UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF NEW YORK

RAY H. DOVELL, JR. Plaintiff, v. EXACTECH, INC. EXACTECH US, INC., Defendants.	Case No.: 1:22-cv-8666 **COMPLAINT AND JURY DEMAND**

COMPLAINT AND JURY DEMAND

COMES NOW, the Plaintiff, RAY H. DOVELL, JR., by and through undersigned counsel and submits 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 to Plaintiff RAY H. DOVELL, JR. 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 Logic" Total Knee System. In support, Plaintiff alleges 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 a defective device sold under various versions of the name "Optetrak"

Total Knee System, including "Optetrak Logic" Total Knee System (hereinafter "Optetrak Logic" or "Optetrak"), by the Defendants directly or through their agents, apparent agents, servants, and/or employees.

2. For approximately a decade, Defendants touted their knee implants, including the Optetrak Logic, as superior to the competition 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 Comprehensive Knee System because these devices were packaged improperly without an additional oxygen barrier layer, which can lead to expedited wear and minimized longevity. 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" 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, April 7, 2022, attached hereto as ***"Exhibit 1"***. (Emphasis in original).

6. On September 12, 2017, Plaintiff underwent Total Knee Replacement surgery on his right knee, in which the Optetrak Logic was implanted.

7. In the years following the surgeries, Plaintiff experienced pain, swelling, instability, and bone loss in both knees caused by early and accelerated polyethylene wear and component loosening. Ultimately, on January 25, 2022, Plaintiff underwent an extensive revision surgery on his right knee.

8. Recipients of the Optetrak Logic and other Exactech knee implants have been required to undergo 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 Logic's and other Exactech knee implants' 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 Device was defective and resulted in premature failures and accompanying complications, Defendants continued to aggressively market and sell the Optetrak Logic and other Exactech knee implants, all the while maintaining that it is safe and effective for use in total knee replacements and concealing the true safety information related to these devices.

II. PARTIES

11. At all times relevant hereto, Plaintiff Ray H. Dovell, Jr. was and is a resident and citizen of Hastings-on-Hudson, New York State.

12. Defendant Exactech, Inc. is a for-profit Florida corporation with its principal place of business at 2320 NW 66th Court, Gainesville, Florida, 32653. 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 Logic, 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 Logic in interstate commerce and throughout the State of New York, including within the area covered by the Southern District of New York (hereinafter the "District"), and generated substantial revenue as a result.

13. Defendant Exactech, Inc. is registered to do business within the District with a registered agent at National Registered Agents, Inc., 28 Liberty Street, New York, New York 10005.

14. 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. 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 New York and the District and generated substantial revenue as a result.

15. 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 the "Defendants."

16. 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

17. This Court has jurisdiction over Defendants in this action pursuant to 28 U.S.C. § 1332 because there is complete diversity of citizenship between Plaintiff 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, and specifically as a result of their long-term relationship selling and providing total knee replacement devices, including the Defective Implants, to the Hospital for Special Surgery (hereinafter "HSS") for implantation into patients such as and including Plaintiff Ray H. Dovell, Jr.

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

19. 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 Logic and

other Exactech implants, within the State of New York and specifically the District, with a reasonable expectation that the products would be used within this District.

20. The Court maintains specific personal jurisdiction over Defendants as they purposely solicited and transacted business on a prolonged and consistent basis with the HSS located at 535 East 70th Street, New York, New York 10021, where Plaintiff had the defective Optetrak Logic implants inserted and where he suffered injury by said products.

21. Based on this relationship, Defendants had a reasonable expectation that their products specifically would be used within this District and would be implanted into patients who received treatment at HSS, including the Plaintiff.

22. Further, Defendants also engaged in making false representations and statements to health care professionals in the State of New York and within the District, including specifically those medical professionals employed at HSS about the nature, durability, and quality of the materials used in their implants, which they claim give their devices superior wear characteristics.

23. Defendants derived substantial revenue and benefit from their business activities within the District and specifically as a result of their relationship with HSS. These activities included the promotion, sale and use of the Optetrak Total Knee System, including the Optetrak Logic and other defective Exactech knee implants.

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

25. 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 New York; because Plaintiff James Burke was implanted with the defective Optetrak Logic device and was thereafter injured by the defective Optetrak Logic device in this judicial district; and because Defendants are subject to personal jurisdiction within the State of New York.

IV. FACTS COMMON TO ALL COUNTS

A. Knee Replacement Surgery and Knee Implants

26. 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.

27. 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"), are surgeries 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.

28. During TKA procedures, surgeons replace the joint surfaces and damaged bone and cartilage with artificial materials, such as the Optetrak Logic 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 try 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. Defendants' Optetrak Knee Devices

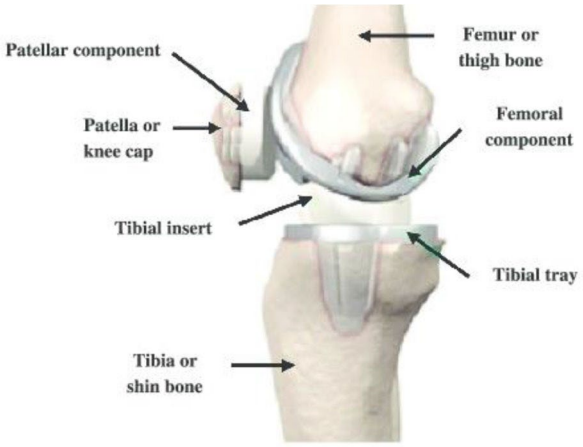
29. The first Optetrak knee device was introduced to orthopedic surgeons in the United States in 1994, building upon technology licensed from the Hospital for Special Surgery in New York City.

30. Since 1994, Defendants have obtained fast-tracked 510(k) clearance from the United States Food and Drug Administration ("FDA") for various subsequent versions of Optetrak devices and tibial inserts, including the Optetrak Comprehensive Total Knee System and the Optetrak Logic Comprehensive Knee System.

31. At all times material hereto, Defendants designed, developed, tested, assembled, selected, manufactured, packaged, labeled, prepared, distributed, marketed, supplied, warranted, and/or sold both the Optetrak Comprehensive Total Knee System and the Optetrak Logic Comprehensive Knee System throughout the United States.

32. 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.

33. The Optetrak Total Knee System is classified as a knee join patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis. It features a mix of polyethylene and metal-based components.



34. The Optetrak Total Knee System, including the Defective Implants, is comprised of the following parts: a patellar cap, femoral cap, tibial insert and tibial tray, as shown above.

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

36. 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.

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

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

39. In their marketing materials, the Defendants promised that, "[i]n 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."

40. 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.

41. 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.

42. 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.

43. Beginning in 2011, the Exactech Defendants began silently replacing the "finned" tibia tray with a "fit" tibia tray and change of the polyethylene insert.

44. 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.

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

46. At all times relevant, Defendants have been aware of a high rate of early failures with Optetrak knee systems which required recipients of the Optetrak Logic device to undergo revision surgeries to remove the defective device.

47. Despite actual knowledge of the increased risk of failure related to the defective

[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.

nature of the Optetrak Logic device, 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.

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

49. Despite Defendants' knowledge of early onset failures of the Optetrak Logic device, Defendants continued to manufacture, package, promote, and distribute the Optetrak Logic without changing, modifying, or improving the device or its packaging to address the increased risk of early failure.

50. Despite Defendants' knowledge of early onset failures of the Optetrak Logic device, 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 manufactured by Defendants or other companies with lesser risks and rates of early failure.

51. Despite Defendants' knowledge of early onset failures of the Optetrak Logic device, Defendants did not 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.

52. 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.

53. 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."

54. 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".

55. In the year 2015, Defendants did over $241 million in sales across all product lines. Defendants state in a 2015 Form 10-K, "to better meet the demand for revision surgeries, we began the initial launch of a new revision knee system in 2015."

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

57. In 2016, Defendants' revenue increased by 7% up to $257.6 million with knee devices sales increasing 4%. Knee device sales for the fourth quarter of 2016 accounted for $19.8 million of this amount.

58. According to Exactech's then Chief Executive Officer and President David Petty, the increases in knee device revenue "reflect excellent surgeon acceptance of Exactech innovations, including our three new revision systems." Mr. Petty further stated that he anticipated the "revision knee rollout in the fourth quarter" of 2016 will "carry momentum into 2017."

59. On February 23, 2017, the Defendants received fast-tracked 510(k) clearance for a new Exactech knee implant, called "Truliant," which is an intentional non-cemented implant system.

60. 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 Comprehensive Total Knee System.

61. 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.

62. Upon information and belief, Defendants have never conducted a clinical trial on the Optetrak devices, including the Optetrak Logic.

63. Had Defendants conducted clinical trials of the Optetrak Logic before the device was first released on the market, they would have discovered at that time 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.

64. At all times relevant to this action, Defendants were aware of the problems with the Optetrak Logic's design and its 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 still did not 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.

65. On February 7, 2022, Defendants issued a Recall of their knee and ankle implants

and sent an "URGET 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", and explained 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.**

https://www.exac.com/wp-content/uploads/2022/02/Exactech-DHCP letter.02.07.2022.pdf.

66. The Notice also acknowledged that the Optetrak Knee System 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 explains 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.

67. Defendants also prepared a sample letter for physicians to send their patients, which explained 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.

Exactech Knee Patient Letter, attached as ***"Exhibit 2"***. https://www.exac.com/product/exactech-knee-patient-letter/.

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

69. An example of a medically reversable health consequence is a revision surgery, such as the revision surgeries that Plaintiff underwent on his right and left knees.

C. Plaintiff Specific Allegations

70. On September 12, 2017, Plaintiff Ray H Dovell, Jr. underwent a right TKR at HSS in New York, New York. The surgery was performed by Dr. Russell F. Warren.

71. During the procedure, a defective Optetrak knee system was implanted using the following components:

a. Optetrak Logic Tibial Tray Trapezoid, Lot No. 4818907;

b. Optetrak Logic PSC Tibial Insert Posterior Stabilized, Lot No. 4561378;

c. Optetrak Logic Femoral Component Posterior Stabilized, Lot No. 4868915; and

d. Optetrak 3 Peg Patella, Lot No. 4970560.

72. The September 12, 2017 arthroplasty was done correctly and did not deviate from accepted medical custom and practice with regards to the implantation of the Optetrak Logic Total Knee System.

73. Defendants designed, developed, tested, assembled, manufactured, packaged, labeled, prepared, distributed, marketed, supplied, warranted and/or sold the defective implants placed inside Plaintiff Ray H. Dovel, Jr's right knee cavities in September 2017.

74. After an initial recovery period and for a period of years thereafter, Plaintiff's

Optetrak devices performed as expected.

75. In the middle of 2020, Plaintiff began experiencing severe pain, swelling, and instability in his right knee.

76. An MRI performed on June 1, 2021 on Plaintiff's right knee demonstrated a "polymeric-induced synovitis", "focal femoral osteolysis and prominent fibrous interface over the patella components", "deficiency of the fibular collateral ligament and degeneration of the popliteus tendon."

77. Plaintiff's clinical, laboratory, and radiological workup on his right knee was negative for infection, but positive for loosening secondary to osteolysis secondary to polyethylene wear. Polyethylene wear causing osteolysis and component loosening is one the precise concerns expressed by Defendants in the letter sent to surgeons.

78. On January 25, 2022, Plaintiff underwent revision of his failed right Optetrak device. This procedure was performed by Dr. William Macaulay at NYU Langone.

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

80. Upon information and belief, the polyethylene inserts used in the Optetrak device were defective, leading to early aseptic loosening. A packaging defect in the packaging containing the Optetrak's polyethylene inserts accelerated polyethylene wear due to oxidation.

81. 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 polyethylene accelerated wear debris leading to Plaintiff's bone loss around the implants.

82. 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.

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

84. Defendants allowed the defective Optetrak devices to be implanted during Plaintiff's two total knee arthroplasties in said condition.

85. Defendants failed with respect to the selection, processes, testing, quality audits, and supervision for their knee implant devices, including the defective Optetrak devices.

86. Upon information and belief, Defendants' violated federal and state laws and regulations regarding the design, selection, 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.

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

D. <u>The Federal Requirements</u>

88. Pursuant to federal law, a device is deemed to be adulterated if, among other things,

it fails to meet established performance standards, or if the methods, facilities or controls used for its manufacture, packing, storage or installation are not in conformity with federal requirements. *See* 21 U.S.C. §351.

89. Pursuant to federal law, a device is deemed to be misbranded if, among other things, its labeling is false or misleading in any particular manner or if it is dangerous to health when used in the manner prescribed, recommended or suggested in the labeling thereof. *See* 21 U.S.C. §352.

90. Pursuant to federal law, manufacturers are required to comply with FDA regulation of medical devices, including FDA requirements for records and reports, in order to prohibit introduction of medical devices that are adulterated or misbranded, and to assure the safety and effectiveness of medical devices. In particular, manufacturers must keep records and make reports of any medical device that may have caused or contributed to death or serious injury, or if the device has malfunctioned in a manner likely to cause or contribute to death or serious injury. Federal law also mandates that the FDA establish regulations requiring a manufacturer of a medical device to report promptly to FDA any correction or removal of a device undertaken to reduce a risk to health posed by the device, or to remedy a violation of federal law by which a device may present a risk to health. See 21 U.S.C. §360(i).

91. Pursuant to federal law, the Secretary of Health and Human Services may prescribe regulations requiring that the methods used in, and that facilities and controls used for, the manufacture, pre-production design validation (including a process to assess the performance of a device but not including an evaluation of the safety or effectiveness of a device), packaging, storage, and installation of a device conform to current good manufacturing practice, as prescribed in such regulations, to assure that the device will be safe and effective and otherwise in compliance with federal law. See 21. U.S.C. §360j(f).

92. Pursuant to FDA regulation, adverse events associated with a medical device must

be reported to the FDA within 30 days after the manufacturer becomes aware that a device may have caused or contributed to death or serious injury, or that a device has malfunctioned and would be likely to cause or contribute to death or serious injury if the malfunction was to recur. Such reports must contain all information reasonably known to the manufacturer, including any information that can be obtained by analysis, testing, or other evaluation of the device, and any information in the manufacturer's possession. In addition, manufacturers are responsible for conducting an investigation of each adverse event, and must evaluate the cause of the adverse event. *See* 21 CFR §803.50.

93. Pursuant to federal regulation, manufacturers of medical devices must also describe every individual adverse event report whether remedial action was taken in regard to the adverse event, and whether the remedial action was reported to FDA as a removal or correction of the device. *See* 21 CFR §803.52.

94. Pursuant to federal regulation, manufacturers must report to FDA within five (5) business days after becoming aware of any reportable MDR event or events, including a trend analysis that necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health. *See* 21 CFR §803.53.

95. Pursuant to federal regulation, device manufacturers must report promptly to FDA any device corrections and removals, and maintain records of device corrections and removals. FDA regulations require submission of a written report within ten (10) working days of any correction or removal of a device initiated by the manufacturer to reduce a risk to health posed by the device, or to remedy a violation of the Act caused by the device, which may present a risk to health. The written submission must contain, among other things, a description of the event giving rise to the information reported and the corrective or removal actions taken, and any illness or injuries that have occurred with the use of the device, including reference to any device report

numbers. Manufacturers must also indicate the total number of devices manufactured or distributed which are subject to the correction or removal, and provide a copy of all communications regarding the correction or removal. *See* 21 CFR §806.

96. Pursuant to federal regulation, manufacturers must comply with specific quality system requirements promulgated by FDA. These regulations require manufacturers to meet design control requirements, including but not limited to conducting design validation to ensure that devices conform to define user needs and intended uses. Manufacturers must also meet quality standards in manufacture and production. Manufacturers must establish and maintain procedures for implementing corrective actions and preventive actions, and investigate the cause of nonconforming products and take corrective action to prevent recurrence. Manufacturers are also required to review and evaluate all complaints and determine whether an investigation is necessary. Manufacturers are also required to use statistical techniques where necessary to evaluate product performance. *See* 21 CFR §820.

97. The regulations requiring conformance to good manufacturing practices are set forth in 21 CFR §820 *et seq.* As explained in the Federal Register, because the Current Good Manufacturing Practice (CGMP) regulations must apply to a variety of medical devices, the regulations do not prescribe the details for how a manufacturer must produce a device. Rather, the quality system regulations provide a framework of basic requirements for each manufacturer to use in establishing a quality system appropriate to the devices designed and manufactured, and the manufacturing processes employed. Manufacturers must adopt current and effective methods and procedures for each device they design and manufacture to comply with and implement the basic requirements set forth in the quality system regulations.

98. Pursuant to 21 CFR §820.1 (c), the failure to comply with any applicable provision in Part 820 renders a device adulterated under section 501(h) of the Federal Food Drug & Cosmetic Act ("the Act") (21 U.S.C. § 351).

99. Pursuant to 21 CFR §820.5, each manufacturer shall establish and maintain a quality system that is appropriate for the specific medical device designed or manufactured. "Quality system" means the organizations structure, responsibilities, procedures, processes and resources for implementing quality management. *See* 21 CFR §820.3(v).

100. Pursuant to 21 CFR §820.22, each manufacturer shall establish procedures for quality audits and conduct such audits to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system.

101. Pursuant to 21 CFR §820.30(a), each manufacturer shall establish and maintain procedures to control the design of the device in order to ensure that specified design requirements are met.

102. Pursuant to 21 CFR §820.30(d), each manufacturer shall establish and maintain procedures for defining and documenting design output in terms that allow an adequate evaluation of conformance to design input requirements.

103. Pursuant to 21 CFR §820.30(e), each manufacturer shall establish and maintain procedures to ensure that formal documented reviews of the design results are planned and conducted at appropriate stages of the device's design development.

104. Pursuant to 21 CFR §820.30(f), each manufacturer shall establish and maintain procedures for verifying the device design to confirm that the device design output meets the design input requirements.

105. Pursuant to 21 CFR §820.30(g), each manufacturer shall establish and maintain procedures for validating the device design. Design validation shall be performed under defined

operating conditions on initial production units, lots, or batches, or their equivalents. Design validations shall ensure that devices conform to defined user needs and intended uses and shall include testing of production units under actual or simulated use conditions.

106. Pursuant to 21 CFR §820.30(h), each manufacturer shall establish and maintain procedures to ensure that the device design is correctly translated into production specifications.

107. Pursuant to 21 CFR §820.30(i), each manufacturer shall establish and maintain procedures for the identification, documentation, validation or where appropriate verification, review, and approval of design changes before their implementation.

108. Pursuant to 21 CFR §820.70(a), each manufacturer shall develop, conduct, control, and monitor production processes to ensure that a device conforms to its specifications. Where deviations from device specifications could occur as a result of the manufacturing process, the manufacturer shall establish and maintain process control procedures that describe any process controls necessary to ensure conformance to specifications. Such process controls shall include:

a. Documented instructions, standard operating procedures (SOP's), and methods that define and control the manner of production;

b. Monitoring and control of process parameters and component and device characteristics during production;

c. Compliance with specified reference standards or codes;

d. The approval of processes and process equipment; and

e. Criteria for workmanship which shall be expressed in documented standards or by other equivalent means.

109. Pursuant to 21 CFR §820.70(b), each manufacturer shall establish and maintain procedures for changes to a specification, method, process, or procedure.

110. Pursuant to 21 CFR §820.70(c), each manufacturer shall establish and maintain procedures to adequately control environmental conditions that could reasonably be expected to

have an adverse effect on product quality, including periodic inspection of environmental control system(s) to verify that the system, including necessary equipment, is adequate and functioning properly.

111. Pursuant to 21 CFR §820.70(e), each manufacturer shall establish and maintain procedures to prevent contamination of equipment or product by substances that could reasonably be expected to have an adverse effect on product quality.

112. Pursuant to 21 CFR §820.70(g), each manufacturer shall ensure that all equipment used in the manufacturing process meets specified requirement and is appropriately designed, constructed, placed, and installed to facilitate maintenance, adjustment, cleaning and use.

113. Pursuant to 21 CFR §820.70(h), each manufacturer shall establish and maintain procedures for the use and removal of manufacturing material which could reasonably be expected to have an adverse effect on product quality to ensure that it is removed or limited to an amount that does not adversely affect the device's quality.

114. Pursuant to 21 CFR §820.70(i), when computers or automated data processing systems are used as part of production or the quality system, the manufacturer shall validate computer software for its intended use according to an established protocol.

115. Pursuant to 21 CFR §820.72, each manufacturer shall ensure that all inspection, measuring, and test equipment, including mechanical, automated, or electronic inspection and test equipment, is suitable for its intended purposes and is capable of producing valid results. Each manufacturer shall establish and maintain procedure to ensure that equipment is routinely calibrated, inspected, checked and maintained.

116. Pursuant to 21 CFR §820.75(a), where the results of a process cannot be fully verified by subsequent inspection and test, the process shall be validated with a high degree of assurance and approved according to established procedures. “Process validation” means

establishing by objective evidence that a process consistently produces a result or product meeting its predetermined specifications. See 21 CFR §820.3(z)(1).

117. Pursuant to 21 CFR §820.75(b), each manufacturer shall establish and maintain procedures for monitoring and control of process parameters for validated processes to ensure that the specified requirements continue to be met. Each manufacturer shall ensure that validated processes are performed by qualified individuals.

118. Pursuant to 21 CFR §820.90, each manufacturer shall establish and maintain procedures to control product that does not conform to specified requirements.

119. Pursuant to 21 CFR §820.100, each manufacturer shall establish and maintain procedures for implementing corrective and preventive action. The procedures shall include requirements for:

a. Analyzing processes, work operations, concessions, quality audit reports, quality records, service records, complaints, returned product, and other sources of quality data to identify existing and potential causes of nonconforming product, or other quality problem;

b. Investigating the cause of nonconformities relating to product, processes and the quality system;

c. Identifying the action(s) needed to correct and prevent recurrence of nonconforming product and other quality problems;

d. Verifying or validating the corrective and preventive action to ensure that such action is effective and does not adversely affect the finished device;

e. Implementing and recording changes in methods and procedures needed to correct and prevent identified quality problems;

f. Ensuring that information related to quality problems or nonconforming product is disseminated to those directly responsible for assuring the quality of such product or the prevention of such problems; and

g. Submitting relevant information on identified quality problems, as well as corrective and preventative actions, for management review.

E. Defendants' Optetrak Logic Total Knee System is a 510(k) Approved Medical Device

120. Defendants submitted a §510(k) premarket notification and obtained marketing approval for Optetrak device(s) from the FDA under Section 510(k) of the Act. See U.S.C. §360 *et seq.*

121. Under the §510(k) approval process, the FDA determined that Defendants' Optetrak devices were "substantially equivalent" to devices that have been reclassified in accordance with the provisions of the Act and did not require FDA approval of a pre-market approval application (PMA).

122. Upon information and belief, Defendants' Optetrak devices are adulterated pursuant to 21 U.S.C. §351 because, among other things, they failed to meet established performance standards, and/or the methods, facilities, or controls used for their manufacture, packing, storage or installation are not in conformity with federal requirements. *See* 21 U.S.C. §351.

123. Upon information and belief, Defendants' Optetrak 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.

124. Upon information and belief, Defendants' Optetrak devices are adulterated pursuant to 21 U.S.C. §351 because Defendants failed to establish and maintain CGMP for their Optetrak Devices in accordance with 21 CFR §820 *et seq.,* as set forth above.

125. Upon information and belief, Defendants failed to establish and maintain CGMP with respect to the quality audits, quality testing and process validation for its Optetrak devices.

126. As a result of Defendants' failure to establish and maintain CGMP as set forth above, Defendants' Optetrak devices were defective and failed, resulting in injuries to the Plaintiff.

127. If Defendants had complied with federal requirements regarding CGMP, Defendants' Optetrak devices would have been manufactured properly such that they would not have resulted in injuries to the Plaintiff.

V. CAUSES OF ACTION

COUNT I STRICT LIABILITY: MANUFACTURING DEFECT (ALL DEFENDANTS)

128. Plaintiff re-alleges and incorporates 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.

129. 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.

130. 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.

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

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

133. 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 Net Compression Molding process as 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.

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

135. 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.

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

137. 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.

138. 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.

139. 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.

140. 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.

141. 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.

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

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

144. By reason of the foregoing acts, omissions and conduct committed by the Defendants, Plaintiff was caused to sustain serious personal injuries, conscious pain and suffering, physical disability, mental anguish, emotional distress, fear, loss of enjoyment of life, medical expenses, and financial losses.

145. By reason of the foregoing acts, omissions and conduct committed by the Defendants, Plaintiff was caused to sustain serious personal injuries, conscious pain and suffering, and physical disability that will require continued and additional medical treatment.

146. By reason of the foregoing acts, omissions and conduct committed by the Defendants, Plaintiff was caused to sustain disabilities in activities of daily living.

147. By reason of the foregoing acts, omissions and conduct committed by the Defendants, Plaintiff has sustained and will sustain medical expenses and related economic losses.

148. The injuries, damages, harm, and losses sustained by Plaintiff were caused solely and wholly by virtue of the foregoing acts, omissions, and conduct of Defendants and were in no way caused and/or contributed to by plaintiff.

149. By reason of the foregoing, Plaintiff is entitled to monetary damages from the Defendants for his past, present and future non-economic and economic injuries, harm and losses in an amount that exceeds the jurisdictional minimum.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT II STRICT LIABILITY: DESIGN DEFECT (ALL DEFENDANTS)

150. 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.

151. 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.

152. Prior to, on, and after the dates of Plaintiff's initial knee surgery, 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.

153. 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.

154. 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.

155. 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.

156. The Optetrak devices implanted in Plaintiff were defective in design by virtue of their size, shape, length, diameter, surface finish, molecular weight and/or materials which cause the devices to have a 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, and cause or contribute to a higher failure rate and/or shorter useful life expectancy than comparable knee replacement products.

157. The design of the packaging in which the Optetrak Total Knee System components are contained is defective and not reasonably safe.

158. 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.

159. 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.

160. 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 Device;

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

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

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 Device, including its components and subassemblies, to ensure that the Optetrak Device functioned properly during and after implantation;

m. that Defendants failed to perform adequate testing on the specific Optetrak Device 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.

161. 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 failure causing serious complications including tissue damage, osteolysis, and other injuries as well as the need for 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.

162. 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.

163. The design defects of the Optetrak devices present an unreasonable risk of harm when they are used and operated for purposes expected and intended by Defendants.

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

165. 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.

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

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

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

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

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

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

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

173. Defendants failed to consider foreseeable safety hazards and serious injury risks arising from designs using conventional polyethylene.

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

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

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

177. 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.

178. As a direct, proximate and legal consequence of Defendants' wrongful conduct as described herein, including the defective design of the Optetrak device, Plaintiff has suffered and will continue to suffer permanent and debilitating injures and damages, including but not limited to, significant pain and discomfort; gait impairment; poor balance; difficulty walking; component part loosening; osteolysis, soft tissue damage; and other injuries presently undiagnosed, which all require ongoing medical care. As a further direct, proximate and legal consequence of the defective nature of the Optetrak device, Plaintiff has sustained and will sustain future damages, including but not limited to additional revision surgeries; cost of medical care; rehabilitation; home health care; loss of earning capacity; mental and emotional distress; and pain and suffering for which he is entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT III STRICT LIABILITY: FAILURE TO WARN (ALL DEFENDANTS)

179. 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.

180. Prior to, on, and after the dates of Plaintiff's initial knee surgery, 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 for implantation into consumers, such as Plaintiff, by physicians and orthopedic surgeons in the United States.

181. 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.

182. 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 its 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 scientifically 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.

183. 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 scientific knowledge available before, at and after the time of manufacture, distribution, and sale of the Optetrak Plaintiff.

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

185. 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.

186. 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.

187. 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.

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

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

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

191. Plaintiff, individually and through his physicians, reasonably relied upon the skill, superior knowledge and judgment of the Defendants.

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

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

194. Plaintiff's orthopedic surgeon used the Optetrak device in the manner in which it was intended to be used, making such use reasonably foreseeable to Defendants.

195. 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 surgery was a substantial factor in causing Plaintiff's injuries, losses and damages as alleged herein.

196. 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.

197. As a direct, proximate and legal consequence of Defendants' wrongful conduct as described herein, including Defendants' lack of sufficient instructions or warnings, Plaintiff has suffered and will continue to suffer permanent and debilitating injures and damages, including but not limited to, significant pain and discomfort; gait impairment; poor balance; difficulty walking; component part loosening; osteolysis; soft tissue damage; and other injuries presently undiagnosed, which all require ongoing medical care. As a further direct, proximate and legal consequence of the defective nature of the Optetrak, Plaintiff has sustained and will sustain future damages, including but not limited to additional revision surgeries; cost of medical care; rehabilitation; home health care; loss of earning capacity; mental and emotional distress; and pain

and suffering for which he is entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT IV NEGLIGENCE (ALL DEFENDANTS)

198. Plaintiff re-alleges and incorporates 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.

199. 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 its products did not pose a significantly increased risk of bodily harm and adverse events and/or a duty to comply with federal requirements.

200. 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.

201. 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 inserts used in the Optetrak devices;

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

c. Negligently failing to properly supervise and monitor the production and packaging of the polyethylene inserts 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.

202. 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.

203. 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.

204. 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.

205. Defendants' conduct as describe above, including but not limited to its failure to adequately design, manufacture and package, as well as its continued marketing and distribution

of Optetrak devices, when it knew or should have known of the serious health risks it created and/or the failure to comply with federal requirements, evidences a flagrant disregard of human life so as to warrant the imposition of punitive damages.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT V NEGLIGENT MISREPRESENTATION (ALL DEFENDANTS)

206. Plaintiff re-alleges and incorporates 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 the time Defendants tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold the Optetrak devices to Plaintiff, 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.

208. 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 orthopedic surgeon, 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.

209. 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 orthopedic surgeons, 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.

210. 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 surgeons 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.

211. 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.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT VI FRAUDULENT INDUCEMENT (ALL DEFENDANTS)

212. Plaintiffs re-alleges and incorporates 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.

213. 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 orthopedic surgeon, and the public regarding the safety and efficacy of the Optetrak.

214. However, Defendants misled Plaintiff, Plaintiff's orthopedic surgeon, 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 orthopedic surgeons 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 orthopedic surgeons 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.

215. 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.

216. 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 including non-peer reviewed studies, deceived orthopedic surgeons, Plaintiff, other patients, and the public about the true risks of the Optetrak device. Defendants falsely and deceptively kept relevant information from orthopedic surgeons, the FDA and the public, including Plaintiff, regarding the safety of the Optetrak.

217. 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.

218. Defendants did not accurately report the results of adverse events by fraudulently and intentionally withholding from the FDA, orthopedic surgeons, 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, orthopedic surgeons, Plaintiff, and the public, while continuing to sell the Optetrak for implantation in patients such as Plaintiff.

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

220. 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 orthopedic surgeons, Plaintiff, other patients, and the public of

the true risks associated with the Optetrak, which were known to Defendants, and continued to assure orthopedic surgeons and patients that the Optetrak was safe and effective device for the purpose of continuing to derive substantial profits from its sale.

221. 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.

222. 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 orthopedic surgeon.

223. Among Defendants' numerous misrepresentations and misleading omissions to Plaintiff, Plaintiff's orthopedic surgeon, 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.

224. Despite their knowledge of the risks with the Optetrak, Defendants urged their sales

representatives to continue marketing it and distributed medical literature including non-peer reviewed studies and other communications to orthopedic surgeons 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.

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

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

227. Plaintiff's orthopedic surgeon relied upon information obtained from Defendants, the medical literature, journal articles, medical conferences and presentations, adverse event reporting data, and discussions with other orthopedic specialists 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.

228. 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 orthopedic surgeon to implant the Optetrak device into his body.

229. As a direct and proximate result of Defendants' wrongful conduct described herein,

Plaintiff suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT VII FRAUDULENT CONCEALMENT (ALL DEFENDANTS)

230. Plaintiff re-alleges and incorporates 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.

231. 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.

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

233. 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 the risks of developing serious and 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 over 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.

234. 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.

235. 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.

236. 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 Plaintiff and Plaintiffs 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.

237. 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.

238. Plaintiff, as well as Plaintiff's doctors, 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.

239. As a direct and proximate result of Defendants' fraudulent misrepresentations and omissions and/or its failure to disclose its violations of federal requirements applicable to its Optetrak devices, Plaintiff used Defendants' Optetrak devices and the Plaintiff suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

240. Defendants' actions and omissions as alleged in this Complaint demonstrate a flagrant disregard for human life, so as to warrant the imposition of punitive damages.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT VIII CONSUMER FRAUD – VIOLATION OF GBL §§ 349 AND 350 (ALL DEFENDANTS)

241. Plaintiff re-alleges and incorporates 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.

242. The Defendants acted, used and employed unconscionable commercial practices, deception, fraud, false pretenses, false promises and misrepresentations, and knowingly concealed, suppressed and omitted material facts with the intent that consumers, including the Plaintiff herein and his physicians and medical providers, rely upon such concealment, suppression and omission, in connection with the sale, advertisement and promotion of Optetrak devices, in violation of all applicable state consumer fraud statutes, for the purpose of influencing and inducing physicians and medical providers to prescribe the Optetrak for knee arthroplasty, to patients/consumers such

as the Plaintiff herein. By reason of the Defendants' unconscionable, deceptive and fraudulent acts and practices, and false pretenses, false promises and misrepresentations, reasonable patients/consumers acting reasonably, such as the Plaintiff herein, were caused to suffer ascertainable loss of money and property and actual damages.

243. The Defendants engaged in consumer-oriented, commercial conduct by selling and advertising the Optetrak devices.

244. The Defendants misrepresented and omitted material information regarding the Optetrak devices by failing to disclose known risks.

245. The Defendants' misrepresentations and concealment of material facts constitute unconscionable commercial practices, deception, fraud, false pretenses, misrepresentation, and/or the knowing concealment, suppression, or omission of material facts with the intent that others rely on such concealment, suppression, or omission in connection with the sale and advertisement of the Optetrak, in violation of New York General Business Law ("GBL") §§349 and 350.

246. New York has enacted statutes to protect consumers from deceptive, fraudulent, and unconscionable trade and business practices. The Defendants violated these statutes by knowingly and falsely representing that the subject product was fit to be used for the purpose for which it was intended, when the Defendants knew it was defective and dangerous, and by other acts alleged herein.

247. The Defendants engaged in the deceptive acts and practices alleged herein in order to sell the subject product to the public, including the Plaintiff herein.

248. As a direct and proximate result of the Defendants' violations of GBL §§349 and 350, the Plaintiff has suffered damages, for which they are entitled to compensatory damages, equitable and declaratory relief, punitive damages, costs and reasonable attorneys' fees.

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

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT IX BREACH OF EXPRESS WARRANTY (ALL DEFENDANTS)

250. Plaintiff re-alleges and incorporates 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.

251. 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.

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

253. 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.

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

255. 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.

256. Plaintiff and Plaintiff's surgeon relied on Defendants' express representations and warranties about the safety and efficacy of the Optetrak device.

257. Plaintiff and Plaintiff's surgeon 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.

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

259. As a direct and proximate result of Defendants' breach of warranty, Plaintiff suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future, as well as damages for loss of consortium.

260. Defendants' conduct as described above, including but not limited to its failure to adequately design, manufacture, and package, as well as its continued marketing and distribution of Optetrak devices when it knew or should have known of the serious health risks it created and/or the failure to comply with federal requirements, evidences a flagrant disregard of human life so as to warrant the imposition of punitive damages.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT X BREACH OF IMPLIED WARRANTY (ALL DEFENDANTS)

261. Plaintiff re-alleges and incorporates 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.

262. 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.

263. 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.

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

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

266. Plaintiff and Plaintiff's surgeon relied on Defendants' implied representations and warranties about the safety and efficacy of the Optetrak device.

267. The Plaintiff and/or his surgeon 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.

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

269. 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.

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

271. Defendants' conduct as described above, including but not limited to its failure to adequately design, manufacture, and package, as well as its continued marketing and distribution of Optetrak devices when it knew or should have known of the serious health risks it created and/or the failure to comply with federal requirements, evidences a flagrant disregard of human life so as to warrant the imposition of punitive damages.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

VI. PRAYER FOR RELIEF

WHEREFORE, Plaintiff requests from Defendants compensatory and punitive damages, together with appropriate equitable relief, costs and attorney's fees as follows:

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

b. For medical, incidental and hospital expenses according to proof;

c. For pre-judgment and post-judgment interest as provided by law;

d. For consequential damages in excess of the jurisdictional minimum of this Court;

e. For compensatory damages in excess of the jurisdictional minimum of this Court;

f. For punitive damages in an amount in excess of any jurisdictional minimum of this Court and in an amount sufficient to deter similar conduct in the future and punish the Defendants for the conduct described herein;

VII. DEMAND FOR JURY TRIAL

Plaintiff hereby demands a trial by jury as to all claims in this action.

Dated: October 12, 2022

GODOSKY & GENTILE, P.C.

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