IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
COLUMBIA DIVISION

MELISSA DAVIS, Plaintiff, **v.** **EXACTECH, INC. and EXACTECH US, INC.,** Defendants.	**Case No.** 3:22-cv-1236-SAL **Jury Demanded**

COMPLAINT

Plaintiff, Melissa Davis, by and through their undersigned attorneys, and hereby file this Complaint against Defendants, Exactech, Inc. ("Exactech") and Exactech US, Inc. ("Exactech US") (collectively "Defendants") for actual, economic, mental anguish, and punitive damages, and such other relief deemed just and proper arising from the injuries to Plaintiff as a result of her injuries suffered as a direct and proximate result of Defendants' designing, developing, testing, assembling, manufacturing, packaging, labeling, preparing, distributing, marketing, supplying, warranting and/or selling the defective device sold under the name "Optetrak" total knee replacement system (hereinafter "Optetrak" or "Defective Device"). In support, Plaintiffs allege the following:

PARTIES

1. At all times relevant hereto, Plaintiff Melissa Davis was a resident and citizen of Leesville, South Carolina.

2. As a result of the implantation of the Defective Device, Plaintiff Melissa Davis suffered personal and economic injuries and sought medical and other healthcare treatment for the

effects of the injuries that were the direct and proximate result of the implantation of the Defective Device and Defendants' conduct.

3. Defendant Exactech, Inc. is a for-profit Florida corporation with its principal place of business at 2320 NW 66th Court, Gainesville, Florida, 32653 and can be served through its registered agent Corporation Service Company, 1201 Hays Street, Tallahassee, Florida 32301. Exactech's stated business purpose is to "develop, manufacture, market, distribute and sell orthopedic implant devices, related surgical instrumentation and biologic services to hospitals and physicians in the United States and internationally" and to introduce its products, including the Defective Device, into interstate commerce, either directly or indirectly through third parties or related entities.

4. Exactech US, Inc., a wholly owned subsidiary of Defendant Exactech, Inc., is a for-profit Florida corporation with its principal place of business at 2320 NW 66th Court, Gainesville, Florida, 32653 and can be served through its registered agent Corporation Service Company, 1201 Hays Street, Tallahassee, Florida 32301. Defendant Exactech Inc.'s "U.S. sales and distribution activities are conducted by [its] wholly owned subsidiary Exactech US, Inc." and Exactech U.S., Inc. is engaged in the business of designing, developing, testing, assembling, manufacturing, packaging, labeling, preparing, distributing, marketing, supplying, warranting, selling, and introducing its products, including the Defective Device, into interstate commerce, either directly or indirectly through third parties or related entities. Collectively, Exactech, Inc. and Exactech US, Inc. are referred to in this pleading as "Exactech" or "Defendants."

JURISDICTION AND VENUE

5. This Court has jurisdiction over Defendants in this action pursuant to 28 U.S.C. § 1332 because there is complete diversity of citizenship between Plaintiffs and Defendants and because the amount in controversy exceeds $75,000 exclusive of interest and costs, and because,

among other reasons, Defendants have significant contacts with this district by virtue of doing business within this judicial district.

6. The Court has supplemental jurisdiction over the remaining common law and state law claims pursuant to 28 U.S.C. § 1367.

7. At all times relevant to this action, Defendants engaged, either directly or indirectly, in the business of designing, developing, testing, assembling, manufacturing, packaging, labeling, preparing, distributing, marketing, supplying, warranting, selling, and introducing into interstate commerce, either directly or indirectly through third parties or related entities, their products, including the Defective Device, within the State of South Carolina with a reasonable expectation that the products would be used or consumed in this state, and thus regularly solicited or transacted business in this state.

8. At all times relevant to this action, Defendants were engaged in disseminating inaccurate, false, and/or misleading information about the Defective Device to healthcare professionals in the State of South Carolina, including Plaintiff's healthcare professionals, with a reasonable expectation that such information would be used and relied upon by healthcare professionals throughout the State of South Carolina, including but not limited to:

a. false representations of duration and survival of the components lasting longer than other knee implants because of proprietary use of materials and processes to give it superior wear characteristics; and/or,

b. false claims of greater forgiveness to sub-optimal implantation conditions.

9. Defendants engaged in substantial business activities in the State of South Carolina. At all relevant times, Defendants transacted, solicited, and conducted business in South Carolina through their employees, agents, and/or sales representatives and derived substantial revenue from

such business in South Carolina. These activities included the promotion, sale, and use of the Defective Device.

10. Further, Defendants committed torts in whole or in part against Plaintiff in the State of South Carolina. As such, this Court has personal jurisdiction over all named defendants.

11. Venue is proper within this district pursuant to 28 U.S.C. § 1391(b)(2) because Plaintiff resides in this district and because a substantial part of the acts and/or omissions giving rise to these claims occurred within this district.

STATEMENT OF FACTS

12. At all times material hereto, Defendants, directly or through their agents, apparent agents, servants, and/or employees designed, developed, tested, assembled, manufactured, packaged, labeled, prepared, distributed, marketed, supplied, warranted and/or sold the Defective Device for the use as a total knee replacement under various versions of the name "Optetrak."

13. Defendants concealed, and continue to conceal, their knowledge of the Defective Device's unreasonably dangerous risks from Plaintiff, Plaintiff's medical providers, other consumers, and the medical community at large.

14. Upon information and belief, the first Optetrak knee device became available to be implanted in a patient in 1994.

15. Since 1994, Defendants have obtained 510(k) clearance for various Optetrak devices and tibial inserts including the Optetrak PS, Optetrak Hi-Flex PS, Optetrak Finned Tibial Tray, Optetrak Offset Tibial Tray, Optetrak RBK Tibial Insert, Optetrak RBK Tibial Tray, Optetrak CR Slope, and Optetrak Logic.

16. These devices are used for knee replacement surgery, referred to as a total knee arthroplasty ("TKA"). The TKA is performed under general anesthesia. The primary indication for

TKA is to relieve severe pain associated with arthritis and may also be used to correct knee trauma or minor knee deformities.

17. During the TKA procedure, the surgeon makes an approximately eight to ten centimeter incision on the front of the leg over the knee. The surgeon will then prepare the femur portion of the knee, the distal femur. This process includes removing any diseased bone and drilling a hole in the femur in which to implant the femoral component of the device. The surgeon will then place a femoral implant onto the distal femur using surgical cement. Next, the surgeon will prepare the proximal tibia, the bone located at the bottom of the knee. The tibial preparation includes removing diseased bone, properly aligning the tibial tray, and drilling a hole in which to implant the tibial tray. The tibial tray is then implanted using surgical cement. A third product, the tibial insert, is a polyethylene product implanted between the femoral implant and tibial tray.

18. In 2017, Plaintiff (53-years-old at the time) underwent this TKA surgery on her left and right knees, wherein the surgeon implanted Defendants' Optetrak knee device. The allegations in this Complaint relate to the early failure of the Defective Device, and in particular its polyethylene tray component. The surgeon noted extreme deterioration of the polyethylene tray component. The degree of deterioration resulted in a complete failure of the Defective Device, requiring total replacement.

19. The components of the device were defective, unreasonably dangerous and failed, resulting in loosening, malpositioning of the implant, and rubbing/wear of the components causing instability, limited mobility, swelling and pain. This was initially discovered upon revision surgery on Plaintiff's right knee, in 2020.

20. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff was admitted to Lexington Medical Center in

Lexington, South Carolina, where she underwent a painful total knee replacement.

21. Plaintiff could not reasonably have discovered the injury and its cause before the date of the revision surgery and/or the date of any recall notification to Plaintiff and his doctor because Defendants never recalled their product and they continue to deny responsibility for the device's premature failure due to premature polyethylene wear and/or tibial base plate loosening.

22. Defendants promoted their Optetrak devices as a system with three decades of clinical success and proven outcomes for patients around the world because of an improved articular design resulting in low polyethylene stresses.

23. As a result of the defective nature of the Optetrak knee replacement procedure, persons who were implanted with a Defective Device, including Plaintiff, have suffered, and may continue to suffer, severe and permanent personal injuries, including painful knee revision surgery to remove or revise the Defective Device, continued rehabilitation, medical care, and possible additional surgeries.

24. Upon information and belief Defendants became aware of a high rate of early failures of their Optetrak products.

25. In 2012, "Poor results of the Optetrak cemented posterior stabilized knee prosthesis after a mean 25-month follow-up: Analysis of 110 prostheses" was published in Orthopaedics and Traumatology, volume 98, issue 4, pages 413-420. The article concluded "the small size of the tibial keel does not seem to resist the stresses applied by the ultracongruent shape of the posterior stabilization of this implant and the increase in intercondyloid eminence height."

26. The Australian joint registry is an authoritative source that the medical community and industry look to in calculating prosthetic survival rates.[1] In the 2016 Australian Registry Annual

[1] Australian Orthopaedic Association National Joint Replacement Registry 2016. Hip Knee and Shoulder Arthroplasty Annual Report 2016. Available from: https://aoanjrr.sahmri.com/documents/10180/275066/Hip%2C%20Knee%20%26%20Shoulder%20Arthroplasty

Report, the compared revision of TKA that had a primary diagnosis of osteoarthritis ("OA"), which is 97% of all diagnosis, as installed in the Plaintiff, was reported as:

a. Not statistically significant rate of revision at 1 year;

b. Optetrak was statistically significant (range not overlap; 3.9>2.8) at 3 years;

c. Optetrak was statistically significant (range not overlap; 56>3.7) at 5 years;

d. Both Optetrak and Optetrak-RBK had significantly increased rates of revision at 7 years.

27. The Australian registry identifies the Optetrak as an implant with a higher than expected rate of revision. The hazard ratio reported is high. Put into perspective, the cumulative percent revision of primary total knee replacement with cemented fixed bearing Optetrak (the type as implanted in the Plaintiff) as compared with all other reported cemented knees was:

a. the second worst mean percent failure rate of 4.7% as compared with all other cemented knees at 3 years;

b. The Optetrak bearing tied for worst failure rate of 6.6% at 5 years as compared to all other cemented knees;

c. The Optetrak fixed bearing had the worst failure rate with a mean of 7.9% at 7 years as compared to all other cemented knees;

d. The Optetrak fixed bearing has worst failure rate with a mean of 9.6% at 10 years, as compared to all other knee implants.

28. Defendants were aware that Optetrak knee implants were failing at a rate higher than promoted. Reports in the Manufacturer and User Facility Device Experience (MAUDE) indicated instances of revision due to "loose tibial component", "aseptic loosening", "polyethylene wear", "pain and visible loosening", and "pain, limited mobility, knee swelling and sensitivity" due to a "loose" joint. These early onset failure MAUDE reports are representative of the increased rate of

incidents of which Defendants had become internally aware. There are currently so many complaints about the Optetrak devices in MAUDE that a search returns the maximum limit of results (500) and cannot display all of the complaints that have been submitted to the database.Upon information and belief, instead of warning consumers and the medical community about the increased failure rates of the Defective Devices, Defendants engaged in a "silent recall" campaign where they slowly replaced all finned tibial trays with a new, more substantial design, referred to as "fit" trays and change of the polyethylene insert. Concurrent with this strategy of product replacement, Defendants also engaged in a campaign of misinformation where any incidents of early onset failure were blamed on surgeon-specific factors instead of acknowledging problems with the tibial tray and polyethylene insert product itself and disclosing them to all patients who had the Defective Device. Because of this activity, Defendants are estopped from claiming Plaintiff should have known about the early onset failure of the Defective Device.

29. Despite Defendants' claims in its promotional materials of over 30 years of successful outcomes with knee devices, Defendants knew of an unacceptably high early failure rate of their Optetrak knee implants. On information and belief, Defendants concealed this information while its CEO and President David Petty bragged about the strong double-digit growth in knee business. From 2012 to 2016, a time when Defendants should have been recalling products, Exactech's Extremities division almost doubled in size, from $52.1 million (2012) to $100.3 million (2016).

30. A defectively designed and manufactured Optetrak knee implant left the hands of Defendants in its defective condition. Defendants delivered the Defective Device into the stream of commerce and allowed it to be implanted in a total knee arthroplasty in Plaintiff.

31. On information and belief, Defendants' knee implant devices are adulterated pursuant to 21 U.S.C. § 351 because, among other things, they failed to meet established performance

standards, and/or methods, facilities, or controls used for their manufacture, packaging, storage or installation and are not in conformity with federal requirements. See 21

U.S.C. § 351.

32. On information and belief, Defendants' knee implant devices are misbranded because, among other things, they are dangerous to health when used in the manner prescribed, recommended or suggested in the labeling thereof. See 21 U.S.C. § 352.

33. On information and belief, Defendants' knee implant devices are adulterated pursuant to 21 U.S.C. § 351 because Defendants failed to establish and maintain Current Good Manufacturing Practices ("CGMP") for its knee implant devices in accordance with 21 CFR § 820, *et seq*.

34. On information and belief, Defendants failed to establish and maintain CGMP with respect to quality audits, quality testing, surveillance related to failures and process validation for its knee implant devices.

35. Defendants had a duty to follow Current Good Manufacturing Practices. As a result of Defendants' failure to establish and maintain CGMP as set forth above, Defendants' knee implant devices were defective and failed, resulting in injuries to the Plaintiff.

36. If Defendants had complied with the federal requirements regarding CGMP, Defendants' knee implant devices would have been manufactured properly and would not have resulted in injuries to the Plaintiff.

COUNT ONE
NEGLIGENCE

37. Plaintiff repeats, reiterates, and re-alleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein. Defendants had a duty to exercise reasonable care in the design, development,

formulation, testing, manufacture, marketing, sale, and distribution of the Defective Device into the stream of commerce, including a duty to assure that their products did not pose a significantly increased risk of bodily harm and adverse events to its users as well.

38. Defendants had an obligation to follow the law in the manufacture, design, testing, assembly, inspection, labeling, packaging, supplying, marketing, selling, advertising, post market surveillance, preparing for use, including a duty to warn Plaintiff and other consumers of the risks and dangers associated with the Defective Device that were known or should have been known to Defendants at the time of the sale to the Plaintiff and otherwise distributing the Defective Device.

39. Defendants' acts and omissions constitute a breach of duty, subjecting Defendants to civil liability for all damages arising therefrom.

40. Defendants owed Plaintiff and other consumers a duty to exercise reasonable care when designing, manufacturing, marketing, advertising, distributing, and selling the Defective Device, including the duty to take all reasonable steps necessary to ensure the product was not unreasonably dangerous to its consumers and users, and to warn Plaintiff and other consumers of the dangers associated with the Defective Device.

41. At all times material hereto, Defendants had actual knowledge, or in the alternative, should have known through the exercise of reasonable and prudent care, of the hazards and dangers of the Defective Device.

42. Defendants breached their duty and failed to exercise ordinary care and/or were negligent, reckless and/or wanton in the design, formulation, manufacture, sale, testing, quality assurance, quality control, labeling, marketing, promotion and distribution of the Defective Device into interstate commerce because Defendants knew or should have known that these products would cause significant bodily harm and were not safe for use by consumers.

43. Defendants failed to exercise ordinary care in the labeling of the Optetrak system and failed to issue adequate pre-marketing or post-marketing warnings to doctors and the general public, including Plaintiff, regarding the risk of serious injury, including tibial base plate loading, premature polyethylene wear, and risk for early revision surgery.

44. Defendants knew or should have known that Plaintiff could suffer injury as a result of Defendants' failure to exercise ordinary care as described above.

45. Despite the fact that Defendants knew or should have known that the Defective Device posed a serious risk of bodily harm to consumers, Defendants continued to manufacture and market the Defective Device for implantation into consumers.

46. Defendants failed to exercise due care under the circumstances, and their negligence and recklessness includes the following acts and omissions:

a. Failing to properly and thoroughly test the Defective Device before releasing the device to market;

b. Failing to properly and thoroughly analyze the data resulting from the premarketing tests of the Defective Device;

c. Failing to conduct sufficient post-market testing and surveillance of the Defective Device;

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

e. Failing to adequately prevent, identify, mitigate, and fix defective designs and hazards associated with the Defective Device in accordance with good design practices;

f. Failing to notify and warn the public including Plaintiff of reported incidents involving injury, and the negative health effects attendant to the use of the Defective Device, thus misrepresenting the safety of the product;

g. Failing to provide warnings, instructions or other information that accurately reflected the risks of early failure of the Defective Device;

h. Failing to exercise due care when advertising and promoting Defective Device;

i. Disseminating information that was inaccurate, false, and misleading, and which failed to communicate accurately or adequately the high early failure rate associated with the implantation of the Defective Device;

j. Continuing to aggressively promote the Defective Device even after Defendants knew or should have known of the unreasonable risks from implantation;

k. Failing to provide information that accurately reflected the high early failure rate of the Defective Device;

l. Downplaying, or otherwise suppressing, through aggressive marketing and promotion the risks associated with the implantation of the Defective Device;

m. Failing to make timely and adequate corrections to the manufacture, design and formulation of the Defective Device so as to prevent and/or minimize the problems suffered by use of the Defective Device;

n. Failing to use due care in training and informing healthcare providers on proper surgical technique and limitations of the device so as to avoid injuries and premature device failure;

o. Failing to use due care in the testing, formulation, inspections, distribution sale and instructions regarding the product at all times prior to Plaintiff's injuries having manifested themselves;

p. Continuing to negligently manufacture, market, advertise, and distribute the Defective Device after the Defendants knew or should have known of its adverse effects and/or the increased early onset failure rates; and

q. Being otherwise careless, reckless and negligent.

47. Defendants knew and/or should have known that it was foreseeable that consumers such as Plaintiff would suffer injuries as a result of Defendants' 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 Defective Device, and otherwise distributing the Defective Device.

48. As a direct and proximate result of Defendants' acts and omissions, Plaintiff was implanted with the Defective Device and has suffered severe and debilitating injuries, and other damages, including but not limited to, cost of medical care, rehabilitation, permanent physical injury and damage, including instability, loss of balance, and immobility, as well as pain and suffering, for which he is entitled to in an amount to be proven at trial.

49. Exemplary damages. Plaintiff's injuries resulted from Defendants' gross negligence and/or actual malice, which entitles him to exemplary damages under South Carolina law.

COUNT TWO
VIOLATIONS OF SOUTH CAROLINA UNFAIR TRADE PRACTICES ACT

50. Plaintiff repeats, reiterates, and re-alleges each and every allegation of this Complaint contained in each of the foregoing paragraphs, with the same force and effect as if more fully set forth herein.

51. Plaintiff is a "consumer" under the South Carolina Unfair Trade Practices Act ("SCUTPA") as an actual recipient of consumer goods from Defendants. Defendants are companies that can be sued under the SCUTPA. The actions of Defendants constitute misrepresentations, breaches of warranties and unconscionable conduct, actionable under the SCUTPA. Specifically, Defendants committed the following acts in violation of the SCUTPA, S.C. Code Ann. § 39-5-140, one or more of which was a proximate cause of damages to Plaintiff:

a. Representing that the consumer goods or services had characteristics, ingredients, uses or benefits which they did not have;

b. Representing that consumer goods were of a particular standard, quality or grade when they were of another; and

c. Failing to disclose information concerning goods or services which was known at the time in order to induce the Plaintiff to enter into a transaction

which Plaintiff would not have otherwise entered; i.e., deceiving Plaintiff by failing to state material facts.

52. Plaintiff relied on these representations to his detriment.

53. Further, Defendants violated the SCUTPA by breaching express and implied warranties as addressed below in this Complaint. Plaintiff fully incorporates the allegations set forth in Count Six and Count Seven below related to breach of express warranty and breach of implied warranty.

54. Defendants' conduct as described herein was a proximate cause of damages to Plaintiff.

COUNT THREE
STRICT PRODUCTS LIABILITY

55. Plaintiff repeats, reiterates, and re-alleges each and every allegation of this Complaint contained in each of the foregoing paragraphs with the same force and effect as if more fully set forth herein.

56. Defendants are strictly liable to Plaintiff under South Carolina law.

57. Defendants have engaged in the business of designing, researching, manufacturing, marketing, supplying, promoting, packaging, selling, testing, and/or distribution of the Defective Device. Through that conduct, Defendants knowingly and intentionally placed the Defective Device into the stream of commerce with full knowledge that it reaches consumers, such as Plaintiff.

58. Defendants 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 Defective Device was unreasonably dangerous in construction and/or composition.

59. Defendants expected the Defective Device to reach, and it did in fact reach, implanting orthopedic surgeons, healthcare professionals and consumers, including Plaintiff and Plaintiff's healthcare professionals, without any substantial change in the condition of the product from when it was initially distributed by Defendants.

60. The Defective Device, as manufactured and/or supplied by Defendants, was defective due to its high early failure rate. Defendants knew or should have known that the product created significant risks of serious bodily harm to consumers, as alleged herein, and they failed to adequately warn consumers and/or their healthcare professionals of such risks.

61. The Defective Device was defective and unsafe such that it was unreasonably dangerous when it left the Defendants' possession and/or control, was distributed by Defendants, and implanted by Plaintiff's surgeon.

62. The Defective Device design created an unreasonable risk of early failure and resulting painful revision surgery.

63. This defect caused serious injury to Plaintiff, who used the Defective Device for its intended purpose and in a reasonably anticipated manner.

64. At all times herein mentioned, Defendants 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.

65. Defendants negligently and recklessly designed, distributed, and promoted the Defective Device.

66. Defendants, as designers, manufacturers, sellers, and/or distributors of medical devices, are held to the knowledge of an expert in the field.

67. Plaintiff could not have discovered any defects in the Defective Device through the exercise of reasonable care and relied upon the skill, superior knowledge, and judgment of Defendants.

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

69. The Defective Device was the actual and proximate cause of Plaintiff's injuries.

70. Exemplary damages. Plaintiff's injuries resulted from Defendants' gross negligence and/or malice, which entitles him to exemplary damages under South Carolina law.

COUNT FOUR
NEGLIGENT MISREPRESENTATION

71. Plaintiff repeats, reiterates, and re-alleges each and every allegation of this Complaint contained in each of the foregoing paragraphs with the same force and effect as if more fully set forth herein.

72. Defendants owed a duty in all of their undertakings, including the dissemination of information concerning the Defective Device, to exercise reasonable care to ensure they did not create unreasonable risks of personal injury to others.

73. Defendants disseminated to healthcare professionals and consumers – through published labels, marketing materials, direct communications, and otherwise – information that misrepresented the efficacy and longevity of the Defective Device with the intention that healthcare professionals and consumers would rely upon that information in their decisions concerning whether to implant the Defective Device.

74. Defendants, as the designers, manufacturers, sellers, promoters, and/or distributors of the Defective Device knew, or reasonably should have known, that healthcare professionals and

consumers of the Defective Device would rely on information disseminated and marketed to them regarding the product when weighing the potential benefits and potential risks of implanting Defective Device.

75. Defendants failed to exercise reasonable care to ensure that the information they disseminated to healthcare professionals and consumers concerning the efficacy and longevity of the Defective Device was accurate, complete, and not misleading. As a result, Defendants disseminated information to healthcare professionals and consumers that was materially inaccurate, misleading, false, and unreasonably dangerous to consumers such as Plaintiff.

76. Defendants, as designers, manufacturers, sellers, promoters, and/or distributors of the Defective Device, knew or reasonably should have known that surgeons would implant the Defective Device in reliance on the information disseminated by Defendants, and that the patients implanted with the Defective Device would suffer early failure and require revision surgery because the information disseminated by Defendants and relied upon by healthcare professionals and consumers, including Plaintiff, was materially inaccurate, misleading, or otherwise false.

77. From the time the Defective Device was first tested, studied, researched, evaluated, endorsed, manufactured, marketed, and distributed, and up to the present, Defendants failed to disclose material facts regarding the safety, efficacy, and longevity of the Defective Device. Defendants made material misrepresentations to Plaintiff, Plaintiff's healthcare professionals, the healthcare community, and the general public, including:

a. Stating that the Defective Device had been tested and found to be safe and effective implant for TKA;

b. Concealing, misrepresenting, and actively downplaying the severe risks of harm related to the implantation of the Defective Device, as compared to comparable alternative TKA devices; and

c. Misrepresenting the Defective Device's risk of unreasonable and dangerous early failure.

78. Defendants made the foregoing representations without any reasonable ground for believing them to be true.

79. These representations were made directly by Defendants, their sales representatives, and other authorized agents, and in publications and other written materials directed to healthcare professionals, medical patients, and the public, including Plaintiff and Plaintiff's physicians.

80. Defendants made these representations with the intent to induce reliance thereon, and to encourage purchase and implantation of the Defective Device.

81. Defendants had a duty to accurately and truthfully represent to medical professionals and consumers, including Plaintiff, the truth regarding Defendants' claims that the Defective Device had been tested and found to be a safe and effective TKA implant option.

82. The misrepresentations made by Defendants, in fact were false and known by Defendants to be false at the time the misrepresentations were made.

83. Defendants failed to exercise ordinary care in making their representations concerning the Defective Device and in the manufacture, sale, testing, quality assurance, quality control, and distribution in interstate commerce of the Defective Device.

84. Defendants engaged in a nationwide marketing campaign, over-promoting the Defective Device in written marketing literature, in written product packaging, and in direct-to-consumer advertising via print and internet advertisements and television commercial ads. Defendants' over-promotion was undertaken by touting the safety and efficacy of Defective Device while concealing, misrepresenting, and actively downplaying the serious, severe, and life- threatening risks of harm to patients implanted with the Defective Device, when compared to comparable alternative TKA implant options. Defendants negligently misrepresented the Defective Device's safety, efficacy, and longevity.

85. Defendants' conduct, as described above, was reckless. Defendants risked the health of consumers and users of the Defective Device, including Plaintiff. Defendants had knowledge of the safety problems and suppressed this knowledge from healthcare professionals, including Plaintiff's healthcare professionals, as well as the general public. Defendants made conscious decisions for years not to redesign or re-label, or to adequately warn or inform the concerned parties or the unsuspecting public. Defendants' reckless conduct warrants an award of punitive damages.

86. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff suffered injuries and damages including a painful knee revision surgery and other related health complications.

87. Exemplary damages. Plaintiff's injuries resulted from Defendants' gross negligence and/or malice, which entitles him to exemplary damages under South Carolina law.

COUNT FIVE
FRAUDULENT CONCEALMENT

88. Plaintiff repeats, reiterates, and re-alleges each and every allegation of this Complaint contained in each of the foregoing paragraphs with the same force and effect as if more fully set forth herein.

89. Throughout the relevant time period, Defendants knew that the Defective Device was defective and unreasonably unsafe for its intended purpose, and intentionally and willfully failed to disclose and/or suppressed information regarding the true nature of the risk of early failure associated with implantation of the Defective Device.

90. Defendants fraudulently concealed information with respect to the Defective Device in the following particulars:

a. Defendants represented through their labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, direct physician communications, and regulatory submission that the Defective Device was safe and fraudulently withheld and

concealed information about the severity of the substantial risks early failure of the Defective Device;

b. Defendants represented through their labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, direct physician communications, and regulatory submission that the Defective Device was safe and fraudulently withheld and concealed information about the risk of early failure; and

c. Upon information and belief, Defendants represented that the Defective Device was safer than other alternative TKA options and fraudulently concealed information that demonstrated that the Defective Device was not safer than alternatives available on the market.

91. Defendants were under a duty to Plaintiff to disclose and warn of the defective and dangerous nature of the Defective Device because:

a. Defendants had sole access to material facts concerning, and unique and special expertise regarding, the dangers and unreasonable risks of implantation of the Defective Device;

b. Defendants knowingly made false claims and omitted important information about the safety, efficacy, and longevity of the Defective Device in the documents and marketing materials Defendants provided to physicians and the general public; and

c. Defendants fraudulently and affirmatively concealed the defective and dangerous nature of the Defective Device from Plaintiff.

92. As the designers, manufacturers, sellers, promoters, and/or distributors of the Defective Device, Defendants had unique knowledge and special expertise regarding the Defective Device. This placed them in a position of superiority and influence over Plaintiff and Plaintiff's healthcare providers. As such, Plaintiff and Plaintiff's healthcare providers reasonably placed their trust and confidence in Defendants and in the information disseminated by Defendants.

93. The facts concealed or not disclosed by Defendants to Plaintiff were material facts that a reasonable person would have considered to be important in deciding whether or not to purchase or be implanted with the Defective Device.

94. The concealment and/or non-disclosure of information by Defendants about the severity of the risks of early failure after implantation of the Defective Device was intentional, and the representations made by Defendants were known by them to be false.

95. The concealment of information and the misrepresentations about the Defective Device were made by Defendants with the intent that doctors and patients, including Plaintiff, rely upon them so that Plaintiff would request and purchase the Defective Device and Plaintiff's healthcare providers would recommend and implant the Defective Device.

96. Plaintiff, Plaintiff's doctors, and others reasonably relied on Defendants' representations and were unaware of the substantial risk of early failure after implantation of the Defective Device.

97. Had Defendants not concealed or suppressed information regarding the severity of the risks of early failure of the Defective Device, Plaintiff's physicians would not have used the Defective Device in Plaintiff's TKA and/or would have medically monitored Plaintiff differently after the Defective Device was implanted in order to minimize and/or mitigate the damages which would result from the Defective Device.

98. Defendants, by concealment or other action, intentionally prevented Plaintiff and Plaintiff's healthcare professionals from acquiring material information regarding the lack of safety, efficacy, and longevity of the Defective Device, thereby preventing Plaintiff from discovering the truth. As such, Defendants are liable for fraudulent concealment.

99. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff suffered a painful knee revision surgery and other related health complications. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, and other losses and damages. Plaintiff has incurred and will continue to incur mental and physical pain and suffering.

100. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff suffered injuries and damages including a painful knee revision surgery and other related health complications.

101. Exemplary damages. Plaintiff's injuries resulted from Defendants' fraud, which entitles him to exemplary damages under South Carolina law.

COUNT SIX
BREACH OF EXPRESS WARRANTY

102. Plaintiff repeats, reiterates, and re-alleges each and every allegation of this Complaint contained in each of the foregoing paragraphs with the same force and effect as if more fully set forth herein.

103. At all times material hereto, Defendants engaged in the business of testing, developing, designing, manufacturing, packaging, labeling, marketing, promoting, selling, and/or distributing the Defective Device, which is unreasonably dangerous and defective, thereby placing the Defective Device into the stream of commerce.

104. Defendants expressly represented to Plaintiff, other consumers, Plaintiff's physicians, and the medical community, by and through statements made and written materials disseminated by Defendants or their authorized agents or sales representatives, that the Defective Device:

a. was safe and fit for its intended purposes;

b. was of merchantable quality; and

c. had been adequately tested and found to be safe and effective for implantation in TKA.

105. These express representations include incomplete marketing materials and labeling that purports, but fails, to include the true risks associated with high early failure rates of the Defective Device. In fact, Defendants knew or should have known of the high early failure rates associated with

implantation of the Defective Device. Despite this, Defendants expressly warranted the Defective Device as safe and effective for implantation in TKA.

106. Defendants advertised, labeled, marketed, and promoted the Defective Device, representing the quality to healthcare professionals, Plaintiff, and the public in such a way as to induce the Defective Device's purchase or implantation, thereby making an express warranty that the Defective Device would conform to the representations. More specifically, the marketing materials and labeling of the Defective Device did not and do not contain adequate information about the true risks of high early failure rate and the injuries complained of herein.

107. Despite this, Defendants expressly represented that the Defective Device was safe and effective, that it was safe and effective for use by individuals such as Plaintiff, and/or that it was safe and effective for implantation in TKA.

108. The representations about the Defective Device contained or constituted affirmations of fact or promises made by the seller to the buyer which related to the goods and became part of the basis of the bargain creating an express warranty that the goods shall conform to the affirmations of fact or promises.

109. The Defective Device does not conform to Defendants' express representations because it is not safe, effective, or have the implantation life warranted by Defendants. Therefore, Defendants breached the aforementioned warranties.

110. At all times relevant, the Defective Device did not perform as safely and as an ordinary consumer would expect when used as intended or in a reasonably foreseeable manner.

111. Neither Plaintiff nor Plaintiff's surgeon had knowledge of the falsity or incompleteness of the Defendants' statements and representations concerning the Defective Device.

112. Plaintiff, other consumers, Plaintiff's physicians, and the medical community justifiably and detrimentally relied upon Defendants' express warranties when recommending and implanting the Defective Device.

113. Had the marketing and labeling information for the Defective Device accurately set forth the true risks associated with the high early failure rate and potential injuries, including Plaintiff's injuries, rather than expressly excluding such information and warranting that the product was safe for its intended purpose, Plaintiff could have avoided the injuries complained of herein.

114. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff suffered injuries and damages including a painful knee revision surgery and other related health complications.

115. Attorney fees. Plaintiff is entitled to recover reasonable and necessary attorney fees for a breach of express warranty.

COUNT SEVEN
BREACH OF IMPLIED WARRANTY

116. Plaintiff repeats, reiterates, and re-alleges each and every allegation of this Complaint contained in each of the foregoing paragraphs with the same force and effect as if more fully set forth herein.

117. Defendants manufactured, distributed, advertised, promoted, and sold the Defective Device.

118. At all relevant times, Defendants knew of the purpose for which the Defective Device was intended and impliedly warranted the product to be of merchantable quality and safe and fit for such use.

119. Defendants were aware that consumers, including Plaintiff, would be implanted with the Defective Device during TKA.

120. The Defective Device was neither safe for its intended purpose nor of merchantable quality, as impliedly warranted by Defendants, in that the Defective Device has dangerous propensities when used as intended and can cause serious injuries, including early failure resulting in additional painful revision surgeries and the risks associated with additional surgery.

121. At all relevant times, Defendants intended that the Defective Device be used in the manner used by Plaintiff, and Defendants impliedly warranted it to be of merchantable quality, safe, and fit for such purpose, despite the fact that the Defective Device was not adequately tested. Defendants were aware that consumers, including Plaintiff, would be implanted with the Defective Device as marketed by Defendants. As such, Plaintiff was a foreseeable user of the Defective Device.

122. Upon information and belief, Plaintiff and/or Plaintiff's healthcare professionals were at all relevant times in privity with Defendants.

123. The Defective Device was dangerous and defective when Defendants placed it into the stream of commerce because of its propensity to cause Plaintiff's injuries.

124. Plaintiff and the medical community reasonably relied upon the judgment and sensibility of Defendants to sell the Defective Device only if it was indeed of merchantable quality and safe and fit for its intended purpose.

125. Defendants breached their implied warranty to consumers, including Plaintiff. The Defective Device was not of merchantable quality, nor was it safe and fit for its intended purpose.

126. Plaintiff and Plaintiff's physicians reasonably relied upon Defendants' implied warranty for the Defective Device when recommending and implanting the Defective Device.

127. Plaintiff's use of the Defective Device was as intended and in a foreseeable manner as intended, recommended, promoted, and marketed by Defendants.

128. The Defective Device was expected to reach and did in fact reach consumers, including Plaintiff, without substantial change in the condition in which it was manufactured and sold by Defendants.

129. Defendants breached the warranties of merchantability and fitness for its particular purpose because the Defective Device was unduly dangerous and caused undue injuries, including Plaintiff's injuries.

130. The harm caused by the Defective Device far outweighed its alleged benefit rendering the Defective Device more dangerous than an ordinary consumer or healthcare professional would expect and more dangerous than alternative products.

131. Neither Plaintiff nor Plaintiff's healthcare professionals reasonably could have discovered or known of the risk of early failure associated with the Defective Device.

132. Defendants' breach of these implied warranties caused Plaintiff's injuries.

133. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff suffered injuries and damages including a painful knee revision surgery and other related health complications.

DEMAND FOR JURY TRIAL

134. Plaintiff demands trial by jury pursuant to Rule 38 of the Federal Rules of Civil Procedure and the Seventh Amendment of the U.S. Constitution.

CONDITIONS PRECEDENT

135. All conditions precedent to the maintenance of each of the causes of action described above have been performed, satisfied, occurred, or rendered moot. All notices, complaints and/or demands were timely and properly given in such a manner as to fully comply with applicable law.

136. In the alternative, as to any such terms, conditions, notices, or requirements, Defendants waived them, is estopped from asserting them, and/or Plaintiffs substantially complied with them.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, and severally, as follows:

a) For damages in a sum in excess of $75,000, the jurisdictional minimum of this Court;

b) For actual and economic damages;

c) For pain and suffering;

d) For mental anguish damages;

e) For damages under the SCUTPA;

f) For punitive damages in an amount sufficient to deter similar conduct in the future and punish the Defendants for the conduct described herein;

g) For attorneys' fees, expenses and costs of this action;

h) For pre-judgment and post-judgment interest as provided by law; and

i) For such further and other relief as this Court deems necessary, just and proper.

Dated: April 15, 2022

[redacted]