IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

JOSEPH D. SEXTON 14276 Brandy Lane Georgetown, DE 19947 (Sussex County, DE)	*	
and	*	
CORRINE M. SEXTON 14276 Brandy Lane Georgetown, DE 19947 (Sussex County, DE)	*	Case No.
Plaintiffs	*	**JURY TRIAL DEMANDED**
v.	*	
EXACTECH, INC. 2320 NW 66th Ct. Gainesville, FL 32653 (Alachua County, FL)	*	
<u>Serve on Resident Agent:</u> Corporation Service Company 1201 Hays Street Tallahassee, FL32301	*	
and	*	
EXACTECH US, INC. 2320 NW 66th Ct. Gainesville, FL 32653 (Alachua County, FL)	*	
<u>Serve on Resident Agent:</u> Corporation Service Company 1201 Hays Street Tallahassee, FL32301	*	

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COMPLAINT AND JURY DEMAND

Plaintiffs, JOSEPH D. SEXTON and CORRINE M. SEXTON by and through undersigned counsel, hereby and submit this Complaint and Jury Demand against EXACTECH, INC. ("Exactech") and EXACTECH US, INC. ("Exactech US") for compensatory and punitive damages, equitable relief, and such other relief deemed just and proper arising from the injuries suffered as a direct and proximate result of Defendants' designing, testing, assembling, selecting, manufacturing, packaging, labeling, preparing distributing, marketing, supplying, warranting, and/or selling the defective devices sold under the name "Optetrak" Total Knee System and/or "Optetrak Logic" Total Knee System (hereinafter "Optetrak"). In support, Plaintiffs allege the following:

I. NATURE OF THE ACTION

1. This case involves claims of strict product liability, failure to warn, breach of express and implied warranties, fraud and negligence in the designing, testing, assembling, selecting, manufacturing, packaging, labeling, preparing, distributing, marketing, supplying, warranting, and/or selling of the defective Optetrak devices by the Defendants directly or through their agents, apparent agents, servants, and/or employees.

2. 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 stress, and due to their proprietary polyethylene materials, which they claimed minimized wear and lead to increased longevity.

3. On August 30, 2021, Defendants initiated a partial recall of their Optetrak devices because these devices were packaged improperly without an additional oxygen barrier layer, which

can lead to expedited wear and minimized longevity of the devices. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRes/res.cfm?ID=189266.

4. On February 7, 2022, the recall was expanded to include "all knee and ankle arthroplasty polyethylene inserts packaged in non-conforming bags" that were sold since 2004.

5. On February 7, 2022, Defendants sent surgeons a letter explaining that they conducted "extensive testing" and confirmed that most of their inserts manufactured since 2004 were packaged in "out-of-specification" or "non-conforming" vacuum bags that did not contain the necessary "secondary barrier layer containing ethylene vinyl alcohol (EVOH) that further augments oxygen resistance." Due to this deficiency, Defendants conceded the following:

> **The use of these non-conforming bags may enable increased oxygen diffusion to the UHMWPE (ultra-high molecular weight polyethylene) insert, resulting in increased oxidation of the material relative to inserts packaged with the specified additional oxygen barrier layer. Over time, oxidation can severely degrade the mechanical properties of conventional UHMWPE, which, in conjunction with other surgical factors, can lead to both accelerated wear debris production and bone loss, and/or component fatigue cracking/fracture, all leading to corrective revision surgery.**

See, URGENT MEDICAL DEVICE CORRECTION to Exactech Knee and Ankle Surgeons, February 7, 2022, a copy of which is attached hereto as Exhibit A (Emphasis in original).

6. On November 20, 2006, Plaintiff JOSEPH D. SEXTON underwent Total Knee Replacement surgery on his right knee, in which an Optetrak device was implanted.

7. In the years following the surgeries, Plaintiff JOSEPH D. SEXTON experienced pain, swelling, instability, and bone loss in his right knee caused by early and accelerated polyethylene wear and/or component loosening. Ultimately, on October 9, 2018, Plaintiff

underwent an extensive revision surgery on his right knee

8. Recipients of the Optetrak knee implants have required painful revision surgeries well before the estimated life expectancy of the devices, and at a much higher rate than should reasonably be expected for devices of this kind.

9. Until February 7, 2022, Defendants concealed their knowledge of the Optetrak devices' unreasonably dangerous risks, including an increased risk of early failure, from Plaintiff, Plaintiff's medical providers, other consumers, and the medical community at large.

10. Despite knowledge that the Optetrak devices were defective and resulted in premature failures and accompanying complications, Defendants continued to aggressively market and sell the Optetrak Logic device, all the while maintaining that these devices were safe and effective for use in total knee replacements and concealing the hazards posed by these defective devices.

II. PARTIES

11. At all times relevant hereto, Plaintiffs JOSEPH D. SEXTON and CORRINE M. SEXTON were residents and citizens of Sussex County, Delaware.

12. 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 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 Optetrak device, into interstate commerce, either directly or indirectly through third

parties or related entities. At all times relevant to this action, Defendant Exactech, Inc. tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold the Optetrak devices in interstate commerce and throughout the State of Maryland, and generated substantial revenue as a result.

13. Defendant 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. According to public filings, Defendant Exactech US, Inc. conducts Defendant Exactech Inc.'s sales and distribution activities in the United States. Defendant 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 Optetrak Logic, into interstate commerce, either directly or indirectly through third parties or related entities. At all times relevant to this action, Defendant Exactech US, Inc., tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold the Optetrak Logic in interstate commerce and throughout the State of Maryland and generated substantial revenue as a result.

14. Exactech US, Inc. is thus also an agent, representative and/or alter ego of Defendant Exactech, Inc. Collectively, Exactech and Exactech US, Inc. are referred to herein as "Exactech" or "Defendants."

15. At all relevant times to this action, each of the Defendants and their directors and officers acted within the scope of their authority of each Defendant and on behalf of each other.

At all times relevant to this action, Defendants possessed a unity of interest between themselves and exercised control over their subsidiaries and affiliates. As such, the Defendants are each individually, as well as jointly and severally, liable to Plaintiffs for Plaintiffs' injuries, losses and damages as described herein.

III. JURISDICTION AND VENUE

16. 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. Defendants have significant contacts with this District by virtue of doing substantial business within this judicial district.

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

18. The Court maintains general personal jurisdiction over Defendants as they purposely engaged in the business of designing, developing, selecting, testing, assembling, manufacturing, packaging, labeling, preparing, distributing, marketing, supplying, warranting, selling, and introducing into interstate commerce, their products, including the Optetrak devices and other Exactech implants, within the District of Maryland, with a reasonable expectation that the products would be used within this judicial district.

19. At all times relevant to this action, Defendants were engaged in disseminating inaccurate, false, and/or misleading information about the Optetrak devices to healthcare professionals in the District of Maryland, including Plaintiff's healthcare professionals, with a reasonable expectation that such information would be used and relied upon by healthcare

professionals throughout the District of Maryland, 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.

20. Defendants derived substantial revenue and benefit from their business activities within the District of Maryland, including the promotion, sale and use of the Optetrak devices.

21. Therefore, this Court has both specific and general personal jurisdiction over all named defendants.

22. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391 because the Defendants have substantial, systematic, and continuous contacts in the State of Maryland and this judicial district; because Plaintiff JOSEPH D. SEXTON was implanted with the defective Optetrak device and was thereafter injured by the defective Optetrak device in this judicial district; and because Defendants are subject to personal jurisdiction within the State of Maryland and this judicial district.

IV. FACTS COMMON TO ALL COUNTS

A. Knee Replacement Surgery and Knee Implants

23. The knee is the largest joint in the human body, consisting of three individual bones: the shin bone (tibia), the thigh bone (femur), and the knee-cap (patella). The knee joint is lined with cartilage to protect the bones from rubbing against each other. This ensures that the joint surfaces can glide easily over one another. The human knee is a complicated joint which supports the entire body weight on four small surfaces through a variety of motions essential to everyday

life. It is also the joint most susceptible to arthritis.

24. With the increases in lifespan, people have begun to suffer pain and disability from knee joint arthritis at significant rates. Total knee arthroplasty ("TKA"), also called total knee replacement ("TKR"), is a surgical procedure intended to relieve pain, improve joint function, and replace bones, cartilage and/or tissue that have been compromised by arthritis, other diseases, or trauma. The knee replacement implants designed and cleared in the 1990s met the goals of reducing pain and restoring function with low failure rates. As TKAs became more common, particularly among younger patients who want to maintain a physically active lifestyle, alternative bearing surfaces such as cross-linked polyethylene have been developed to address the issue of wear.

25. During TKA procedures, surgeons replace the joint surfaces and damaged bone and cartilage with artificial materials, such as the Optetrak device. The femoral implant is placed into the distal femur using surgical bone cement. The tibial tray is also placed with surgical bone cement. A polyethylene insert or liner is placed between the femoral implant and tibial tray to act as a cushion between the components. The replacement redistributes weight and removes the tissue and/or bone causing inflammation, and thus reduces pain while improving the joint's function. Replacement requires a mechanical connection between the bones and the implant components.

B. <u>Defendants' Optetrak Knee Devices</u>

26. The first Optetrak knee device was introduced to orthopedic surgeons in the United States in 1994, building upon technology licensed from the Hospital for Special Surgery in New York City.

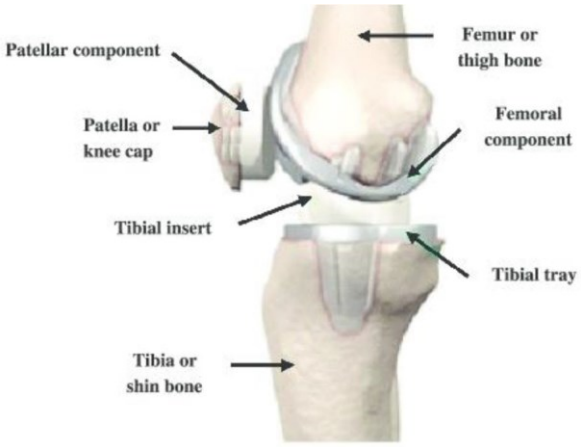
27. Since 1994, Defendants have obtained fast-tracked 510(k) clearance from the

United States Food and Drug Administration ("FDA") for various versions of 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.

28. At all times material hereto, Defendants designed, developed, tested, assembled, selected, manufactured, packaged, labeled, prepared, distributed, marketed, supplied, warranted, and/or sold the Optetrak devices throughout the United States.

29. Although they began marketing and selling the Optetrak "Logic" Total Knee System for implantation into patients in 2009, Defendants did not receive 510(k) approval for the Optetrak "Logic" Total Knee System until January 11, 2010.

30. The Optetrak devices are classified as knee joint patellofemorotibial cemented prostheses. They features a mix of polyethylene and metal-based components.



31. The Optetrak devices are comprised of the following parts: a patellar cap, femoral component, tibial insert and tibial tray, as shown above.

32. The patellar cap and tibial insert are made of polyethylene.

33. As of 2012, the Defendants were utilizing a proprietary Net Compression Molded ("NCM") conventional polyethylene instead of cross-linked polyethylene ("XLPE") in their Optetrak devices, including Optetrak Logic.

34. The Defendants claim that Optetrak's longevity is a function of using proprietary NCM inserts in the total knee system.

35. Defendants touted the Optetrak system as being first-in-class in their product brochures.

36. In their marketing materials, the Defendants promised that, "in clinical and laboratory data," the Optetrak implants demonstrate "excellent long-term clinical outcomes" and "surgeons and patients can have every confidence in the performance and longevity of the Optetrak knee system."

37. However, upon information and belief, by 2007 at the latest, the Defendants began receiving numerous reports regarding extremely high failure rates of the Optetrak devices, which required patients to undergo premature knee revisions.

38. Between 2007-2008, the Defendants performed an internal investigation through which they determined that the Optetrak devices had material design flaws based on verified reports from surgeons using the devices. The internal investigation further determined that there were engineering and design process failures that the Defendants attributed to the device failures.

39. Around 2008, the Defendants determined that the Optetrak Total Knee System posed a safety risk to patients due to various defects in the implant, including substantial problems with the Optetrak Tibia "Finned" Tray.

40. Beginning in 2011, the Exactech Defendants began silently replacing the "finned"

tibia tray with a "fit" tibia tray and change of the polyethylene insert.

41. In studies published in 2012 and 2016, the Optetrak total knee system performed poorly when compared to its competitors.[1] The Australian Registry, a preeminent, internationally recognized orthopedic implant registry, identified the Optetrak as an implant with a higher-than-expected rate of revision.

42. Defendants promoted their Optetrak devices as having nearly three decades of clinical success and proven outcomes for patients around the world owing to an improved articular design resulting in low polyethylene stresses.

43. At all relevant times, Defendants were aware of the high rate of early failures of Optetrak devices that required patients to undergo painful revision surgeries to remove the defective device and replace it with another product.

44. Despite having actual knowledge of the increased risk of failure related to the defective nature of the Optetrak devices, Defendants made the decision not to recall, stop selling, or otherwise change the warnings for the affected devices until there was a suitable replacement approved for the U.S. market.

45. Despite Defendants' knowledge of the high rate of early onset failures of the Optetrak devices, Defendants continued to manufacture, package, promote, and distribute the Optetrak devices without alerting surgeons of the potential increased risks of early onset failures of the device.

46. Despite Defendants' knowledge of the high rate of early onset failures of the

[1] See Thelu, C. et al., Orthopedics and Traumatology 2012; 98:413-420; see also Australian Orthopaedic Association, National Joint Replacement Registry, Hip Knee & Shoulder Arthroplasty, 2016 Annual Report.

Optetrak devices, Defendants continued to manufacture, package, promote, and distribute the Optetrak devices without changing, modifying, or improving the devices or their packaging to address the increased risk of early failure.

47. Despite Defendants' knowledge of the high rate of early onset failures of the Optetrak devices, Defendants did not change the labeling, marketing materials or product inserts to adequately and accurately warn patients or physicians of the associated increased risks, longevity, and alternative product options with lower risks and lower rates of early failure.

48. Despite Defendants' knowledge of the high rate of early onset failures of the Optetrak devices, Defendants did not even partially alert the FDA of the known increased risks until August 30, 2021, and did not more fully alert the FDA until February 7, 2022.

49. By 2012, Defendants had further clinical evidence that Optetrak knee implants were failing at a rate higher than promoted. Reports in the Manufacturer and User Facility Device Experience (MAUDE) indicate instances of revision due to "loose tibial component", "aseptic loosening", "pain and visible loosening", "polyethylene deformation", "polyethylene worn", and "pain, limited mobility, knee swelling and sensitivity" due to "loose" joint. These early onset failure mode reports are representative of the increased rate of incidents of which Defendants has 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.

50. In 2013, complaints continued to be reported. Some examples include revision for "tibial loosening" just two years postoperatively, "revision due to tibial loosening", "during revision, the tibial component was found to be loose and easily removed", "revision of knee

component due to loosening", "revision due to pain and loosening."

51. The complaints of early onset failures continued in 2014. Some examples include "revision due to tibial loosening", "tibial loosening", "revision of Optetrak knee components due to tibial loosening", "revision due to pain and loosening", "revision of Optetrak knee components due to aseptic loosening", several reports described as "revision of knee components due to tibial loosening", and "revision of Optetrak knee components reportedly due [to] aseptic loosening".

52. In the year 2015, Defendants sold more than $241 million worth of devices across all product lines.

53. Of the more than $241 million in Defendants' total sales in 2014, knee device sales accounted for over $70 million in sales, or 29.3% of all Defendants' sales in 2015.

54. On February 23, 2017, the Defendants received fast-tracked 510(k) clearance for a new Exactech knee implant, called "Truliant."

55. Shortly thereafter in 2017, the Defendants began a pilot program for the Truliant Total Knee System, which they offered as an improved upgrade to the Optetrak line.

56. Despite Defendants' claims in its promotional materials of over thirty years of successful outcomes with knee devices, Defendants knew, at all times relevant, of an unacceptably high early failure rate of its Optetrak knee implants.

57. Upon information and belief, Defendants never conducted a clinical trial on the Optetrak devices.

58. Had Defendants conducted clinical trials of the Optetrak devices before the devices were released on the market, they would have discovered at that time the devices' propensity to undergo substantial early polyethylene wear, component loosening and/or other

failure causing serious complications including tissue damage, osteolysis, and other injuries as well as the need for revision surgery in patients.

59. At all times relevant to this action, Defendants were aware of the problems with the Optetrak devices' design and their propensity to undergo substantial early polyethylene wear, component loosening and/or other failure causing serious complications including tissue damage, osteolysis, and other injuries as well as the need for revision surgery in patients. Nonetheless, Defendants failed to adequately warn patients, the medical community, or the public about these risks, and continued and continued to promote, market, sell and defend the Optetrak devices without limitation until February 7, 2022.

60. On February 7, 2022, Defendants issued a Recall of their knee and ankle implants, sending an "URGENT MEDICAL DEVICE CORRECTION" Notice to "Exactech Knee and Ankle Surgeons, Hospitals, [and] Health Care Professionals" to alert them to the defects in their knee and ankle arthroplasty polyethylene inserts. The Notice explained that all three generations of Exactech knee systems had polyethylene inserts packaged in "non-conforming bags", stating specifically:

> **The use of these non-conforming bags may enable increased oxygen diffusion to the UHMWPE (ultra-high molecular weight polyethylene) insert, resulting in increased oxidation of the material relative to inserts packaged with the specified additional oxygen barrier layer. Over time, oxidation can severely degrade the mechanical properties of conventional UHMWPE, which, in conjunction with other surgical factors, can lead to both accelerated wear debris production and bone loss, and/or component fatigue cracking/fracture, all leading to corrective revision surgery.**

61. The Notice also acknowledged that the Optetrak devices demonstrated statistically

significant higher overall revision rates compared to other knee systems in the Australian, United Kingdom, and New Zealand registries. In fact, the Notice admits that the reasons for revision potentially associated with polyethylene wear (e.g., loosening, lysis, pain) were increased three-to seven-fold in the most used Exactech Optetrak TKR combination (Optetrak-PS/Optetrak) which had a total of 263 TKR revision procedures among 2,410 primary TKRs when compared to other TKRs in the Australian Registry.

62. Defendants also prepared a sample letter for physicians to send their patients, which explains the defect in their products as follows:

> During a recent review of its knee implant manufacturing process, Exactech learned that one of the packaging layers for the plastic insert has been out of specification and may allow oxygen from the air to diffuse into the plastic insert prior to it being implanted in your knee. If a large amount of oxygen diffuses into the plastic insert while it's being stored and before it is implanted, this can lead to a process called oxidation, which can cause the plastic to wear out earlier than expected or to become damaged after it is implanted into the patient's body.

63. The FDA classified Defendants' recall as a class II recall meaning that exposure to the product may cause temporary or medically reversable health consequences.

64. An example of a medically reversable health consequence is a revision surgery, such as the revision surgeries that Plaintiff underwent on his right knee.

C. Plaintiff Specific Allegations

65. On November 20, 2006, Plaintiff JOSEPH D. SEXTON underwent a right TKR at Peninsula Regional Medical Center in Salisbury, Maryland. The surgery was performed by Dr. Pasquale Petrera.

66. During the procedure, a defective Optetrak device was implanted using the

following components:

a. Exactech Optetrak Femoral Component Size 4;

b. Exactech Optetrak tibial component Size 4 — All polyethylene; and

c. Optetrak Patella 35.

67. The November 20, 2006 arthroplasty was done correctly and did not deviate from accepted medical custom and practice with regards to the implantation of the Optetrak device.

68. Defendants designed, developed, tested, assembled, manufactured, packaged, labeled, prepared, distributed, marketed, supplied, warranted and/or sold the defective implant[s] placed inside Plaintiff JOSEPH D. SEXTON's right knee cavity.

69. After an initial recovery period and for a period of years thereafter, Plaintiff's Optetrak device performed as expected.

70. Over time, Plaintiff JOSEPH D. SEXTON began experiencing "popping," "locking-up," pain, swelling, instability, and an inability to bear weight on his right knee. Eventually, he was unable to walk without the aid of a cane and knee brace.

71. On October 9, 2018, Plaintiff underwent revision of his failed right Optetrak device. Upon explantation of the Optetrak device, Plaintiff's surgeon observed that the post of the polyethylene tibial component had fractured, and that there was delamination of the bearing surface of the polyethylene. There were also numerous pieces of loose polyethylene in the joint. This procedure was performed by Dr. Pasquale Petrera at Peninsula Regional Medical Center in Salisbury, Maryland.

72. Upon information and belief, the defective Optetrak device failed prematurely in Plaintiff's right knee.

73. Upon information and belief, the polyethylene component used in the Optetrak device was defective, leading to early aseptic loosening. A packaging defect in the packaging containing the Optetrak polyethylene inserts accelerated polyethylene wear due to oxidation.

74. Upon information and belief, the defective polyethylene substance used in the Optetrak devices, and/or the defective or non-conforming packaging of said devices, caused and/or contributed to accelerated polyethylene wear leading to early failure.

75. Upon information and belief, the defective Optetrak devices were defective in their design, manufacturing and materials at the time they left the Defendants' hands and were delivered into the stream of commerce in their defective condition.

76. It was foreseeable, expected and intended, by the Defendants that the defective Optetrak devices would be used in a knee arthroplasty patient, such as JOSEPH D. SEXTON.

77. Defendants allowed the defective Optetrak device to be implanted during Plaintiff's total knee arthroplasty in said condition.

78. Defendants failed with respect to the selection of materials, processes, testing, quality audits, and supervision of the manufacturing of their knee implant devices, including the defective Optetrak devices

79. Upon information and belief, Defendants violated federal and state laws and regulations regarding the design, selection of materials, testing, manufacturing, packaging, storage, selling, and/or distribution of medical knee implant devices, including without limit the following: 21 U.S.C. § 351, *et seq*. and 21 C.F.R. § 820 *et seq*. regarding federal regulations for medical devices and Current Good Manufacturing Practices; as well as 15 U.S.C. § 2051, *et seq*. and 16 C.F.R. § 1101, *et seq*. regarding the Consumer Product Safety Act.

80. As a direct and proximate result of the deficiencies in the defective Optetrak devices described herein, Plaintiff JOSEPH D. SEXTON has suffered and continues to suffer injuries and damages, including without limit the following: having to undergo a painful revision surgery; having required and will continue to require additional medical care and treatment, having required and will continue to require physical therapy and pain management; and having experienced and will continue to experience prolonged and lasting pain and suffering and loss of enjoyment of life.

D. The Federal Requirements

81. Upon 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.

82. Upon 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.

83. Upon 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*.

84. Upon 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.

85. 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.

86. 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.

V. CAUSES OF ACTION

COUNT I
STRICT LIABILITY:
MANUFACTURING DEFECT

93. Plaintiffs re-allege and incorporate by reference 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.

94. Defendants had a duty to manufacture and package the Optetrak devices in a manner that prevents unreasonable risk of harm or injury to users and patients, including Plaintiff.

95. Defendants had a duty to distribute, market, and/or sell the Optetrak devices without manufacturing defects to prevent an unreasonable risk of harm or injury to users and patients, including Plaintiff.

96. The defective Optetrak devices manufactured by the Defendants were not reasonably safe for their expected, intended, and/or foreseeable uses, functions and purposes.

97. The defective Optetrak devices were not reasonably safe as manufactured, packaged, distributed, marketed and/or sold by Defendants.

98. The defective Optetrak devices were defectively manufactured and packaged for a multitude of reasons, including but not limited to the following:

a. The polyethylene substance within the defective Optetrak devices was of an inferior grade or quality than that advertised and promoted by the Defendants;

b. Defendants packaged the defective Optetrak devices in out-of-specification or non-conforming vacuum bags that did not contain secondary barrier layer containing ethylene vinyl alcohol (EVOH) that further augments oxygen resistance;

c. The polyethylene substance within the defective Optetrak devices was not made using the molding process advertised and promoted by the Defendants;

d. The polyethylene substance within the defective Optetrak devices did not comply with the required specifications for the polyethylene inserts that should be used in the devices;

e. The polyethylene inserts used in the defective Optetrak devices were not of the correct shelf age;

f. Defendants failed to perform quality control or other such testing on the polyethylene inserts used in the defective Optetrak devices to ensure they complied with required specifications;

g. Defendants failed to exercise sufficient quality control to ensure the polyethylene inserts in the defective Optetrak devices were safe for implantation in users and patients and would not degrade abnormally under average and regular use;

h. Defendants violated applicable state and federal laws and regulations; and in all other ways.

99. Defendants knew or should have known and been aware that the defective Optetrak devices were defectively manufactured and/or packaged.

100. The defective Optetrak devices were defective in their manufacturing, materials, and packaging at the time they left the Defendants' hands, and they were delivered into the stream

of commerce in their defective condition.

101. The defective Optetrak devices should not have been distributed, marketed, and/or sold by Defendants in a defectively manufactured and/or defectively packaged condition.

102. It was foreseeable, expected and intended by the Defendants for the defective Optetrak devices to be used in a knee arthroplasty patient, such as Plaintiff.

103. The manufacturing and packaging defects of the defective Optetrak devices presented an unreasonable risk of harm to users and patients exposed to their danger, including Plaintiff, when used and operated for the purposes intended by Defendants.

104. The manufacturing and packaging defects of the defective Optetrak devices presented an unreasonable risk of harm to users and patients exposed to their danger, including Plaintiff, when they were used and operated in a manner that was foreseeable to Defendants.

105. Defendants breached their duty to manufacture and package the Optetrak devices in a manner that eliminated or prevented an unreasonable risk of harm or injury to users and patients exposed to their danger, including Plaintiff.

106. Defendants breached their duty to distribute, market, and/or sell the Optetrak devices without manufacturing and packaging defects to eliminate or prevent an unreasonable risk of harm or injury to users and patients exposed to their danger, including Plaintiff.

107. Plaintiff was seriously injured as a result of the manufacturing and packaging defects in the Optetrak devices caused by Defendants.

108. Defendants are strictly liable for the defective manufacture and/or defective packaging of the defective Optetrak devices; the distribution, marketing, and/or sale of the defectively manufactured Optetrak devices; and the injuries sustained by Plaintiff.

109. 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.

COUNT II
STRICT LIABILITY:
DESIGN DEFECT

110. Plaintiffs re-allege and incorporate by reference 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.

111. Defendants had a duty to design the defective Optetrak devices in a manner that did not present an unreasonable risk of harm or injury to users and patients exposed to their danger, including Plaintiff.

112. Prior to, on, and after the dates of Plaintiff's initial knee surgeries, and at all times relevant to this action, Defendants tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold the Optetrak devices for implantation into consumers, such as Plaintiff, by physicians and orthopedic surgeons in the United States.

113. The Optetrak devices were defective in design and unreasonably dangerous when they entered the stream of commerce and were received by Plaintiff, because the risks were outweighed by any utility of the design of the devices and because the devices were dangerous to an extent beyond that which would be contemplated by the ordinary consumer. At no time did

Plaintiff have reason to believe that the Optetrak devices were in a condition not suitable for their proper and intended use.

114. The Optetrak devices were defective in design and unreasonably dangerous when they entered the stream of commerce and were received by Plaintiff, because the foreseeable risks exceeded or outweighed the purported benefits associated with the device.

115. At all times relevant to this action, the Defendants tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold the Optetrak devices, which were implanted in Plaintiff, such that they were dangerous, unsafe, and defective in design.

116. The Optetrak devices implanted in Plaintiff were defective in design by virtue of their size, shape, length, diameter, surface finish, molecular weight, post-consolidation treatment or lack thereof, and/or other material properties that cause the devices to undergo substantial early polyethylene wear, component loosening, and/or other failure causing serious complications including tissue damage, osteolysis, and other injuries, as well as the need for revision surgery in patients, and cause or contribute to a higher failure rate and/or shorter useful life expectancy than comparable knee replacement products.

117. The design of the packaging in which the Optetrak device components are contained is defective and not reasonably safe.

118. Plaintiff's physicians employed the Optetrak devices in the manner in which they were intended to be used, making such use reasonably foreseeable to Defendants.

119. The Optetrak devices as tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or

sold by Defendants reached Plaintiff without substantial change in its condition.

120. At all times herein mentioned, the Defendants tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold the Optetrak devices, which were implanted in Plaintiff, such that they were dangerous, unsafe, and defective. The defects in design include but are not limited to the following respects:

a. that the Optetrak has propensity to undergo substantial early polyethylene wear, component loosening and/or other failure causing serious complications including tissue damage, osteolysis, and other injuries as well as the need for revision surgery in patients;

b. that the components of the Optetrak were packaged in improperly designed vacuum bags that did not contain secondary barrier layer containing ethylene vinyl alcohol (EVOH) to prevent oxidation;

c. that the materials used within the Optetrak were of an inferior grade or quality than advertised and promoted by Defendants;

d. that the Defendants failed to conduct adequate mechanical testing, including wear or other testing, on components, subassemblies and/or the finished Optetrak;

e. that Defendants failed to test an adequate number of samples of Optetrak devices on an ongoing basis;

f. that Defendants failed to take adequate steps to specifically identify failure modes with the Optetrak with clarity and to suggest methods to monitor, avoid, and/or prevent further failures;

g. that Defendants failed to identify and/or note the significance of any testing that resulted in failure of the Optetrak Device;

h. that Defendants failed to take corrective actions to eliminate or minimize further failures of the Optetrak devices;

i. that Defendants failed to adequately explain performance specifications for the components, subassemblies, and/or the finished Optetrak

devices;

j. that Defendants failed to adequately explain or justify all test conditions and acceptance criteria for the Optetrak devices;

k. that Defendants failed to perform adequate testing in an environment that adequately simulated in vivo conditions;

l. that Defendants failed to perform adequate testing of the Optetrak devices, including the components and subassemblies, to ensure that the Optetrak devices functioned properly during and after implantation;

m. that Defendants failed to perform adequate testing on the specific Optetrak devices components which were intended to be sold to and implanted with consumers including Plaintiff and instead conducted testing with "dummy" parts designed and intended only for manufacturer testing purposes; and

n. that Defendants failed to perform adequate quality assurance testing and validation before and after sterilization.

121. As alleged herein, Defendants knew and had reason to know that the Optetrak caused an increased risk of harm to the Plaintiff and other consumers due to the device's propensity to undergo substantial early polyethylene wear, component loosening and/or other premature failure causing serious complications including tissue damage, osteolysis, and other injuries as well as the need or revision surgery in patients. Defendants consciously disregarded this increased risk of harm by failing to adequately warn of the risk; unlawfully concealing the dangerous problems associated with implantation of the Optetrak; and continuing to market, promote, sell, and defend the Optetrak devices.

122. It was foreseeable, expected and intended by the Defendants for the defective Optetrak devices to be used in a knee arthroplasty patient, such as Plaintiff.

123. The design defects of the Optetrak devices presented an unreasonable risk of harm

when they were used and operated for purposes expected and intended by Defendants.

124. The design defects of the Optetrak and Optetrak packaging presented an unreasonable risk of harm when they were used in a manner that was or should have been foreseeable to Defendants.

125. Pre-existing feasible safer alternative designs providing the same functional purpose were available to the Defendants at the time the Optetrak devices and Optetrak packaging were designed and offered for sale in the market.

126. Defendants failed to balance the feasibility of safer alternative designs for the Optetrak and Optetrak packaging against existing risks of injury.

127. Defendants failed to use pre-existing feasible safer alternative designs providing the same functional purpose.

128. Defendants failed to use their own pre-existing feasible safer alternative designs providing the same functional purpose.

129. Defendants failed to take into account the reasonable cost of feasible safer alternative designs.

130. Defendants failed to balance the risks of injury against the utility and costs of feasible safer alternative designs.

131. Defendants failed to develop feasible safer alternative designs providing the same functional purpose with reasonable price adjustments.

132. Defendants failed to take into account improvements related to safety and injury prevention presented by feasible safer alternative designs.

133. Defendants failed to consider foreseeable safety hazards and serious injury risks

arising from the Optetrak device's design.

134. Defendants breached their duty to design the Optetrak devices in a manner that eliminates or prevents an unreasonable risk of harm or injury.

135. As alleged herein, the defects in design of the Optetrak were a substantial factor in causing Plaintiff's injuries.

136. Plaintiff was seriously injured as a result of the design defects in the Optetrak devices.

137. Defendants are strictly liable for the defective design of the Optetrak; the distribution, marketing, and/or sale of the defectively designed Optetrak devices; and the injuries sustained by Plaintiff as a result thereof.

138. Defendants' conduct as described herein was a proximate cause of Plaintiff's injuries and damages.

COUNT III
STRICT LIABILITY:
FAILURE TO WARN

139. Plaintiffs re-allege and incorporate by reference 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.

140. At all times relevant to this action, Defendants tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold the Optetrak devices for implantation into consumers, such as Plaintiff, by physicians and orthopedic surgeons in the United States.

141. The Optetrak device was defective and unreasonably dangerous when it entered the

stream of commerce and was received by Plaintiff because the risks were outweighed by any utility of the design of the device and because the device was dangerous to an extent beyond that which would be contemplated by the ordinary consumer. At no time did Plaintiff have reason to believe that the Optetrak device was in a condition not suitable for its proper and intended use.

142. The Optetrak device was defective and unreasonably dangerous when it entered the stream of commerce and was received by Plaintiff because the warnings in the instructions for use, operative techniques, directions, marketing and promotional materials, advertisements, white papers, and other communications provided by Defendants or their sales force to physicians and patients with or about the Optetrak failed to adequately convey the potential risks and side effects of the Optetrak device and the dangerous propensities of the device, which risks were known or were reasonably knowable to Defendants. In particular, Defendants failed to adequately disclose the device's propensity to undergo substantial early polyethylene wear, component loosening and/or other failure causing serious complications including tissue damage, osteolysis, and other injuries as well as the need for revision surgery in patients which risks exceeded or outweighed the purported benefits associated with the device.

143. The Optetrak device was defective and unreasonably dangerous when it entered the stream of commerce and was received by Plaintiff because the Optetrak device posed increased risks of harm and side effects that were known or knowable to Defendants by the use of available scientific knowledge.

144. Defendants knew or should have known of the defective condition, dangerous characteristics, and risks associated with the Optetrak device as alleged herein.

145. Defendants consciously disregarded the increased risks of harm by failing to

adequately warn of such risks; unlawfully concealing the dangerous problems associated with implantation of the Optetrak; and continuing to market, promote, sell and defend the Optetrak.

146. The Optetrak device that was manufactured, distributed, and sold by the Defendants to Plaintiff was in a defective condition that was unreasonably dangerous to any user or ordinary consumer of the device, including Plaintiff.

147. Such ordinary consumers, including Plaintiff, would not and could not have recognized or discovered by the exercise of reasonable care, the defects mentioned herein and perceived their danger.

148. Defendants, as manufacturers and/or distributors of the Optetrak devices, are held to the level of knowledge of an expert in the field.

149. The warnings that were given by the Defendants were not accurate, clear, and/or were ambiguous.

150. The Optetrak device was expected to and did reach Plaintiff and Plaintiff's healthcare providers without substantial change in its condition as manufactured, packaged, distributed, and sold by Defendants.

151. Plaintiff, individually and through Plaintiff's physicians, reasonably relied upon the skill, superior knowledge and judgment of the Defendants.

152. Defendants had a continuing duty to warn Plaintiff of the dangers associated with Optetrak devices.

153. Had Plaintiff received adequate warnings regarding the risks of the Optetrak device, Plaintiff would not have used it or allowed his surgeon to implant it in his body.

154. Plaintiff's healthcare providers stored, handled, and used the Optetrak device in the

manner in which it was intended to be stored, handled, and used, making such use reasonably foreseeable to Defendants.

155. The lack of adequate and accurate warnings in the instructions for use, operative techniques, directions, marketing and promotional materials, advertisements, white papers, and other communications provided by Defendants or its sales force to physicians and patients with or about the Optetrak device prior to, on, and after the dates of Plaintiff's initial knee surgeries were a substantial factor in causing Plaintiff's injuries, losses and damages as alleged herein.

156. Defendants failed to develop and make available alternative products that were designed in a safe or safer manner, even though such products were feasible and marketable and, in fact, were being sold and marketed by Defendants and/or other manufacturers at the time Defendants sold the Optetrak device to Plaintiff.

157. Defendants' conduct as described herein was a proximate cause of Plaintiff's injuries and damages.

COUNT IV
NEGLIGENCE

158. Plaintiffs re-allege and incorporate by reference 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.

159. Defendants had a duty to exercise reasonable care in the design, manufacture, packaging, sale and/or distribution of Optetrak devices 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 and/or a duty to comply with federal requirements.

160. Defendants breached their duty and failed to exercise ordinary care in the design, formulation, manufacture, packaging, sale, testing, quality assurance, quality control, labeling, marketing, promotions and distribution of Optetrak devices into interstate commerce in that Defendants knew or should have known that the product caused significant bodily harm and was not safe for use by consumers, and/or through failure to comply with federal requirements.

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

a. Negligently manufacturing, or failing to select appropriate third-parties to produce, the polyethylene components used in the Optetrak devices;

b. Negligently packaging, or failing to select appropriate third-parties to package, the polyethylene components used in the Optetrak devices;

c. Negligently failing to properly supervise and monitor the production and packaging of the polyethylene components used in the Optetrak devices;

d. Negligently failing to properly and thoroughly select the material used in the Optetrak devices;

e. Negligently failing to properly and adequately test the Optetrak devices and their attendant parts before releasing the devices to market;

f. Negligently failing to conduct sufficient post-market testing and surveillance of the defective Optetrak devices;

g. Negligently failing to adequately prevent, identify, mitigate, and fix defective designs and hazards associated with the defective Optetrak devices in accordance with good practices;

h. Negligently designing, manufacturing, packaging, marketing, advertising, distributing, and selling the Optetrak devices;

i. Continuing to negligently manufacture and distribute the defective Optetrak devices after the Defendants knew or should have known of their adverse effects and/or the increased early onset failure rates; and

j. Negligently violating applicable state and federal laws and regulations.

162. Despite the fact that Defendants knew or should have known that the Optetrak devices posed a serious risk of bodily harm to consumers, Defendants continued to manufacture and market devices for use by consumers and/or continued to fail to comply with federal requirements.

163. Defendants knew or should have known that consumers such as Plaintiff would foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care as described above, including the failure to comply with federal requirements.

164. As a direct and proximate result of Defendants' negligence, Plaintiff suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

165. Defendants' conduct as described herein was a proximate cause of Plaintiff's injuries and damages.

166. Exemplary damages. Plaintiff's injuries resulted from Defendants' gross negligence and/or actual malice, which entitles Plaintiffs to exemplary damages under Maryland law.

COUNT V
NEGLIGENT MISREPRESENTATION

167. Plaintiffs re-allege and incorporate by reference 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.

168. At the time Defendants tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or

sold the Optetrak devices to Plaintiff and/or Plaintiff's healthcare providers, Defendants knew or should have known of the use for which the devices were intended and the serious risks and dangers associated with such use of the Optetrak devices.

169. Defendants owed a duty to orthopedic surgeons, other healthcare providers and to consumers of the Optetrak device, including Plaintiff, to accurately and truthfully represent the risks of the Optetrak device. Defendants breached their duty by misrepresenting and/or failing to adequately warn Plaintiff's healthcare providers, the medical community, Plaintiff, and the public about the risks of the Optetrak device, including the device's propensity to undergo substantial early polyethylene wear, component loosening and/or other failure causing serious complications including tissue damage, osteolysis, and other injuries as well as the need for revision surgery in patients, which Defendants knew or in the exercise of diligence should have known.

170. Among Defendants' numerous misrepresentations and misleading omissions are Defendants' assurances that the Optetrak device was safe, had an excellent performance record, and did not have a greater propensity to undergo substantial early polyethylene wear, component loosening and/or other failure causing serious complications including tissue damage, osteolysis, and other injuries as well as the need for revision surgery in patients. Instead, and in Plaintiff's case, Defendants stated or implied to physicians, patients and the FDA that any problem with the Optetrak devices in a particular patient was attributable to "surgical technique" or patient factors such as body mass index, bone composition, and post-implantation activity level. Defendants made such statements even after they became aware of numerous and serious complications with the Optetrak device. Defendants did not reveal (and instead concealed) their knowledge of numerous and serious complications and other bad data during their meetings with orthopedic surgeons and

the FDA.

171. Despite their knowledge of serious problems with the Optetrak device, Defendants urged their sales representatives to continue marketing the Optetrak device, and distributed medical literature, white papers, non-peer reviewed studies, and other communications to physicians in an effort to mislead them and the general public about the risks associated with the Optetrak device and instead create the image and impression that the Optetrak device was safe.

172. Defendants' conduct as described herein was a proximate cause of Plaintiff's injuries and damages.

COUNT VI
FRAUDULENT INDUCEMENT

173. Plaintiffs re-allege and incorporate by reference 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.

174. Defendants, having undertaken to test, study, research, design, formulate, manufacture, inspect, label, package, promote, advertise, market, distribute and sell the Optetrak device, owed a duty to provide accurate and complete information to Plaintiff, his healthcare providers, and the public regarding the safety and efficacy of the Optetrak.

175. However, Defendants misled Plaintiff, Plaintiff's healthcare providers, and the public into believing that the Optetrak device was safe and effective for use in total knee replacement surgery and engaged in deceptive, misleading and unconscionable promotional, marketing and sales tactics to convince healthcare providers and patients to use the Optetrak, even though Defendants knew or should have known that the Optetrak was unreasonably dangerous as

alleged herein. Defendants also failed to warn healthcare providers and the public about the serious risks associated with the use of the Optetrak including the device's propensity to undergo substantial early polyethylene wear, component loosening and/or other failure causing serious complications including tissue damage, osteolysis, and other injuries as well as the need for revision surgery in patients.

176. Defendants' advertising campaigns, marketing materials and promotional items, by containing affirmative misrepresentations and omissions, falsely and deceptively sought to create the image and impression that the Optetrak was safe for human use and had no unacceptable risks.

177. Defendants purposefully concealed, failed to disclose, misstated, downplayed and understated the risks associated with the use of the Optetrak. Defendants, through sales representatives, advertisements, and other marketing and promotional practices and communications as well as through the publication of medical literature and non-peer reviewed studies, deceived healthcare providers, Plaintiff, other patients, and the public about the true risks of the Optetrak device. Defendants falsely and deceptively kept relevant information from healthcare providers, the FDA and the public, including Plaintiff, regarding the safety of the Optetrak.

178. Defendants expressly denied that the Optetrak created an increased risk of injury and took affirmative steps to prevent the discovery and dissemination of any evidence regarding the increased likelihood of injury from the Optetrak device including but not limited to the device's propensity to undergo substantial early polyethylene wear, component loosening and/or other failure causing serious complications including tissue damage, osteolysis, and other injuries as well as the need for revision surgery in patients.

179. Defendants did not accurately report the results of adverse events by fraudulently and intentionally withholding from the FDA, healthcare providers, Plaintiff, and the public, the truth regarding Optetrak's failures for years, all the while undertaking sales, marketing and promotional campaigns to sell the Optetrak. Defendants received reports of defects in its Optetrak devices from various sources, including those alleged herein, and intentionally withheld this information from the FDA, healthcare providers, Plaintiff, and the public, while continuing to sell the Optetrak for implantation in patients such as Plaintiff.

180. Further, even as Defendants disclosed some information regarding the Optetrak device's defects, the disclosures were inadequate, incomplete, and misleading.

181. Through their wrongful conduct, Defendants effectively deceived and misled the scientific and medical communities regarding the risks and benefits of the Optetrak device. Defendants failed to fully inform healthcare providers, Plaintiff, other patients, and the public of the true risks associated with the Optetrak, which were known to Defendants, and continued to assure healthcare providers and patients that the Optetrak was safe and effective device for the purpose of continuing to derive substantial profits from its sale.

182. Through their advertising campaigns, sales and marketing materials and promotional items, Defendants falsely and deceptively misrepresented and omitted numerous material facts regarding the Optetrak, including but not limited to the device's propensity to undergo substantial early polyethylene wear, component loosening and/or other failure causing serious complications including tissue damage, osteolysis, and other injuries as well as the need for revision surgery in patients.

183. Defendants possessed evidence demonstrating the Optetrak caused serious injuries.

Nevertheless, Defendants continued to market the Optetrak by providing false and misleading information about the device's safety and efficacy to Plaintiff and Plaintiff's healthcare providers.

184. Among Defendants' numerous misrepresentations and misleading omissions to Plaintiff, Plaintiff's healthcare providers, and the public were Defendants' assurances that the Optetrak was a safe device and had a low failure rate. Defendants stated or implied to orthopedic surgeons that any problem with the Optetrak in a particular patient was attributable to "surgical technique" or patient factors such as body mass index, bone composition, and post-implantation activity level. Defendants made such statements even after they became aware of numerous and serious complications with the Optetrak Device. Defendants did not reveal (and instead concealed) their knowledge of numerous and serious complications and other bad data during their meetings with orthopedic surgeons.

185. Despite their knowledge of the risks with the Optetrak, Defendants urged their sales representatives to continue marketing it and distributed medical literature, non-peer reviewed studies, and other communications to healthcare providers which did not adequately convey the risks of the device in an effort to mislead them and the public about the serious risks associated with its use.

186. Defendants engaged in all the acts and omissions alleged herein with the intent that Plaintiff and Plaintiff's healthcare providers would rely on the misrepresentations, deceptions and concealments in deciding to implant and use the Optetrak rather than another of product.

187. Plaintiff and Plaintiff's healthcare providers justifiably relied to their detriment on Defendants' intentional and fraudulent misrepresentations and this reliance proximately caused Plaintiff's injuries and damages as alleged herein.

188. Plaintiff's healthcare providers relied upon information obtained from Defendants, the medical literature, journal articles, medical conferences and presentations, adverse event reporting data, and discussions with other healthcare providers to get information about the performance and safety profile of medical devices including the Optetrak device. However, all these sources of information failed to include information about the true risks of the Optetrak device because these risks, which were known to Defendants, were actively concealed or mispresented by Defendants.

189. Had Defendants disclosed accurate, complete and truthful information about the device's propensity to undergo substantial early polyethylene wear, component loosening and/or other failure causing serious complications including tissue damage, osteolysis, and other injuries as well as the need for revision surgery in patients, Plaintiff would not have allowed his physician to implant the Optetrak device into his body.

190. Defendants' conduct as described herein was a proximate cause of Plaintiff's injuries and damages.

COUNT VII
FRAUDULENT CONCEALMENT

191. Plaintiffs re-allege and incorporate by reference 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.

192. At all times during the course of dealing between the Defendants, Plaintiff, Plaintiff's healthcare providers, and/or the FDA, the Defendants misrepresented the safety of Optetrak devices for their intended use.

193. Defendants knew or were reckless in not knowing that their representations were false.

194. In representations to Plaintiff, Plaintiff's healthcare providers, and/or the FDA, the Defendants fraudulently concealed and intentionally omitted material information, including but not limited to the fact that:

a. the subject product was not as safe as other similar devices indicated for knee arthroplasty;

b. that the subject product was defective, and that it caused dangerous side effects, including but not limited to component loosening, component mal-alignment, substantial early polyethylene wear, pain, irritation and discomfort, as well as the need for additional procedures to remove and replace the device, notwithstanding the Defendants' knowledge of an increased risk of these injuries and side effects versus other knee arthroplasty devices;

c. that the subject product was manufactured and/or packaged negligently;

d. that the subject product was manufactured and/or packaged defectively;

e. that the subject product was manufactured and/or packaged improperly;

f. that the subject product and/or product packaging was designed negligently;

g. that the subject product and/or product packaging was designed defectively; and

h. that the subject product and/or product packaging was designed improperly.

195. Defendants were under a duty to disclose to Plaintiff, Plaintiff's healthcare providers, and/or the FDA the defective nature of the subject product, including but not limited to the risk of the device's propensity to undergo substantial early polyethylene wear, component loosening and/or other failure causing serious complications including tissue damage, osteolysis,

and other injuries, as well as the need for revision surgery in patients.

196. Defendants had sole access to material facts concerning the defective nature of the subject product and its propensity to cause serious and dangerous side effects, and hence, cause damage to persons who used Optetrak devices, including the Plaintiff.

197. Defendants' concealment and omissions of material facts concerning, *inter alia,* the safety of Optetrak devices was made purposefully, willfully, wantonly, and/or recklessly, to mislead Plaintiffs and Plaintiff's physicians, hospitals and healthcare providers into reliance on the use of the devices, and to cause them to purchase, prescribe, dispense and/or use the subject product.

198. Defendants knew that Plaintiff, Plaintiff's healthcare providers, and/or the FDA had no way to determine the truth behind the Defendants' concealment and omissions, as set forth herein.

199. Plaintiff, as well as Plaintiff's physicians, healthcare providers, and/or hospitals, reasonably relied on facts revealed which negligently, fraudulently and/or purposefully did not include facts that were concealed and/or omitted by the Defendants.

200. Defendants' conduct as described herein was a proximate cause of Plaintiff's injuries and damages.

COUNT VIII
CONSUMER FRAUD – VIOLATIONS OF MARYLAND CONSUMER PROTECTION ACT

201. Plaintiffs repeat, reiterate, and re-allege 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.

202. Plaintiff is a "consumer" under the Maryland Consumer Protection Act ("MCPA") as an actual recipient of consumer goods from Defendants. Defendants are companies that can be sued under the MCPA. The actions of Defendants constitute misrepresentations, breaches of warranties and unconscionable conduct, actionable under the MCPA. Specifically, Defendants committed the following acts in violation of the MCPA, Md. Code Ann., Com. Law § 13-301, 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, qualities 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.

203. Plaintiff relied on these representations to his detriment.

204. Further, Defendants violated the MCPA by breaching express and implied warranties as addressed below in this Complaint. Plaintiff fully incorporates the allegations set forth in Count IX and Count X below related to breach of express warranty and breach of implied warranty.

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

COUNT IX
BREACH OF EXPRESS WARRANTY

206. Plaintiffs re-allege and incorporate by reference 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.

207. At all times herein mentioned, the Defendants manufactured, packaged, distributed, recommended, merchandized, advertised, promoted, and sold the Optetrak devices. These actions were under the ultimate control and supervision of Defendants.

208. Defendants expressly represented and warranted that Optetrak Devices were safe and effective devices for those patients requiring a knee replacement.

209. Optetrak devices manufactured, packaged, and sold by Defendants did not conform to these express representations and warranties because they caused serious injury to the Plaintiff when used as recommended and directed.

210. Defendants knew or should have known that, in fact, said representations and warranties were false, misleading and untrue.

211. The Optetrak device was injected into the stream of commerce by Defendants in a defective, unsafe, and inherently dangerous condition, and the product's materials were expected to and did reach users, handlers, and persons encountering said products without substantial change in the condition in which they were sold.

212. Plaintiff and Plaintiff's healthcare providers relied on Defendants' express representations and warranties about the safety and efficacy of the Optetrak device.

213. Plaintiff and Plaintiff's healthcare providers reasonably relied upon the skill and judgment of Defendant as to whether the Optetrak was of merchantable quality and safe and fit for its intended use.

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

COUNT X
BREACH OF IMPLIED WARRANTY

215. Plaintiffs re-allege and incorporate by reference 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.

216. At all times herein mentioned, the Defendants manufactured, packaged, distributed, recommended, merchandized, advertised, promoted, and sold the Optetrak devices. These actions were under the ultimate control and supervision of Defendants.

217. At the time Defendants designed, manufactured, packaged, marketed, sold, and distributed the Optetrak device for use by the Plaintiff, Defendants knew of the use for which the Optetrak device was intended, impliedly warranted the product to be of the use for which the Optetrak device was intended, impliedly warranted the product to be of merchantable quality and safe for such use, and that its design, manufacture, packaging, labeling, and marketing complied with all applicable federal requirements.

218. These representations and warranties were false, misleading, and inaccurate in that the Optetrak device was unsafe, unreasonably dangerous, not of merchantable quality, and defective.

219. Defendants knew or should have known that, in fact, said representations and warranties were false, misleading and untrue.

220. Plaintiff and Plaintiff's healthcare providers relied on Defendants' implied representations and warranties about the safety and efficacy of the Optetrak device.

221. The Plaintiff and/or Plaintiff's healthcare providers reasonably relied upon the

skill and judgment of Defendants as to whether the Optetrak device was of merchantable quality and safe for its intended use, and upon Defendants' implied warranty as to such matters, including that it was in compliance with all federal requirements.

222. The Defendant breached the aforesaid implied warranties, as its Optetrak device was not fit for its intended purposes and uses.

223. Contrary to Defendants' implied warranties, the Optetrak device was not of merchantable quality or safe for its intended use, because the product was defective as described above, and/or it failed to comply with federal requirements.

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

COUNT XI
LOSS OF CONSORTIUM

225. Plaintiffs re-allege and incorporate by reference 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.

226. Prior to the initial implantation of Defendants' Defective Device, and at all other times material hereto, Plaintiff CORRINE M. SEXTON was legally married to Plaintiff JOSEPH D. SEXTON.

227. As a direct and proximate result of the acts and omissions of the Defendants, as set forth above, Plaintiff CORRINE M. SEXTON, as spouse of Plaintiff JOSEPH D. SEXTON, has suffered consequential damages and has been deprived of her spouse's full society, care, comfort, companionship, and has otherwise suffered a loss of consortium.

VI. CONDITIONS PRECEDENT

228. 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.

229. 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.

VII. 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 MCPA;

f) For loss of consortium damages;

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

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

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

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

Dated: November 11, 2022

Respectfully submitted,

_____/s/_____

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DEMAND FOR JURY TRIAL

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

_____/s/_____
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