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IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

Diane Smith;

Plaintiff,

v.

Arthrex, Inc.; Arthrex Trauma, Inc.; Arthrex Corporation; Arthrex Global Sales, Inc.; John Does I-X; Jane Does I-X; Black Corporations I-X; White Partnerships I-X;

Defendants.

Case: _____

COMPLAINT

(Demand for Jury Trial)

COMES NOW the Plaintiff, Diane Smith, by and through her attorney undersigned, and for her cause of actions against the Defendants, Arthrex, Inc. et al. ("Defendants") states and alleges as follows:

PARTIES, JURISDICTION AND VENUE

1. Diane Smith ("Plaintiff") is a resident of Maricopa County, Arizona, and was so at all times relevant hereto.

2. Upon information and belief Defendants Arthrex, Inc.; Arthrex Trauma, Inc.; Arthrex Corporation; Arthrex Global Sales, Inc. ("Arthrex") are Florida Corporations, having principle executive offices in the state of Florida, and doing business in Arizona, and were at all times relevant hereto.

3. Upon information and believe Defendant Arthrex Trauma, Inc.; Arthrex Corporation; Arthrex Global Sales, Inc. are subsidiaries, agents and/or dba entities of Arthrex, Inc.

4. This Court has jurisdiction over this matter pursuant to 28 U.S.C. §1332. Jurisdiction in this case is based on the diversity of citizenship of the parties and the amount in controversy. Plaintiff is a citizen of the State of Arizona. Defendants Arthrex have principle executive offices in the state of Florida. Defendants Arthrex were originally incorporated in the state of Delaware. The amount in controversy exceeds $75,000 exclusive of interest and costs.

5. Venue is proper in this Court pursuant to 28 U.S.C. §1391 because a substantial portion of the acts giving rise to this Complaint arose in Arizona.

FACTUAL ALLEGATIONS

6. Defendants, caused events to occur in Maricopa County, Arizona, that give rise to the causes of action set forth here.

7. Defendants, manufacture and distribute the item known as a Arthrex iBalance total knee replacement system such as was surgically implanted in Plaintiff Diane Smith's left knee on or about December 21, 2017.

8. Defendants, manufacture and distribute the item known as a Arthrex iBalance

total knee replacement system such as was surgically implanted in Plaintiff Diane Smith's right knee on or about December 1, 2018.

9. The Arthrex iBalance is intended to be used in the repair of injured or damaged knee joints.

10. Plaintiff came under the care of Dr. Mark Campbell of The Core Institute in Arizona, indicating that she had bilateral knee pain.

11. Plaintiff received several bilateral knee injections and conservative treatment.

12. On October 24, 2017, Dr. Campbell suggested surgical intervention for her left knee.

13. On December 21, 2017 Dr. Campbell performed a left knee unicompartmental knee arthroplasty using the Arthrex iBalance unicompartmental knee system with a size 3 femoral component, size 4 tibial tray, and an 8-mm tibial bearing insert into her left knee medial parapatellar facetectomy.

14. On July 6, 2018, Dr. Campbell suggested surgical intervention for her right knee.

15. On December 1, 2018, Dr. Campbell performed a right knee medial unicompartmental knee arthroplasty using the Arthrex iBalance unicompartmental knee system with a size 3 femoral component and size 4 tibial tray.

16. Plaintiff was feeling pain in her left knee so on April 1, 2019 Plaintiff obtained an MRI of the left knee which showed "Metallic artifact is present involving the medial compartment obscuring and distorting the underlying and adjacent structures.

17. On April 24, 2019, Plaintiff complained of "crunching sensation on the medial aspect of the left knee."

18. On October 22, 2019, Plaintiff complained to Dr. Campbell of "aches and pains in both knees right worse on [sic] left." Dr. Campbell further states during this visit "We

discussed with the patient the loosening of the tibial baseplate on the right. We discussed potential revision."

19. On January 22, 2020 Dr. Campbell states "she has continued to struggle with occasional aches and pains and weakness in both of her knees."

20. On June 18, 2020 Plaintiff presented to Dr. Cucchetti with complaints of left knee pain. He referred her for a triple phase bone scan.

21. On June 22, 2020 Plaintiff obtained a triple phase bone scan of the left knee.

22. On June 25, 2020 Plaintiff presented back to Dr. Cucchetti and he sent "Referral to Evangelista and Tarlow to discuss revision options due to loosening of implant."

23. On July 14, 2020 Plaintiff presented to Dr. Evangelista and complained of left knee pain, difficulty ambulating, numbness and tingling on the anterior aspect of her left leg. Dr. Evangelista performed an aspiration of the left knee.

24. On July 20, 2020 Dr. Evangelista advised Plaintiff of his diagnosis of "infected left medial unicompartmental knee arthroplasty." He advised an immediate revision surgery was needed once they received medical clearance.

25. On August 4, 2020 due to defective nature of Defendants' products, Dr. Perry Jaymes Evangelista performed an "Explantation and antibiotic spacer placement, left total knee arthroplasty, saucerization of femoral tibial bone for infection."

26. On August 12, 2020 Plaintiff presented to Dr. Evangelista for follow up regarding her 8/4/2020 surgery.

27. Plaintiff was required to maintain IV antibiotics through a PICC line.

28. On October 22, 2020 again, due to the defective nature of Defendants' product, Dr. Evangelista performed a "Revision left total knee arthroplasty, wound vacuum placement, left knee."

29. On October 28, 2020 Plaintiff presented to Dr. Evangelista and "states she has no pain. She is no longer taking pain medications....doing extremely well and states that she does not feel as if she needs any assist device either."

30. On December 2, 2020 Plaintiff presented to Dr. Evangelista with complaints of right knee pain and tenderness. Dr. Evangelista performed an aspiration of the right knee. Her right knee range of motion is limited.

31. On December 2, 2020, Dr. Evangelista states "grossly loosening and becoming more painful right partial knee replacement." "We will therefore plan for a revision right total knee arthroplasty...."

32. On January 5, 2021 Dr. Evangelista performed a "right revision total knee arthroplasty, both components." This revision was necessary due to the defective nature of Defendants' products.

33. Dr. Evangelista documented the preoperative diagnosis as "mechanical failure, right partial knee replacement."

34. On January 28, 2021 Plaintiff presented to Dr. Evangelista and stated she was "doing extremely well."

COUNT I

STRICT LIABILITY- DEFECT IN DESIGN- PRODUCT LIABILITY

Plaintiff re-alleges and incorporates by reference the allegations contained in Paragraphs 1 through 34 of this Complaint, to avoid repetition.

35. Defendants participated in the manufacture and sale of a knee implant product, specifically the Arthrex iBalance total knee replacement system Plaintiff received during her surgical procedures on December 21, 2017 and December 1, 2018.

36. The use of said knee implant hardware was used as set forth and expected by the Defendants and, therefore, was reasonably foreseeable, as defined in A.R.S. §12-681. There was no modification of the product as defined by A.R.S. §12-681.

37. This products liability action is brought against the Defendants, each of them, as manufacturers or sellers of a product which may have caused damages and bodily injury, directly caused by or resulting from the poor manufacture, construction, design, formula, installation, preparation, assembly, testing, packaging, labeling, sale, use or consumption of any product, the failure to warn or protect against danger or hazard in the use or misuse of the product or the failure to provide proper instructions for the use or consumption of the subject product.

38. The Defendants, each of them, owed a duty of care in the manufacture, design, testing and marketing of the subject the Arthrex iBalance total knee replacement system Plaintiff received during her surgical procedure on December 21, 2017 and December 1, 2018. Said duty was owed to Plaintiff as a foreseeable purchaser or user of said knee implant product. Defendants failed to meet this duty.

39. As a direct result of the failure of said Arthrex iBalance total knee replacement system, Plaintiff, Diane Smith has suffered injury, and will continue to suffer including, but not limited to, physical, mental, and economic damages.

40. Furthermore, said Arthrex iBalance total knee replacement system was insufficient for the purpose for which it was sold or otherwise designed. Its failure to perform as it was sold to do so, caused direct harm to the Plaintiff.

41. The Arthrex iBalance total knee replacement system, in the absence of appropriate warnings, is an unreasonably dangerous product, and was so at the time of its manufacture and at the time it was shipped from the manufacturing facility. The failure to

provide any warning to Plaintiff had direct consequences to Plaintiff in the form of her injuries as set forth above.

42. The Arthrex iBalance total knee replacement system, was defective at the time of its manufacture, was unreasonably dangerous and was so at the time it was shipped from the manufacturing facility, and was a direct cause of injury to Plaintiff.

43. As a result of the unreasonably dangerous condition of the Arthrex iBalance total knee replacement system, the Defendants are subject to strict liability.

COUNT II

NEGLIGENCE

Plaintiff re-alleges and incorporates by reference the allegations contained in Paragraphs 1 through 43 of this Complaint, to avoid repetition.

44. Upon information and belief, the Defendants were aware of the defective nature of the product and the fact that it would not meet its intended purpose. Defendants had a duty to anticipate and design their product against any reasonably foreseeable hazards.

45. Despite full knowledge of these defects, and the knowledge that their failure to take any steps to fully advice physicians and patients would certainly cause injury to patients, including Plaintiff, the Defendants negligently took no action. Defendants breached their duty to effectively anticipate and design its product against any reasonably foreseeable hazards.

46. Despite full knowledge of the certainty of injury to patients, including Plaintiff Diane Smith, the Defendants negligently took no action. Defendants' breach of their duty was the proximate cause of the injury and damage to Plaintiff.

47. As further proximate result of the failures of the Defendants as alleged above and in addition to the physical and economic damages suffered by Plaintiff. Plaintiff Diane

Smith has suffered and will in the future continue to suffer grievous emotional distress including, but not limited to, emotional pain, anguish, stress, grief, depression, and other mental suffering.

48. Based on this failure, and the intentional actions of Defendants, Plaintiff is entitled to recover punitive damages against Defendants.

49. Plaintiff has suffered economic, mental, and physical damages, all as a direct result of the actions and inactions of the Defendants.

DAMAGES

Plaintiff re-alleges and incorporates herein by reference Paragraphs 1-49 of this Complaint, to avoid repetition.

50. As a proximate result of the acts and omissions by Defendants, Plaintiff has suffered greatly. The untimely discovery of Plaintiff's condition has caused extensive unnecessary medical procedures including invasive surgeries, rigorous therapy and countless other medical difficulties. Plaintiff, Diane Smith has further suffered from permanent disability.

51. As a further proximate result of the failures, omissions and acts of Defendants, Plaintiff has suffered and continues to suffer from depression, shock, stress, anguish and emotional distress

52. As a further proximate result of the failures, omissions and acts of Defendants, Plaintiff has suffered and continues to suffer from the loss of care, comfort, companionship, love and affection.

53. The life of Diane Smith has forever been altered by the events of the Defendants. Plaintiff will pursue general damages, as well as the claim for punitive damages.

54. That as a direct and proximate result of the aforementioned, Plaintiff has

sustained general damages in a sum to be determined, such sum, however, being in excess of the minimal jurisdictional limits of this Court.

55. Plaintiff is entitled to a judgement in her favor and against the above Defendants, in an amount to be determined, to be full, fair, and reasonable compensation for the negligent actions and/or inactions of Defendants; and to compensate Plaintiff for pain, anxiety, depression, economic damage and emotional trauma suffered as a result thereof, plus costs, interest, and attorney's fees.

WHEREFORE, Plaintiff prays for judgment against the Defendants, both individually and jointly, as follows:

1. For general and special damages in a reasonable and appropriate amount, as may be proven at trial;
2. For exemplary and/or punitive damages as may be proven at trial in a reasonable and appropriate amount;
3. For Plaintiff's costs and expenses in prosecuting this matter;
4. For Plaintiff's reasonable attorneys' fees; and
5. For such other and further relief as the Court deems just and proper.

JURY DEMAND

Plaintiff demands a trial by jury on all claims for which they have the right to trial by jury.

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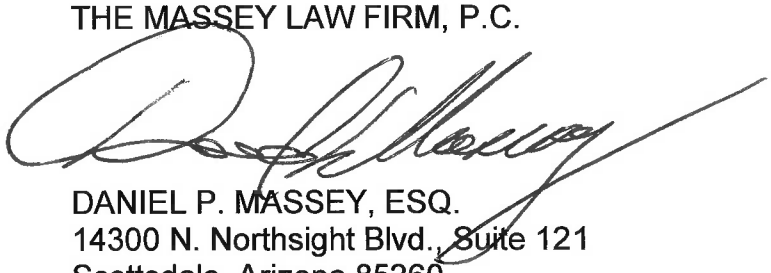
RESPECTFULLY SUBMITTED this 21st day of July, 2022.

THE MASSEY LAW FIRM, P.C.



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