**UNITED STATES DISTRICT COURT**
**EASTERN DISTRICT OF NEW YORK**

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| [redacted]<br><br>Plaintiff,<br><br>v.<br><br>EXACTECH, INC.<br>EXACTECH US, INC.,<br><br>Defendants. | Case No.:<br><br>**COMPLAINT AND JURY DEMAND** |

## COMPLAINT AND JURY DEMAND

COMES NOW, the Plaintiffs, [redacted] and [redacted], 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 [redacted] 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, Plaintiffs allege the following:

## I. NATURE OF THE ACTION

1. This case involves claims of strict product liability, failure to warn, breach of express and implied warranties, 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 Device" 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. 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 the devices were safe and effective for use in total knee replacements and concealing the true safety information related to these devices.

5. Defendants only first issued a nationwide recall on February 7, 2022 advising the public that "most of our inserts since 2004 were packaged in out-of-specification… vacuum bags that are oxygen resistant but do not contain a secondary barrier layer containing ethylene vinyl alcohol (EVOH) that further augments oxygen resistance." This recall included "all knee and ankle arthroplasty polyethylene inserts packaged in non-conforming bags" since 2004.

6. As a result of Defendants' failure to properly package the Optetrak Device prior to distribution, the polyethylene liner prematurely degraded and Plaintiff required revision surgery due to severe pain, swelling, and instability in the knee and leg. These injuries were caused by early and preventable wear of the polyethylene insert and resulting component loosening and/or

other failures causing serious complications including tissue damage, osteolysis, permanent bone loss and other injuries.

7. Recipients of the Optetrak Device, like the Plaintiff, have been required to undergo revision surgeries well before the estimated life expectancy of a knee implant and at a much higher rate than should reasonably be expected for devices of this kind and have suffered pain and disability leading up to and subsequent to the revision surgery.

8. As a direct and proximate result of the defective nature of the Defendants' Optetrak Device surgically implanted in Plaintiff which necessitated premature removal, Plaintiff [redacted] suffered and will continue to suffer serious personal injuries, including pain, impaired mobility, rehabilitation, medical care, loss of enjoyment of life, and other medical and non-medical sequalae. His wife, [redacted], has likewise suffered injury including the loss of consortium, society and services of her husband as a result of his injuries from the defective device.

9. Plaintiffs bring this action for personal injuries suffered as a proximate result of failure of the Optetrak Device. Plaintiffs accordingly seek compensatory and punitive damages, and all other available remedies provided to Plaintiffs under the law as a result of injuries [redacted] and [redacted] sustained due to the Defendants' negligent, reckless and wrongful conduct.

## II. PARTIES

10. At all times relevant hereto, Plaintiffs [redacted] and [redacted] were and are residents and citizens of Lloyd Harbor, New York.

11. At all times relevant hereto, Plaintiff [redacted] was and is the lawful and loving spouse of Plaintiff [redacted].

12. Defendant EXACTECH, INC. is a domestic, Florida corporation with its principal place of business at 2320 NW 66th Court, Gainesville, Florida, 32653.

13. Defendant EXACTECH, INC., develops, manufactures, packages, stores, distributes, markets, and sells orthopedic implant devices, including Optetrak Devices and related surgical instrumentation throughout the United States, including in and throughout the United States and the state of New York.

14. Defendant EXACTECH, INC. manufactured the Optetrak Devices implanted in Plaintiff CHARLES CUNEO.

15. 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 Device in interstate commerce and throughout the State of New York and generated substantial revenue as a result.

16. 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.

17. According to public filings, Defendant EXACTECH US, INC. conducts Defendants' sales and distribution activities in the United States.

18. Defendant EXACTECH US, INC. is engaged in the business of designing, developing, testing, assembling, manufacturing, packaging, labeling, preparing, distributing, marketing, supplying, warranting, selling, and introducing Defendants' products, including the Optetrak Devices, into interstate commerce throughout the United States and the state of New York.

19. Upon information and belief, the Optetrak Devices manufactured by Defendant EXACTECH, INC. were distributed by Defendant EXACTECH US, INC. throughout the United States, including to the Hospital for Special Surgery (HSS) in New York, New York where Plaintiff CHARLES CUNEO received his implants.

20. At all times relevant to this action, Defendant EXACTECH US, INC., tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, stored, promoted, advertised, marketed, distributed, and/or sold the Optetrak Device in interstate commerce and throughout the State of New York and generated substantial revenue as a result.

21. EXACTECH US, INC. is an agent, representative and/or alter ego of Defendant EXACTECH, INC. Collectively, EXACTECH, INC. and EXACTECH US, INC. are referred to herein as the "Defendants."

22. 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

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

24. The court has personal jurisdiction over Defendants because at all relevant times they have engaged in substantial business activities in the State of New York. At all relevant times Defendants transacted, solicited, and conducted business in New York through their employees, agents, and/or sales representatives, and derived substantial revenue from such business in New York.

25. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391 because Plaintiffs are citizens and residents of Suffolk County, 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. Upon information and belief, the first Optetrak total knee system was introduced to orthopedic surgeons in the United States in 1994, building upon technology licensed from HSS in New York City.

30. 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, including to HSS in New York, New York.

31. Defendants obtained 510(k) clearance from the United States Food and Drug Administration ("FDA") for various Optetrak total knee system devices and components between 1994-2017, including under the names: Optetrak, Optetrak Logic and Truliant.

32. 510(k) clearance is distinct from the FDA's pre-market approval ("PMA") process in that clearance does not require clinical confirmation of safety and effectiveness and as such the manufacturer retains all liability for the assertions of safety and effectiveness.

33. 510(k) clearance only requires the manufacturer to notify the FDA under section 510(k) of the Medical Device Amendments of 1976 to the Food Device Cosmetic Act (MDA) of its intent to market a device at least 90 days prior to the device's introduction on the market, and to explain the device's substantial equivalence to a pre-MDA predicate device. The FDA may then "clear" the new device for sale in the United States.

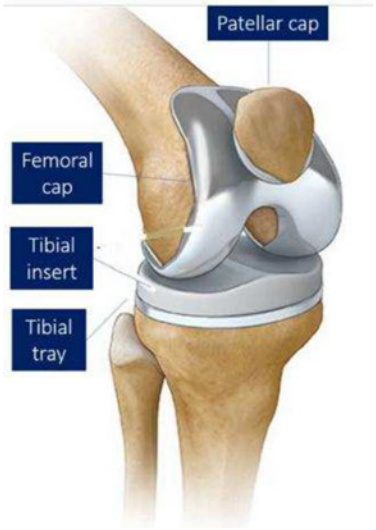
34. All the component parts comprising Plaintiff's Optetrak Device were cleared for marketing by the FDA pursuant to 510(k) process or were marketed without receiving either 510(k) clearance or PMA approval by the FDA.

35. 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.

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

37. According to the Defendants, the device "introduces novel implants and instruments to make the total knee procedure, easier, faster and more consistent, improving patient satisfaction for a more diverse population requiring total knee replacements."

38. The Optetrak Device is comprised of the following parts: a patellar cap, femoral cap, tibial insert and tibial tray, as shown below.




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

40. 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.

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

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

43. In their marketing materials, the Defendants promised that, the Optetrak Device had "excellent long-term clinical outcomes" and that "surgeons and patients can have every confidence in the performance and longevity of the Optetrak knee system."

44. 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.

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

46. According to the 2020 Australian National Joint Replacement Registry, the rate of revision for a total knee replacement utilizing an Optetrak tibial component with a Optetrak-CR femoral component was 8.5% at ten years and 10.2% at ten years when implanted with a Optetrak-PS femoral component which far exceeds international guidelines for accepted revision rates.

47. Per the recommendations established by the International Benchmarking Working Group and applied by the Australian Orthopaedic Association, the Optetrak Devices do not qualify for a "superiority benchmark" or even a "non-inferiority benchmark."

48. At all times relevant, Defendants have been aware of a high rate of early failures associated with the Optetrak Device.

49. Upon information and belief, by 2012, Defendants had further clinical evidence that Optetrak Devices 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.

50. Upon information and belief, in 2013, complaints continued to be reported. Some examples include revision for "tibial loosening" just two years postoperatively, "revision due to

[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.

tibial loosening", "during revision, the tibial component was found to be loose and easily removed", "revision of knee component due to loosening", "revision due to pain and loosening."

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

52. In the year 2015, Defendants 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."

53. 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.

54. 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.

55. 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."

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

57. 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.

58. The general practice in orthopedic implant surgeries generally, and with Exactech implants specifically, is for the sale representative of the manufacturer, in this case Exactech's authorized representative and agent, hereinafter "the sales rep", to be present at the time of surgery to provide implant components to the surgeon, relieving the hospital of the responsibility for having on stock all potential sizes and components that may be needed in surgeries. This practice includes the original implant surgery and any revision surgery.

59. The sales reps of Exactech observed many instances of premature failures of the Optetrak Device with plain evidence upon revision of polyethylene debris that needed to get removed, a/k/a "debrided", visible bone loss or osteolysis and plainly loose components that were easy to remove due to lack of fixation. Often these sales reps would take the component from the surgeon to return to the company for inspection and analysis.

60. The sales reps of Exactech were under a duty to report these findings to the engineering and medical departments of Exactech who were under a duty to then do an investigation, analyze the removed component when available, also known as "retrieval analysis" and honestly and thoroughly report such findings to the FDA and the surgeons.

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. Despite Defendants' knowledge of early onset failures of the Optetrak Device, Defendants continued to manufacture, promote, and distribute the Optetrak Device without alerting surgeons, patients or the FDA of the potential increased risks of early onset failures of the Optetrak Device.

65. Defendants never changed the labeling, marketing materials or product inserts to adequately and accurately warn patients or physicians of the associated increased risks of early failure due to loosening and/or polyethylene wear.

66. Not until August 30, 2021 did the Defendants take some action and issue a partial recall of all Optetrak All-polyethylene tibial components, including the OPTETRAK All-polyethylene CC Tibial Components; OPTETRAK All-polyethylene CR Tibial Components; OPTETRAK All-polyethylene CR Tibial Sloped Components; OPTERAK All-polyethylene PS Tibial Components; OPTETRAK HI-FLEX PS Polyethylene Tibial Components; OPTETRAK Logic All-polyethylene CR Tibial Components; OPTETRAK Logic All-polyethylene CRC Tibial Components; OPTETRAK Logic All-polyethylene PSC Tibial Components; OPTETRAK Logic Modular PS Tibial Components; OPTETRAK Logic RBK PS Tibial Components; TRULIANT CR Tibial Inserts; TRULIANT CRC Tibial Inserts; TRULIANT PS Tibial Inserts; and TRULIANT PSC Tibial Inserts.

67. In issuing the August 2021 recall, Defendants stated "inserts were packaged in vacuum bags that lacked an additional oxygen barrier layer." *See* https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRes/res.cfm?ID=189266.

68. According to the FDA website, "Exactech began notification to distributors and sales representatives on about 08/30/2021 via letter titled "URGENT MEDICAL DEVICE RECALL." Actions being taken by Exactech included removing all Knee and Ankle UHMWPE products labeled with an 8-year shelf life and not packaged in EVOH/Nylon bags. This will be performed in a phased approach over the next 12 months. Phase 1 includes immediately return of all knee and ankle UHMWPE devices labeled with an 8-year shelf life that will be 5 years old or older by 08/31/2022 not packaged in EVOH/Nylon bags. Phase 2 includes, between 05/31/2022 to 08/31/2022, returning all remaining knee and ankle UHMWPE devices labeled with an 8-year shelf life not packaged in EVOH/Nylon bags." *Id.*

69. Despite initial communications with distributors and sales representatives, Defendants did not issue any communications to surgeons who had implanted Optetrak Device with a recalled polyethylene component or to patients who had received an Optetrak Device with a recalled polyethylene component until months later in February 2022.

70. On February 7, 2022, Defendants issued an "Urgent Medical Device Correction" in which they informed health care professionals that:

> After extensive testing, we have confirmed that most of our inserts manufactured since 2004 were packaged in out-of-specification (referred to hereafter as "non-conforming") vacuum bags that are oxygen resistant but do not contain a secondary barrier layer containing ethylene vinyl alcohol (EVOH) that further augments oxygen resistance. **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

71. The "Urgent Medical Device Correction" went on to further state that Defendants were expanding the recall to include all knee arthroplasty polyethylene inserts packed in nonconforming bags regardless of label or shelf life. The components subject to the recall now included: OPTETRAK®: All-polyethylene CR Tibial Components, All-polyethylene PS Tibial Components, CR Tibial Inserts, CR Slope Tibial Inserts, PS Tibial Inserts, HI-FLEX® PS Tibial Inserts; OPTETRACK Logic®: CR Tibial Inserts, CR Slope Tibial Inserts, CRC Tibial Inserts, PS Tibial Inserts, PSC Tibial Inserts, CC Tibial Inserts; and TRULIANT®: CR Tibial Inserts, CR Slope Tibial Inserts, CRC Tibial Inserts, PS Tibial Inserts, PSC Tibial Inserts. *Id.*

72. It is estimated that a total of 147,732 inserts implanted in the United States since 2004 were produced with non-conforming packaging. *Id.*

73. Defendants further acknowledged the original Optetrak knee system has shown statistically significant higher overall revision rates compared to other total knee arthroplasties in the Australian, United Kingdom and New Zealand joint registries. *Id.*

74. Specifically, reasons for revision associated with polyethylene wear, including loosening, lysis, and pain, were increased three-to seven-fold with the Optetrak total knee replacement combination of the Optetrak-PS/Optetrak according to the 2021 Australian National Joint Replacement Registry with revision diagnoses related to accelerated polyethylene wear possibly related to the non-conforming packaging. *Id.*

75. Implanting surgeons were advised in the February 2022 notice to contact patients previously implanted with recalled components and to schedule an evaluation if the patient is experiencing any new or worsening knee swelling, pain while walking, inability to bear weight, grinding or other noise, instability, or any new symptoms of clicking in the knee. *Id.*

76. Furthermore, Defendants advised surgeons that revision surgery should be considered for patients who exhibit premature polyethylene wear. *Id.*

77. Based on Defendants' own representations, since 2004, Defendants manufactured, promoted, and distributed the Optetrak Device without ensuring the polyethylene components were properly packaged to prevent or minimize oxidation. At no point until August 2021 did Defendants first modify the packaging in an effort to address this defect.

78. In approximately 2017 – 2018, Exactech, Inc. was in the process of being acquired by the Private Equity Group TPG Capital which in February 2018 successfully completed a merger agreement. As a result, TPG acquired all of the issued and outstanding common stock of Exactech. In connection with the transaction, Exactech's founders, CEO and certain other management shareholders exchanged a portion of their shares in the transaction, for new equity securities in the post-closing ownership of the Company. *See* https://www.exac.com/exactech-announces-completion-of-merger-with-tpg-capital/.

79. Disclosure of knowledge of the improper packaging and excessive premature failure rates could have harmed this transaction.

80. At all times relevant to this action, Defendants were aware of the Optetrak Device's propensity to undergo substantial early polyethylene wear consisting of the degradation and breakdown of the plastic chemicals causing toxicity to the tissue and bone and component loosening and/or other failure causing serious complications including tissue damage, osteolysis,

and other injuries as well as the need for revision surgery and its attendant complications in patients.

81. At all times relevant to this action, Defendants failed to acknowledge the manufacturing defects in the Optetrak Device due to poor and inadequate quality assurance procedures and due to a wanton and reckless disregard for public safety. Defendants also failed to implement or utilize adequate safeguards, tests, inspections, validation, monitoring and quality assessments to ensure the safety of the Optetrak Device.

82. At the time the Optetrak Device was manufactured and sold to patients, including Plaintiff, the device was defectively manufactured, packaged and unreasonably dangerous, and did not conform to the federal regulations subjecting patients to unreasonable risks of injury.

83. At all times relevant to this action, Defendants' inadequate manufacturing processes also led to material flaws in the quality systems at its manufacturing, packaging, storage and distribution facilities.

84. During the course of manufacturing and distributing the Optetrak Device, Defendants failed in several ways, including, without limitation, by:

a. failing to conduct adequate mechanical testing, including oxygen-resistance or other wear testing for the components, subassemblies, and/or finished Optetrak Device;

b. failing to test an adequate number of sample devices on an ongoing basis;

c. failing to take adequate steps to specifically identify failure modes with clarity and to suggest methods to monitor, avoid, and/or prevent further failures;

d. failing to identify and/or note the significance of any testing that resulted in failure of the Optetrak Device;

e. failing to take corrective actions to eliminate or minimize further failures of the Optetrak Device;

f. failing to adequately explain packaging specifications for the components, subassemblies, and/or finished Optetrak Device;

g. failing to perform adequate quality control before the components, subassemblies, and/or finished Optetrak Device were distributed;

h. failing to properly address reports from their sales representatives who reported their observations while attending revision surgeries where evidence of polyethylene debris and osteolysis was apparent and noted by the surgeons and the sales representatives themselves;

i. failing to timely implement corrective action and investigations to understand the root cause of these failures while continuing to sell the components knowing they would be implanted into the bodies of thousands of people; and

j. by becoming aware of the potential cause or causes but unreasonably avoiding informing patients and surgeons and delaying the ability to minimize damages as the devices continued to degrade and do damage in the patients' bodies.

85. On or before the date of Plaintiff's initial knee replacement surgery, Defendants knew or should have known the Optetrak Device was failing and causing serious complications after implantation in patients. Such complications included, but were not limited to, catastrophic

polyethylene wear including the deposition of plastic particulate wear debris throughout the knee, a high rate of component loosening, and overall early system failure resulting in tissue destruction, osteolysis, and other injuries causing severe pain, swelling, instability and dysfunction in the knee and leg necessitating revision surgery.

86. Defendants as manufacturers of orthopedic devices know that each surgery, especially a revision surgery, is always more complicated than an initial knee replacement surgery and is fraught with serious risks of infection, anesthesia errors, dislocations and other serious complications that should be avoided.

87. Defendants, however, ignored reports of early failures of their Optetrak Device and failed to promptly investigate the cause of such failures or issue any communications or warnings to orthopedic surgeons and other healthcare providers.

88. Before the date of Plaintiff's initial knee replacement surgery, Defendants knew or should have known that the Optetrak Device was defective and unreasonably dangerous to patients, that the product had an unacceptable failure and complication rate, and that the product had 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.

**C. Plaintiff Specific Allegations**

89. On December 18, 2013, Plaintiff [redacted] underwent bilateral TKR and was implanted with Optetrak Devices in his left and right knees, including Optetrak Logic Tibial Inserts made of polyethylene. Plaintiff's TKR was performed at HSS in New York, New York. The surgery was performed by Dr. Thomas P. Sculco.

90. The December 18, 2013 arthroplasty was done correctly and did not deviate from accepted medical custom and practice with regards to the implantation of the Optetrak device.

91. MRIs performed on both knees in March of 2022 demonstrated bone loss, inflammation, and debris consistent with polymetric wear.

92. In or around March of 2022, Plaintiff was advised that his knee replacement failed with respect to both knees for reasons related to the defective device.

93. Upon information and belief, as a result of the Optetrak device failure, Plaintiff underwent revision surgery on his right knee on May 11, 2022 at HSS for issues including but not limited to polyethylene wear, bone loss, osteolysis, and/or component loosening.

94. Upon information and belief, as a result of the Optetrak device failure, Plaintiff also requires revision surgery on his left knee for issues including but not limited to polyethylene wear, bone loss, osteolysis, and/or component loosening.

95. Plaintiff experiences daily pain and discomfort in his knees which limits his activities of daily living and impacts his quality of life.

96. Further, Defendants, through their affirmative misrepresentations and omissions, actively concealed from Plaintiff and Plaintiff's health care providers the true and significant risks associated with the Optetrak Device and the need to vigilantly do diagnostic procedures to promptly diagnose the insidious process of the toxic polyethylene particles degrading and causing osteolysis.

97. Defendants know that after the one-year checkup following a total knee arthroplasty, typically patients are not expected to return for monitoring absent problems. Thus, Defendants knew that unless they informed surgeons to call their patients back for periodic

radiologic monitoring that polyethylene chemical degradation and attendant osteolysis could be occurring unchecked until it reached the stage of severe bone loss.

98. As a direct, proximate and legal consequence of the defective nature of the Optetrak Device as described herein, Plaintiff [redacted] has suffered and continues 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; soft tissue damage; bone loss; and other injuries presently undiagnosed, which all require ongoing medical care.

99. As a further direct, proximate and legal consequence of the defective nature of the Optetrak Device, Plaintiffs have sustained and will sustain future damages, including but not limited to cost of medical care; rehabilitation; home health care; loss of earning capacity; mental and emotional distress; loss of consortium and pain and suffering.

**D. The Federal Requirements**

100. 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.

101. 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.

102. 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).

103. 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).

104. 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.

105. 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.

106. 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.

107. 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.

108. 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.

109. 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.

110. 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).

111. 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).

112. 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.

113. 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.

114. 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.

115. 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.

116. 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.

117. 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.

118. 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.

119. 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.

120. 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.

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

122. 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.

123. 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.

124. 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.

125. 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.

126. 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.

127. 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.

128. 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).

129. 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.

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

131. 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. <u>Defendants' Optetrak Device is a 510(k) Approved Medical Device</u>**

132. 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.*

133. 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).

134. 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.

135. 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.

136. 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.

137. 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.

138. 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.

139. 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.

**F. Tolling of Statute of Limitations**

140. Pursuant to NY CPLR § 214-C(2), Plaintiff sustained injuries caused by the latent effects of exposure to polyethylene and the resins used to process the polyethylene and the degradation byproducts of those toxic materials.

141. The breakdown and wear of polyethylene, a plastic, leads to the release of toxic compounds, including chemical additives and nanoplastics. *See* Rillig, Matthias C. *et al.*, "The Global Plastic Toxicity Debt," *Environ. Sci. Technol.* 2021, 55, 2717-2719.

142. All plastics contain additional chemicals or additives and may contain impurities such as catalyst residues, unreacted monomers or breakdown products which possess toxic properties that can adversely affect human health. *Id.*

143. A comparison of muscle tissue from patients implanted with ceramic liners versus polyethylene liners during total hip arthroplasty demonstrated decreased osteolysis and capsule atrophy as well as less structural change to the muscles. *See* Hernigou, Phillippe *et al.*, "Ceramic on-ceramic THA Associated With Fewer Dislocations and Less Muscle Degeneration by Preserving Muscle Progenitors," *Clin Orthop Relat Res* (2015) 473:3762-3769.

144. In patients who develop osteolysis, there is osteolysis-associated reduced bone regenerative capacity with a decreased in mesenchymal stem cells (MSCs) that is accompanied by reduced muscle mass and increased fatty degeneration. *Id.*

145. For polyethylene implants with resulting osteolysis, a "possible mechanism was evaluated by an experimental study demonstrating that contact PE (polyethylene) particles inhibit the osteogenic activity of osteoprogenitor cells…which may result in reduced periprosthetic bone regeneration." *Id.*

146. To date, most plastic chemicals remain unknown and the toxic hazards of potentially thousands of chemicals humans are exposed to remain unknown, and thus, unregulated. *See*

Zimmerman, Lisa *et al.*, "Plastic Products Leach Chemicals That Induce *In Vitro* Toxicity under Realistic Use Conditions," *Environ. Sci. Technol.* 2021, 55, 11814-11823.

147. Plastics contain several thousand extractable chemicals which induce *in vitro* toxicity. *Id.*

148. "Our study highlights that plastic products leach chemicals triggering toxicity… the prevalent antiandrogenicity is an indicator for the leaching of endocrine-disrupting chemicals relevant for human health. Our results also show that many more chemicals are migrating from plastics than previously known." *Id.*

149. Furthermore, gamma-sterilized ultra-high molecular weight polyethylene contains macroradicals that will react with available oxygen in air or dissolved in bodily fluids. Kurtz, Steven M., *UHMWPE Biomaterials Handbook*, "Packaging and Sterilization of UHMWPE" (2016).

150. By virtue of Defendants' recall notice and representations on their website, Defendants describe a process by which sterilization of the tibial insert is achieved by gamma radiation in a reduced oxygen environment by use of oxygen barrier packaging. *See* https://www.exac.com/wp-content/uploads/2022/02/Exactech-DHCP letter.02.07.2022.pdf; "Optimizing Polyethylene Materials to the Application: When it Comes to Manufacturing Methods, Hips are Not Knees," available at https://www.exac.com/optimizing-polyethylene-materials-to-the-application/ (March 14, 2017).

151. "Gamma sterilization… initiate[s] a complex cascade of chemical reactions in the polymer, which ultimately result[s] in oxidation and subsequent degradation of material properties." *See UHMWPE Biomaterials Handbook.*

152. To the extent it is claimed that Plaintiff suffered symptoms prior to undergoing revision surgery, the statute of limitations is tolled under NY CPLR § 214-C(2) because development of osteolysis and bone loss are latent conditions caused by years of exposure to the

unknown, toxic properties of polyethylene that could not be appreciated until the time of revision surgery.

153. Furthermore, pursuant to NY CPLR § 214-C(4), Plaintiff exhibited due diligence but did not possess technical, scientific or medical knowledge and information sufficient to ascertain the cause of his injuries until after Defendants initiated a recall process of the Optetrak Device in February of 2022 and Plaintiff received the recall letter from HSS in April of 2022.

154. Defendants, through its affirmative misrepresentations and omissions, actively concealed from Plaintiff and Plaintiff's healthcare providers the true and significant risks associated with the Optetrak Device.

155. Following implantation of the Optetrak Device, Plaintiff and Plaintiff's healthcare providers relied on Defendants' continued representations that the Optetrak Device had excellent long-term clinical outcomes.

156. Defendants made these representations with knowledge of their falsity given their knowledge of reports of high failure rates.

157. As early as 2007, the Australian Joint Registry identified the Optetrak Device as having a higher than anticipated rate of revision.

158. According to the Australian Joint Registry published in 2007, use of the Optetrak-PS femoral component with an Optetrak tibial component resulted in a 6.23% revision rate at three years and 6.64% revision rate at four years. The Registry identified use of these components as "Individual Primary Total Knee Prostheses with higher than anticipated revision rates either alone or in combination."

159. The cumulative rate of revision with use of the Optetrak-PS femoral component and an Optetrak tibial component continued to increase. Data from the 2008 and 2009 Australian Joint Registry demonstrated a revision rate of 6.7% and 7.0% at five years, respectively.

160. By 2010, the use of the Optetrak-PS femoral component and Optetrak-PS tibial components were "identified and no longer used" as a result of a 21% cumulative revision rate at five years. This rate increased to 22.7% the following year.

161. Identification of problems with the Optetrak-PS tibial component continued to grow. According to the 2015 registry data, "[t]he Optetrak PS all-polyethylene prosthesis has a cumulative percent revision of 19.4% at seven years."

162. Defendants themselves have acknowledged, "[e]very Exactech Optetrak TKR polyethylene component combination demonstrated statistically significant increased revision rates compared to other TKR systems," citing 2021 Australian Registry data, however, data demonstrating high rates of premature failure were available to Defendants as early as 2007. *See* https://www.exac.com/wp-content/uploads/2022/02/Exactech-DHCP letter.02.07.2022.pdf.

163. The Optetrak Device had similarly high failure rates as documented in the United Kingdom National Joint Registry. In 2015, the revision rate for the Optetrak Device was 5.02% at seven years and 6.92% at ten years. In 2016, the revision rate for the Optetrak Device was 5.15% at seven years and 7.79% at ten years. In 2017, the revision rate for the Optetrak Device was 5.23% at seven years and 7.45% at ten years. In 2018, the revision rate for the Optetrak CR was 5.53% at seven years and 7.61% at 10 years.

164. The failure rates for the Opterak Device in the UK Registry were consistently higher compared to other knee replacement devices.

165. Defendants sold these implants worldwide and had a duty to monitor the international registries to assess how their prostheses were faring. Unfortunately, since the United States does not have a single payor health system, there is no national registry and doctors in the Unites States are not privy to nor expected to be aware of such data from other continents.

166. Defendants never informed physicians of the high failure rates associated with the Optetrak Devices reported annually in the international registries.

167. Although clinical evidence demonstrated that Optetrak Devices were failing at a rate higher than promoted with instances of excessive revision rates due to device loosening and polyethylene wear, Defendants failed to initiate a recall earlier or issue any communications to healthcare providers that patients should be monitored.

168. Furthermore, earlier disclosure of these failure rates could have impacted the sale of the company to private equity.

169. Had Defendants not actively concealed evidence of growing reports of premature device failures, Plaintiff would have obtained radiological intervention at an earlier time.

170. Such intervention would have led to an earlier diagnosis of bone loss and earlier removal of the Optetrak Device thereby reducing damage to bone and tissue.

171. As a result of Defendants' actions, Plaintiff and Plaintiff's healthcare providers were unaware, and could not have reasonably known or have learned through reasonable diligence, that Plaintiff had been exposed to the risks identified herein, and that those risks were the result of defects in the product due to Defendants' acts, omissions, and misrepresentations.

172. Accordingly, no limitations period ought to accrue until such time as Plaintiff knew or reasonably should have known of some causal connection between Plaintiff being implanted

with the Optetrak Device and the resulting harm later suffered by Plaintiff as a result by reason of Defendants' fraudulent concealment.

173. Additionally, Defendants are equitably estopped from asserting any limitations defense by virtue of their fraudulent concealment and other misconduct as described herein.

174. Further, the limitations period ought to be tolled under principles of equitable tolling.

## V. CAUSES OF ACTION

### COUNT I
### STRICT LIABILITY: MANUFACTURING DEFECT
### (ALL DEFENDANTS)

175. 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.

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

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

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

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

180. The Optetrak Devices were not reasonably safe as manufactured, packaged, distributed, marketed and/or sold by the Defendants.

181. The defects in manufacture of the Optetrak Device were a substantial factor in causing Plaintiffs' injuries.

182. 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 Device, which was implanted in Plaintiff, such that it was dangerous, unsafe, and defective in manufacture. The defects include but are 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. failure to package the polyethylene components of the Optetrak Device in vacuum bags that contain a secondary barrier layer containing ethylene vinyl alcohol (EVOH) as to prevent the components from undergoing increased oxidation and causing patients to experience 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;

c. the materials used to package the Optetrak Device were of an inferior grade or quality;

d. that the Optetrak Device as manufactured differed from Defendants' intended specifications;

e. that Defendants failed to measure and/or test an adequate number of samples of Optetrak Devices on an ongoing basis;

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

g. that Defendants failed to perform adequate quality control or other such testing on the polyethylene inserts used in the Optetrak Device to ensure they complied with required specifications and were not prematurely degrading while stored;

h. failing to select appropriate third-parties to package the polyethylene inserts used in the Optetrak Device;

i. failing to properly supervise and monitor the packaging of the polyethylene inserts used in the Optetrak Device;

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

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

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

184. The manufacturing defects in the Optetrak Device existed when the device left the Defendants' control.

185. Plaintiff's physicians implanted the Optetrak Device in the manner in which it was intended and recommended to be used, making such use reasonably foreseeable to Defendants.

186. The Optetrak Device as tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or old by Defendants reached Plaintiff without substantial change in its condition.

187. As alleged herein, Defendants knew or had reason to know that the Optetrak Device 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.

188. The manufacturing defects of the Optetrak Device 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.

189. The manufacturing defects of the Optetrak Device 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.

190. Plaintiff could not, by the exercise of reasonable care, have discovered the manufacturing defect and perceived its dangers or avoided injury.

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

192. 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.

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

194. As a direct, proximate and legal consequence of the defective nature of the Optetrak Device as described herein Plaintiff [redacted] has suffered and continues 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; soft

tissue damage; bone loss; and other injuries presently undiagnosed, which all require ongoing medical care.

195. As a further direct, proximate and legal consequence of the defective nature of the Optetrak Device, Plaintiffs have sustained and will sustain future damages, including but not limited to cost of medical care; rehabilitation; home health care; loss of earning capacity; mental and emotional distress; loss of consortium and pain and suffering.

196. Defendants acted intentionally, recklessly and wantonly without regard for Plaintiff's rights beyond all standards of decency, entitling Plaintiff to recover punitive damages.

WHEREFORE, Plaintiffs demand 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)**

197. 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.

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

199. 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.

200. The design of the Optetrak Device and corresponding packaging is defective and not reasonably safe for its expected, intended, and/or foreseeable uses, functions and purposes.

201. The Optetrak Device and corresponding packaging are not reasonably safe as designed, distributed, marketed, delivered and/or sold by Defendants.

202. The defective design of the Optetrak Device and packaging received by Plaintiff's implanting surgeon were a substantial factor in causing Plaintiffs' injuries.

203. 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 Device, which was implanted in Plaintiff, such that it was dangerous, unsafe, and defective. The defects in design include but are not limited to:

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. failure to design the packaging for the polyethylene components of the Optetrak Device in vacuum bags that contain a secondary barrier layer containing ethylene vinyl alcohol (EVOH) as to prevent the components from undergoing increased oxidation and causing patients to experience 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;

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 testing, including wear or other testing, on components, subassemblies and/or the finished Optetrak Device and packaged and distributed;

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

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

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

i. Defendants failed to adequately design packaging specifications for the components, subassemblies, and/or the finished Optetrak Device;

j. The polyethylene material used in the Optetrak Device in conjunction with the inferior vacuum bags caused and/or contributed to the devices having a higher failure rate than other similar devices available at the time the Optetrak Devices were put on the market;

k. The polyethylene material used in the Optetrak Device in conjunction with the inferior vacuum bags caused and/or contributed to the devices having a shorter effective lifetime than other similar devices available at the time the Optetrak Devices were put on the market;

l. The Defendants' method of designing the polyethylene insert and packaging increased the risk of users and patients suffering from pain, discomfort, injury and the need for revision surgery; and

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

204. Defendants knew or reasonably should have known and been aware that the Optetrak Devices and packaging were defectively designed.

205. The design defects in the Optetrak Device and packaging existed when the device left the Defendants' control.

206. Plaintiff's physicians implanted the Optetrak Device in the manner in which it was intended and recommended to be used, making such use reasonably foreseeable to Defendants.

207. The Optetrak Device 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.

208. As alleged herein, Defendants knew or had reason to know that the Optetrak Device 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.

209. The Optetrak Device and packaging as designed carried risks that were outweighed by any utility of the design of the device and packaging because when paired together the implant, the Optetrak 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 and the packaging in which it was received were in a condition not suitable for proper and intended use.

210. The Optetrak Device and packaging were defective in design and unreasonably dangerous when it entered the stream of commerce and was received by Plaintiff, because the foreseeable risks exceeded or outweighed the purported benefits associated with the device.

211. Feasible safer alternative designs providing the same functional purpose were available to the Defendants at the time the Optetrak Device was designed and packaged and offered for sale in the market.

212. For example, Defendants could have utilized vacuum bags containing a secondary barrier layer containing ethylene vinyl alcohol (EVOH) as to prevent the polyethylene components from undergoing increased oxidation according to their own admissions.

213. The design defects of the Optetrak Device and corresponding packaging 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.

214. The design defects of the Optetrak Device and corresponding packaging 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.

215. Plaintiff could not, by the exercise of reasonable care, have discovered these design defects and perceived its dangers or avoided injury.

216. The Defendants are strictly liable for the defective design of the Optetrak Device; defective design of the packaging of the Device; the distribution, marketing, and/or sale of the Optetrak Device; and the injuries sustained by Plaintiff.

217. 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.

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

219. As a direct, proximate and legal consequence of the defective nature of the Optetrak Device as described herein, Plaintiff [redacted] has suffered and continues 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; soft

tissue damage; bone loss; and other injuries presently undiagnosed, which all require ongoing medical care.

220. As a further direct, proximate and legal consequence of the defective nature of the Optetrak Device, Plaintiffs have sustained and will sustain future damages, including but not limited to cost of medical care; rehabilitation; home health care; loss of earning capacity; mental and emotional distress; loss of consortium and pain and suffering.

221. Defendants acted intentionally, recklessly and wantonly without regard for Plaintiffs' rights beyond all standards of decency, entitling Plaintiffs to recover 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 III**
**STRICT LIABILITY: FAILURE TO WARN**
**(ALL DEFENDANTS)**

222. 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.

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

224. Defendants had a duty to provide adequate warnings regarding the Optetrak Device in a manner that did not present an unreasonable risk of harm or injury to users and patients exposed to their danger, including Plaintiff.

225. Defendants had a duty to distribute, market, and/or sell the Optetrak Device with adequate warnings that did not present an unreasonable risk of harm or injury to users and patients exposed to their danger, including Plaintiff.

226. The warnings that accompanied the Optetrak Device and corresponding packaging were defective thereby making the product not reasonably safe for its expected, intended, and/or foreseeable uses, functions and purposes.

227. The Optetrak Device and corresponding packaging are not reasonably safe as labeled, distributed, marketed, delivered and/or sold by Defendants.

228. Inadequate labeling accompanying the Optetrak Device and packaging received by Plaintiff's implanting surgeon was a substantial factor in causing Plaintiffs' injuries.

229. 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 Device, which was implanted in Plaintiff, such that it was dangerous, unsafe, and defective.

230. 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 Device 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.

231. 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, bone loss, osteolysis, and other injuries as well as the need for revision surgery in patients.

232. 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 Device; and continuing to market, promote, sell and defend the Optetrak Device until the very recent recall.

233. Defendants knew or reasonably should have known and been aware that the Optetrak Devices and packaging contained inadequate warnings.

234. The inadequate warnings for the Optetrak Device existed when the device left the Defendants' control.

235. Plaintiff's physician implanted the Optetrak Device in the manner in which it was intended and recommended to be used, making such use reasonably foreseeable to Defendants.

236. The Optetrak Device 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.

237. As alleged herein, Defendants knew or had reason to know that the Optetrak Device 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.

238. The Optetrak Device that was labeled, 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.

239. The labeling defects of the Optetrak Device and corresponding packaging 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.

240. The labeling defects of the Optetrak Device and corresponding packaging 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.

241. Plaintiff could not, by the exercise of reasonable care, have discovered these defects and perceived its dangers or avoided injury.

242. Defendants failed to issue new warnings or initiate a recall in a timely manner as to help minimize the damage and bone loss occurring in patients, including Plaintiff.

243. The Defendants are strictly liable for providing inadequate warnings accompanying the Optetrak Device and packaging of the Device; the distribution, marketing, and/or sale of the Optetrak Device; and the injuries sustained by Plaintiff.

244. 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.

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

246. As a direct, proximate and legal consequence of the defective nature of the Optetrak Device as described herein, Plaintiff [redacted] has suffered and continues 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; soft tissue damage; bone loss; and other injuries presently undiagnosed, which all require ongoing medical care.

247. As a further direct, proximate and legal consequence of the defective nature of the Optetrak Device, Plaintiffs have sustained and will sustain future damages, including but not limited to cost of medical care; rehabilitation; home health care; loss of earning capacity; mental and emotional distress; loss of consortium and pain and suffering.

248. Defendants acted intentionally, recklessly and wantonly without regard for Plaintiffs' rights beyond all standards of decency, entitling Plaintiffs to recover 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 IV**
**NEGLIGENCE**
**(ALL DEFENDANTS)**

249. 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.

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

251. Prior to, on, and after the dates of Plaintiff's initial knee surgery, and at all times relevant to this action, Defendants had a duty to exercise reasonable care in testing, study, research,

design, formulation, manufacture, inspection, labeling, packaging, promotion, advertisement, marketing, distribution and sale of the Optetrak Device for implantation into consumers, such as Plaintiff, by physicians and surgeons in the United States.

252. Prior to, on, and after the dates of Plaintiff's initial knee surgery, Defendants breached this duty and failed to exercise reasonable care and were grossly negligent and careless in the testing, study, research, design, formulation, manufacture, inspection, labeling, packaging, promotion, advertisement, marketing, distribution and sale of the Optetrak Device.

253. Following Plaintiff's initial knee surgery, Defendants breached this duty and failed to exercise reasonable care and were grossly negligent and careless in failing to recall the Optetrak Device.

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

255. Defendants had access to registry data and were aware of complaints that the Optetrak Device caused serious complications including but not limited to polyethylene wear and/or other failure causing serious complications including component loosening, tissue damage, osteolysis, bone loss and the need for revision surgery in patients.

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

257. Despite the fact Defendants knew or should have known the Optetrak Device posed a serious risk of bodily harm to consumers, Defendants continued to manufacture and market the

Optetrak Device for implantation into consumers without revising any warning language or issuing an earlier recall.

258. Defendants failed to advise surgeons and patients of the need for regular follow-up beyond the ordinary practices after a total knee implant as to promptly detect polyethylene degradation and osteolytic failure and timely revise the device to prevent or at least minimize bone loss, osteolysis and related injuries.

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

a. Negligently failing to properly package the polyethylene components of the Optetrak Device;

b. Negligently failing to select appropriate third-parties to package the polyethylene inserts used in the Optetrak Device;

c. Negligently failing to properly supervise and monitor the packaging of the polyethylene inserts used in the Optetrak Device;

d. Negligently failing to properly and thoroughly select the material that would be used in the packaging of the Optetrak Device;

e. Negligently failing to properly and thoroughly select the materials that would be used in the Optetrak Device;

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

g. Negligently failing to conduct sufficient post-market testing and surveillance of the Optetrak Device;

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

i. Negligently designing, manufacturing, marketing, advertising, distributing, and selling the Optetrak Device;

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

k. Negligently designing, manufacturing, marketing, advertising, distributing, and selling the Optetrak Device to consumers, including Plaintiff, without an adequate warning of the dangerous risks of the Optetrak Device;

l. Negligently failing to notify and warn the public, including Plaintiff, and physicians of reported incidents involving injury and the negative health effects attendant to the use of the Optetrak Device;

m. Negligently misrepresenting the safety of the Optetrak Device;

n. Negligently failing to provide warnings, instructions or other information that accurately reflected the risks of early failure of the Optetrak Device;

o. Negligently failing to provide warnings, instructions or other information that accurately reflected the risks of early degradation of the polyethylene substance in the Optetrak Device;

p. Negligently failing to exercise due care in the advertisement and promotion of the Optetrak Device;

q. Negligently disseminating information that was inaccurate, false, and misleading, and which failed to communicate accurately or adequately the high early failure rate associated with the implantation of the Optetrak Device;

r. Aggressively promoting the Optetrak Device without proper warnings of the risk of early failure or material degradation in the average user;

s. Aggressively promoting the Optetrak Device even after Defendants knew or should have known of the unreasonable risks from implantation;

t. Negligently failing to warn consumers, doctors, users and patients that the Optetrak Device would contain polyethylene materials not properly packaged and/or in accordance with Defendants' specifications;

u. Negligently diminishing or hiding the risks associated with the implantation of the Optetrak Device;

v. Negligently failing to recall the Optetrak Device at an earlier date and institute a process to have patients notified; and

w. Negligently violating applicable state and federal laws and regulations; and in all other ways.

260. Defendants knew and/or should have known that it was foreseeable that consumers such as Plaintiff would suffer injuries as a result of Defendants' failure to exercise ordinary care in the manufacture, design, testing, assembly, inspection, labeling, packaging, supplying, marketing, selling, advertising, preparing for use, warning of the risks and dangers of the Defective Implants, and otherwise distributing the Optetrak Device.

261. 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.

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

263. As a direct and proximate result of Defendants' acts and omissions, including their failure to exercise ordinary care in the design, formulation, testing, manufacture, labeling, sale, and distribution of the Optetrak Device, Plaintiff [redacted] was implanted with the Optetrak Device and 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.

264. As a further direct, proximate and legal consequence of Defendants' acts and omissions, including their failure to exercise ordinary care in the design, formulation, testing, manufacture, labeling, sale, and distribution of the Optetrak Device, Plaintiffs have sustained and will sustain future damages, including but not limited to cost of medical care; rehabilitation; home

health care; loss of earning capacity; mental and emotional distress; loss of consortium and pain and suffering.

265. Defendants acted intentionally, recklessly and wantonly without regard for Plaintiffs' rights beyond all standards of decency, entitling Plaintiffs to recover 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)**

266. 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.

267. 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.

268. 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.

269. The Defendants, as the designers, manufacturers, sellers, promoters, and/or distributors of the Optetrak Device knew, or reasonably should have known, that health care professionals and consumers of the Optetrak Device would rely on information disseminated and marketed to them regarding the product when weighing the potential benefits and potential risks of implanting Optetrak Device.

270. The Defendants, as the designers, manufacturers, sellers, promoters, and/or distributors of the Optetrak Device knew, or reasonably should have known, that the patients implanted with Optetrak Device would suffer early failure and require revision surgery because the information disseminated by Defendants and relied upon by health care professionals and consumers, including Plaintiff, was materially inaccurate, misleading, or otherwise false.

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

272. 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.

273. 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.

274. 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.

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

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

277. Misrepresentations spanned a number of years, but also include the critical time period of 2017 – 2018 when the company was in the process of being acquired by the Private Equity Group TPG Capital which in February 2018 successfully completed a merger agreement. As a result, TPG acquired all of the issued and outstanding common stock of Exactech. In connection with the transaction, Exactech's founders, CEO and certain other management shareholders exchanged a portion of their shares in the transaction, for new equity securities in the post-closing ownership of the Company. *See* https://www.exac.com/exactech-announces-completion-of-merger-with-tpg-capital/.

278. Full disclosure of the magnitude of the problem with the polyethylene failure might have negatively impacted the merger prospects and the merger may have been one of the reasons the problems were concealed.

279. Nevertheless, after the merger in 2018, it still took four years for Defendants to reveal the product defects and their health consequences to the medical community and to the patients, including Plaintiff, even though the key officers of Exactech generally continued with their roles in the newly merged company.

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

281. 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.

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

283. As a direct and proximate result of Defendants' acts and omissions, including Defendants' negligent misrepresentations regarding the Optetrak Device, Plaintiff [redacted] was implanted with the Optetrak Device and 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.

284. As a further direct, proximate and legal consequence of Defendants' acts and omissions, including Defendants' negligent misrepresentations regarding the Optetrak Device, Plaintiffs have sustained and will sustain future damages, including but not limited to cost of

medical care; rehabilitation; home health care; loss of earning capacity; mental and emotional distress; loss of consortium and pain and suffering.

285. Defendants acted intentionally, recklessly and wantonly without regard for Plaintiffs' rights beyond all standards of decency, entitling Plaintiffs to recover 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 VI**
**BREACH OF EXPRESS WARRANTY**
**(ALL DEFENDANTS)**

286. 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.

287. Prior to Plaintiff's knee surgery, and at all times relevant to this action, the Defendants tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and sold the Optetrak Device for implantation into consumers, such as Plaintiff, by orthopedic surgeons in the United States. These actions were under the ultimate control and supervision of Defendants.

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

289. Defendants promised that the Optetrak Device had excellent long-term clinical outcomes and that "surgeons and patients can have every confidence in the performance and longevity of the Optetrak knee system."

290. At the time Defendants manufactured, marketed, sold and/or distributed the Optetrak Devices, they knew that the devices were intended for human use, and that Plaintiff was a foreseeable user of the Optetrak Device.

291. The express warranties represented by Defendants were a part of the basis for Plaintiff's use of the Optetrak Device, and he and his surgeon relied on these warranties in deciding to use the Optetrak Device.

292. At the time of the making of the express warranties, Defendants had knowledge of the purpose for which the Optetrak Devices were to be used and warrantied the same to be in all respects safe, effective and proper for such purpose.

293. The Optetrak Devices do not conform to these express representations as demonstrated by the fact that Plaintiff's implant failed prematurely due to reasons related to the recall and defects with the device and he is scheduled to undergo revision surgery.

294. At the time Defendants marketed, sold and/or distributed the Optetrak Devices, Defendants expressly warranted that the total knee replacement systems, including all of their component parts, were safe and merchantable for their intended use.

295. Plaintiff [redacted] and his implanting physician reasonably relied upon Defendants' express warranties.

296. Plaintiff [redacted] used the Optetrak Device for its intended purpose, and in a reasonable foreseeable manner.

297. The Optetrak Devices manufactured and sold by Defendants, did not conform to Defendants' express representations because the Optetrak Device caused serious injury to Plaintiff when used as recommended and directed.

298. As a direct and proximate result of Defendants' acts and omissions, including breach of express warranty, Plaintiff [redacted] was implanted with the Optetrak Device and 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.

299. As a further direct, proximate and legal consequence of Defendants' acts and omissions, including breach of express warranty, Plaintiffs have sustained and will sustain future damages, including but not limited to cost of medical care; rehabilitation; home health care; loss of earning capacity; mental and emotional distress; loss of consortium and pain and suffering.

300. Defendants acted intentionally, recklessly and wantonly without regard for Plaintiffs' rights beyond all standards of decency, entitling Plaintiffs to recover punitive damages.

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

**COUNT VII**
**BREACH OF IMPLIED WARRANTY**
**(ALL DEFENDANTS)**

301. 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.

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

303. Defendants impliedly warranted, through its marketing, advertising, distributors and sales representatives, that the Optetrak Device was of merchantable quality, and fit for the ordinary purposes and uses for which it was sold.

304. In fact, the Optetrak Device was not of merchantable quality nor fit for the ordinary purposes and uses for which it was sold and did not meet the expectations of consumers.

305. The Optetrak Device manufactured and supplied by Defendants was not of merchantable quality and was not fit for the ordinary and/or particular purpose for which it was intended as physicians and patients would expect the components to be properly packaged and stored as to avoid premature degradation of component materials.

306. Plaintiff CHARLES CUNEO and/or his physician reasonably relied upon the skill and judgment of Defendants as to whether the Optetrak Device was of merchantable quality and safe for its intended and particular use and purpose.

307. Contrary to such implied warranties, the Optetrak Device was not of merchantable quality or safe for its intended and particular use and purpose, because Defendants failed to package the polyethylene components of the Optetrak Device in vacuum bags containing a secondary barrier layer containing ethylene vinyl alcohol (EVOH) as to prevent the components from undergoing increased oxidation and causing patients to experience 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.

308. As a direct and proximate result of Defendants' acts and omissions, including breach of implied warranties, Plaintiff [redacted] was implanted with the Optetrak Device and 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.

309. As a further direct, proximate and legal consequence of Defendants' acts and omissions, including breach of implied warranties, Plaintiffs have sustained and will sustain future damages, including but not limited to cost of medical care; rehabilitation; home health care; loss of earning capacity; mental and emotional distress; loss of consortium and pain and suffering.

310. Defendants acted intentionally, recklessly and wantonly without regard for Plaintiffs' rights beyond all standards of decency, entitling Plaintiffs to recover punitive damages.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory 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)**

311. 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.

312. 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.

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

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

315. 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 Device, in violation of New York General Business Law ("GBL") §§349 and 350.

316. 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.

317. 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.

318. 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.

319. As a direct and proximate result of Defendants' conduct, the Plaintiff used Defendants' Optetrak Device 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**
**LOSS OF CONSORTIUM AND SERVICES**
**(ALL DEFENDANTS)**

320. 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.

321. Plaintiffs hereby incorporate by reference all previous paragraphs of this Complaint as if fully set forth herein and further allege as follows:

322. At all relevant times, Plaintiff [redacted] was and is the lawfully wedded wife of Plaintiff [redacted], and as such, was and is entitled to the services, consortium and society of [redacted]

323. As a result of the foregoing strict products liability, negligence, negligent misrepresentations and breach of warranties by the Defendants, Plaintiff [redacted] was deprived of the services, consortium and society of [redacted].

324. As a direct, proximate and legal consequence of Defendants' wrongful conduct as described herein, whether through strict liability or negligence, Plaintiff [redacted] has suffered and will continue to suffer the loss of support, companionship, service, love, affection, society, intimate relations and other elements of consortium all to the detriment of their marital

relationship for which Plaintiff [redacted] is entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

## VI. PRAYER FOR RELIEF

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

a. Judgment in favor of Plaintiffs and against all Defendants, for damages in such amounts as may be proven at trial;

b. Compensation for both economic and non-economic losses, including but not limited to medical expenses, loss of earnings, loss of consortium, disfigurement, pain and suffering, mental anguish, and emotional distress, in such amounts as may be proven at trial;

c. Punitive and/or exemplary damages in such amounts as may be proven at trial;

d. Attorneys' fees and costs;

e. Interest; and

f. Any and all further relief, both legal and equitable, that the Court may deem just and proper.

## VII. DEMAND FOR JURY TRIAL

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

Dated: June 11, 2022

[redacted]

[redacted]

*Attorneys for Plaintiffs*