a shorter life span and required the need for additional surgeries than the alternative knee replacement systems on the market.

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

85. Defendant's misrepresentations included knowingly withholding material information from the medical community and the public, including the Plaintiffs herein, concerning the safety and efficacy of the subject product.

86. At all times material hereto, the Defendant knew and recklessly disregarded the fact

that Defective Device was subject to failure with far greater frequency than safer alternative knee replacement systems.

87. Notwithstanding the foregoing, the Defendant continued to aggressively market the subject product without disclosing the aforesaid side effects when there were safer alternative methods, and fraudulently claimed that the Defective Device was superior in wear characteristics and longevity.

88. 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 Plaintiffs, in conscious disregard of the foreseeable harm.

89. Defendant failed to provide updated information so as to educate physicians to monitor patients that had previously implanted devices.

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

91. The aforesaid conduct of the Defendant was committed with knowing, conscious, and deliberate disregard for the rights and safety of consumers, including the Plaintiff Angela Owen, thereby entitling the Plaintiffs to punitive damages in an amount appropriate to punish the Defendant and deter them from similar conduct in the future.

92. The Plaintiffs seek actual and punitive damages from the Defendants as alleged herein.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against the Defendant on each of the above-referenced claims and Causes of Action and as follows:

1. Awarding compensatory damages to Plaintiff for past and future damages, including, but not limited to, pain and suffering for severe and permanent injuries sustained by the

plaintiff, health care costs, and medical monitoring damages together with interest and costs as provided by law;

2. Punitive and/or exemplary damages for the wanton, willful, fraudulent, reckless acts of the Defendant who demonstrated a complete disregard and reckless indifference for the safety and welfare of the general public and to the Plaintiff in an amount sufficient to punish Defendant and deter future similar conduct;

3. Awarding Plaintiff, the costs of these proceedings;

4. Pre-judgment and post-judgment interest;

5. Such other and further relief as the Court deems just and proper.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands trial by jury as to all issues in the above captioned matter.

Dated this 22nd day of February 2019.

Respectfully Submitted

/s Thomas P. Thrash

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