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7
8 **IN THE UNITED STATES DISTRICT COURT**
9 **FOR THE DISTRICT OF ARIZONA**

10 Diane Smith;

11 Plaintiff,

Case: _____

12
13 v.

COMPLAINT

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

(Demand for Jury Trial)

18 Defendants.

19 COMES NOW the Plaintiff, Diane Smith, by and through her attorney undersigned, and
20 for her cause of actions against the Defendants, Arthrex, Inc. et al. ("Defendants") states and
21 alleges as follows:
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23 **PARTIES, JURISDICTION AND VENUE**

24 1. Diane Smith ("Plaintiff") is a resident of Maricopa County, Arizona, and was so
25 at all times relevant hereto.
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1 total knee replacement system such as was surgically implanted in Plaintiff Diane Smith's right
2 knee on or about December 1, 2018.

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

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

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

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

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

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

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

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

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

23 18. On October 22, 2019, Plaintiff complained to Dr. Campbell of "aches and pains
24 in both knees right worse on [sic] left." Dr. Campbell further states during this visit "We
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1 discussed with the patient the loosening of the tibial baseplate on the right. We discussed
2 potential revision.”

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

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

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

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

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

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

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

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

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

22 28. On October 22, 2020 again, due to the defective nature of Defendants’ product,
23 Dr. Evangelista performed a “Revision left total knee arthroplasty, wound vacuum placement,
24 left knee.”
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1 36. The use of said knee implant hardware was used as set forth and expected by
2 the Defendants and, therefore, was reasonably foreseeable, as defined in A.R.S. §12-681.
3 There was no modification of the product as defined by A.R.S. §12-681.

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

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

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

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

22 41. The Arthrex iBalance total knee replacement system, in the absence of
23 appropriate warnings, is an unreasonably dangerous product, and was so at the time of its
24 manufacture and at the time it was shipped from the manufacturing facility. The failure to
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1 provide any warning to Plaintiff had direct consequences to Plaintiff in the form of her injuries
2 as set forth above.

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

6 43. As a result of the unreasonably dangerous condition of the Arthrex iBalance total
7 knee replacement system, the Defendants are subject to strict liability.
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10 **COUNT II**
11 **NEGLIGENCE**

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

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

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

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

24 47. As further proximate result of the failures of the Defendants as alleged above
25 and in addition to the physical and economic damages suffered by Plaintiff. Plaintiff Diane
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1 Smith has suffered and will in the future continue to suffer grievous emotional distress
2 including, but not limited to, emotional pain, anguish, stress, grief, depression, and other
3 mental suffering.

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

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

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

12 50. As a proximate result of the acts and omissions by Defendants, Plaintiff has
13 suffered greatly. The untimely discovery of Plaintiff's condition has caused extensive
14 unnecessary medical procedures including invasive surgeries, rigorous therapy and countless
15 other medical difficulties. Plaintiff, Diane Smith has further suffered from permanent disability.
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17 51. As a further proximate result of the failures, omissions and acts of Defendants,
18 Plaintiff has suffered and continues to suffer from depression, shock, stress, anguish and
19 emotional distress

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

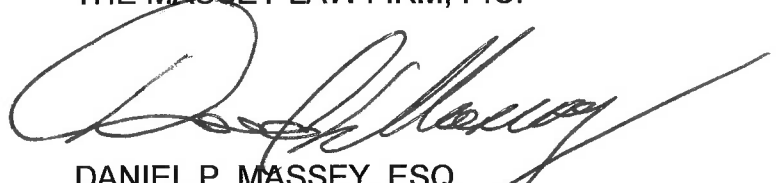
23 53. The life of Diane Smith has forever been altered by the events of the Defendants.
24 Plaintiff will pursue general damages, as well as the claim for punitive damages.

25 54. That as a direct and proximate result of the aforementioned, Plaintiff has
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RESPECTFULLY SUBMITTED this 21st day of July, 2022.

THE MASSEY LAW FIRM, P.C.



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