UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW YORK

IN RE: EXACTECH POLYETHYLENE ORTHOPEDIC PRODUCTS LIABILITY LITIGATION	**MDL No. 3044** **Case No. 22-md-3044 (NGG) (MMH)**
DAVID J. CAPUTO AND JEAN ABBRIANO-CAPUTO, Plaintiffs, vs. EXACTECH, INC. and EXACTECH U.S., INC. Defendants. Case No .: _____	**DIRECT FILED COMPLAINT PURSUANT TO AMENDED PRACTICE AND PROCEDURE ORDER NO. 2**

NOW COMES Plaintiffs DAVID J. CAPUTO and JEAN ABBRIANO-CAPUTO (hereafter collectively referred to as "Plaintiffs"), by and through the undersigned attorneys, and brings this action against EXACTECH, INC. ("EXACTECH") and EXACTECH U.S., INC. ("EXACTECH US") (hereafter collectively referred to as "Defendants"), for personal injuries suffered as a proximate result of the implantation of the OPTETRAK® Comprehensive Knee System (hereafter referred to as the "Optetrak Device" or "Device") and allege as follows:

NATURE OF THE ACTION

1. This is an action for damages relating to Defendants' development, designing, testing, assembling, manufacturing, packaging, monitoring, labeling, preparing, distribution, marketing, supplying, storage, and/or selling of the Optetrak Device. The Optetrak Device as

referred to in this Complaint includes the Optetrak Logic PS Polyethylene Tibial Insert.

2. Thousands of patients, like Plaintiff DAVID J. CAPUTO (hereafter individually referred to as "Plaintiff"), have been, and/or will be, required to undergo extensive revision surgery to remove and replace defective Optetrak Devices due to a recent recall which first revealed to patients and surgeons that the polyethylene components within the prosthesis prematurely degrades over time causing an inflammatory response resulting in bone necrosis (death), also known as osteolysis. The recall notice admits that the recall and problems arose from the failure to properly package the polyethylene insert component of the Optetrak Device.

3. As a result of Defendants' failure to properly package the Optetrak Device prior to distribution, the polyethylene liner prematurely degraded and Plaintiff endured revision surgery due to severe pain, swelling, and instability in the knee and leg. These injuries were caused by accelerated and preventable wear of the polyethylene insert.

4. 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 resulting in pain and disability leading up to and subsequent to the revision surgery.

5. Despite knowledge that the Optetrak Device was defective and resulted in premature failures and accompanying complications, 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."

6. As a direct and proximate result of the defective nature of Defendants' Optetrak Device surgically implanted in Plaintiff, which necessitated premature removal, Plaintiff DAVID J.

CAPUTO 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 sequelae.

7. 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 Plaintiff DAVID J. CAPUTO sustained due to the Defendants' negligent, reckless, and wrongful conduct.

JURISDICTION & VENUE

8. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332, because the amount in controversy exceeds Seventy-Five Thousand Dollars ($75,000.00), exclusive of interest and costs, and because there is complete diversity of citizenship between the Plaintiffs and all Defendants.

9. The original district court, the Western District of Texas, has personal jurisdiction over Defendants because at all relevant times they have engaged in substantial business activities in the State of Texas. At all relevant times, Defendants transacted, solicited, and conducted business in Texas through their employees, agents, and/or sales representatives, and derived substantial revenue from such business in Texas as a result.

10. Venue is proper in this Judicial District and Division pursuant to Amended Practice and Procedure Order No. 2.

THE PARTIES

11. Plaintiff DAVID J. CAPUTO and JEAN ABBRIANO-CAPUTO are residents and citizens of Austin, Texas.

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

13. Defendant EXACTECH, INC. develops, manufactures, packages, stores, distributes, markets, and sells orthopedic implant devices, including the OPTETRAK® Comprehensive Knee System, and related surgical instrumentation throughout the United States and the State of Texas.

14. Defendant EXACTECH, INC. manufactured the Optetrak Device implanted in Plaintiff DAVID J. CAPUTO.

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 Texas, and generated substantial revenue as a result.

16. Defendant EXACTECH U.S., INC., a wholly owned subsidiary of Defendant EXACTECH, INC., is a domestic Florida corporation with its principal place of business located at 2320 NW 66th Court, Gainesville, Florida 32653.

17. According to public filings, Defendant EXACTECH U.S., INC., conducts Defendants' U.S. sales and distribution activities.

18. EXACTECH U.S., INC. is engaged in the business of designing, developing, testing, assembling, selecting, manufacturing, packaging, labeling, preparing, distributing, marketing, supplying, warranting, selling, and introducing Defendants' products, including the Optetrak Device described herein, into commerce throughout the United States and the State of Texas.

19. Upon information and belief, the Optetrak Device manufactured by Defendant EXACTECH, INC. was distributed by Defendant EXACTECH U.S., INC. throughout the United

States, including to Cedar Park Regional Medical Center in Cedar Park, Texas, where Plaintiff DAVID J. CAPUTO received his implant.

20. At all times relevant to this action, Defendant EXACTECH U.S., 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 Texas, and generated substantial revenue as a result.

FACTUAL BACKGROUND

21. Upon information and belief, the first Optetrak Total Knee system was available for implantation in 1994, building upon technology licensed from HSS.

22. At all times material hereto, Defendants designed, developed, tested, assembled, selected, manufactured, packaged, labeled, prepared, distributed, marketed, supplied, warranted, and/or sold the Optetrak Comprehensive Total Knee System and the Optetrak Logic Comprehensive Knee System to hospitals in many states, including to Cedar Park Regional Medical Center in Cedar Park, Texas.

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

24. 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.

25. 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

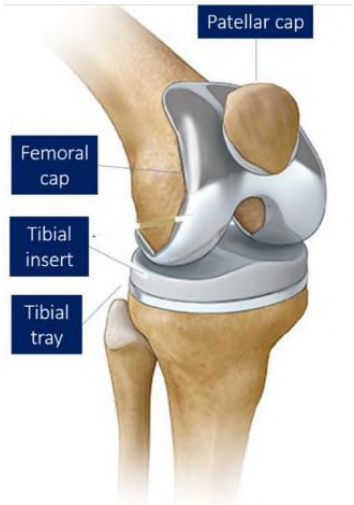
to explain the device's substantial equivalence to a pre-MDA predicate device. The FDA may then "clear" the new device for sale in the United States.

26. 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.

27. 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.

28. According to 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."

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



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

31. Defendants touted the Optetrak Device as being first-in-class in their product brochures.

32. In their marketing materials, 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."

33. 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.

34. However, Optetrak Devices have performed poorly when compared to its competitors. For example, the Australian Orthopaedic Association, a preeminent, internationally recognized orthopedic implant registry, has identified the Optetrak as an implant with a higher-than-expected rate of revision.

35. 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.

36. 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."

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

38. 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) indicated 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."

39. Upon information and belief, in 2013, complaints continued to be reported. Additional examples include: "revision for tibial loosening just two years postoperatively;" "revision due to tibial loosening;" "during revision, the tibial component was found to be loose and easily removed;" "revision of knee component due to loosening;" and "revision due to pain and loosening."

40. Upon information and belief, the complaints of early onset failures continued in 2014. Examples further included: "revision due to tibial loosening;" "tibial loosening;" "revision of Optetrak knee components due to tibial loosening;" "revision due to pain and loosening;" and "revision of Optetrak knee components reportedly due [to] aseptic loosening."

41. The general practice in orthopedic implant surgeries, and with Exactech implants specifically, is for the sales representative of the manufacturer (hereafter the "sales reps") to be present at the time of surgery to provide implant components to the surgeon, thus relieving the hospital of the responsibility for having on stock all potential sizes and components that may be needed in surgeries. This practice of having a sales representative present applies to both the original implant surgery and any revision surgery.

42. Thus, the sales reps of Exactech observed many instances of premature failures of the Optetrak Device and plain evidence of polyethylene debris that needed to get removed, a/k/a "debrided." Additionally, the sales reps observed other injuries such as visible bone loss, osteolysis, and/or 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.

43. The sales reps of Exactech were under a duty to report these findings to the

engineering and medical departments of Exactech who were in turn under a duty to do an investigation, analyze the removed component when available (i.e., conduct a "retrieval analysis"), and then honestly and thoroughly report such findings to the FDA and the surgeons.

44. 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.

45. 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.

46. 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; OPTETRAK 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.

47. 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

48. 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: immediately return 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: 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.*

49. Despite initial communications with distributors and sales representatives, Defendants did not issue any communications to surgeons who had implanted Optetrak Devices 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.

50. On February 7, 2022, Defendants issued an "Urgent Medical Device Correction" in which it 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.**

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

51. The "Urgent Medical Device Correction" went on to further state that Defendants

were expanding the recall to include all knee arthroplasty polyethylene inserts packaged in non-conforming 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; OPTETRAK 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.*

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

53. 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.*

54. Specifically, reasons for revision associated with polyethylene wear, including loosening, osteolysis, 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.*

55. 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.*

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

57. 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.

58. 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/

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

60. At all times relevant to this action, Defendants were aware of the Optetrak Devices' propensity to undergo substantial early polyethylene wear consisting of the degradation and breakdown of the plastic chemicals causing toxicity to the tissue and bone, 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.

61. 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 exhibiting 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.

62. At the time the Optetrak Devices were manufactured and sold to patients, including Plaintiff, the Devices were defectively manufactured, packaged, unreasonably dangerous, and did not conform to the federal regulations subjecting patients to unreasonable risks of injury.

63. 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.

64. During the course of manufacturing and distributing the Optetrak Devices, 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 Devices;

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 Devices;

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

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

g. failing to perform adequate quality control before the components, subassemblies, and/or finished Optetrak Devices 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. 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.

65. On or before the date of Plaintiff's initial knee replacement surgery, Defendants knew or should have known the Optetrak Devices were 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.

66. 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.

67. 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.

68. 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.

DAVID J. CAPUTO'S IMPLANT AND REVISION SURGERY

69. On August 3, 2016, Plaintiff DAVID J. CAPUTO underwent left total knee replacement surgery at Cedar Park Regional Medical Center in Cedar Park, Texas where he was implanted with a recalled Optetrak Logic PS Polyethylene Tibial Insert (Serial #: 2299055).

70. On August 10, 2022, Plaintiff DAVID J. CAPUTO underwent left knee revision surgery at Cedar Park Regional Medical Center in Cedar Park, Texas due to accelerated and preventable wear of the Optetrak Logic PS Polyethylene Tibial Insert.

71. Defendants, through its affirmative misrepresentations and omissions, actively and fraudulently 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.

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

73. As a direct, proximate, and legal consequence of the defective nature of the Optetrak Device as described herein, Plaintiff DAVID J. CAPUTO 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 which all require ongoing medical care.

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

TOLLING OF STATUTE OF LIMITATIONS

A. Latent Injury

75. To the extent it is claimed that Plaintiff suffered symptoms prior to undergoing revision surgery, the statute of limitations is tolled because development of osteolysis, bone loss, and device loosening are latent conditions cause by years of exposure to toxic polyethylene wear debris that could not be appreciated until the date Exactech disseminated information justifying its recall of the Exactech Knee Devices.

76. As a plastic, polyethylene wear debris contains chemicals or additives and many contain impurities such as catalyst residues, unreacted monomers, or breakdown products which process toxic properties that can adversely affect human health. *See* Mathias C. Rillig et al., The Global Plastic Toxicity Debt, 44 ENV'T. SCI. & TECH. 2717, 2717-19 (2021).

77. As described above, such toxic effects on the human body include, but are not limited to, osteolysis, tissue necrosis, and destruction of the bony integration between the component parts of the prosthetic and the patient's anatomy.

78. Prior to Exactech initiating its recall and disseminating information about the recalls to Plaintiff, technical, scientific, or medical knowledge and information sufficient to ascertain the cause of the failure of the Exactech Knee had not been known.

79. Thus, Plaintiff exhibited due diligence and did not possess "technical, scientific, or medical knowledge" or information sufficient to ascertain the cause of his injury until after Exactech recalled their Exactech Knee Devices.

B. Fraudulent Concealment

80. Exactech, through its affirmative misrepresentations and omissions, actively concealed from Plaintiff and Plaintiff's healthcare providers the defects in and true and significant risks associated with Exactech's Hip, Knee, and Ankle Devices, claiming any failures were due to surgical technique, positioning, or patient characteristics.

81. Following implantation of the Device, Plaintiff and Plaintiff's healthcare providers relied on Exactech's continued representations that the Device, including their polyethylene components, had excellent long-term clinical outcomes.

82. Exactech made these representations with knowledge of their falsity, an intent to defraud, and/or disregard for the truth given its knowledge of reports of high failure rates.

83. Furthermore, following implantation of the Device, Plaintiffs and Plaintiff's healthcare providers relied on Exactech to provide them with urgent safety information regarding Exactech's Hip, Knee, and Ankle Devices, including recalls, communications regarding defects and increased rates of failure, and warnings and instructions on how to assess, diagnose, and

mitigate risks associated with the defects in these Devices.

84. Although clinical evidence demonstrated that the polyethylene used in Exactech Hip, Knee, and Ankle Devices was failing at a rate higher than promoted, with instances of excessive revision rates due to device loosening and polyethylene wear, Exactech failed to initiate recalls earlier or issue any communications to healthcare providers that Exactech Hip, Knee, and Ankle Devices were defective and patients should be monitored.

85. Until recently, Exactech lacked highly-crosslinked polyethylene for its Hip, Knee, or Ankle Devices. Accordingly, without a viable substitute, earlier disclosure of these failure rates could have negatively impacted Exactech's ongoing business and sale to TPG in 2017/2018.

86. As a result of Exactech's actions, omissions, and misrepresentations, Plaintiff and their healthcare providers were unaware, and could not have reasonably known, learned, or discovered that any Plaintiffs' symptoms or radiological findings indicative of a potential problem with Plaintiffs' joints were the result of defects in Exactech's Hip, Knee, and Ankle Devices.

87. Furthermore, had Exactech not actively concealed evidence of growing reports of accelerated polyethylene wear and Device failures, Plaintiff's surgeon would have not implanted Exactech devices in them, and for those patients already implanted with Exactech devices, their surgeons would have initiated monitoring for device failures at an earlier time.

88. Such intervention would have led to an earlier diagnosis of loosening and bone loss, and earlier removal of the Exactech Hip, Knee, and Ankle Devices, thereby reducing damage to bone and tissue.

89. As a result of Exactech's actions, omissions, and misrepresentations, many Plaintiffs underwent revision surgeries during which they received new Exactech polyethylene components, subjecting them to a new exposure to the defective polyethylene and the need for yet

another revision in the following years, while Exactech profited from selling more of its products.

90. As a result of Exactech's actions, omissions, and misrepresentations, Plaintiff and Plaintiff's healthcare providers were unaware, and could not have reasonably known, learned, or discovered through reasonable diligence, that Plaintiff had been exposed to the risks identified herein, and that those risks were the result of defects in Exactech's Hip, Knee, and Ankle Devices.

91. Accordingly, no limitations period should accrue until such time as Plaintiffs knew or reasonably should have known of some causal connection between Plaintiff being implanted with Exactech's Knee Device, and the resulting harm later suffered by Plaintiff as a result and by reason of Exactech's fraudulent concealment.

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

93. Further, the limitations period should be tolled under principles of equitable tolling.

CAUSES OF ACTION

FIRST CAUSE OF ACTION
STRICT LIABILITY – MANUFACTURING DEFECT

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

95. 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.

96. 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.

97. 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.

98. The Optetrak Device manufactured by the Defendants was not reasonably safe for its expected, intended, and/or foreseeable uses, functions, and purposes.

99. The Optetrak Device was not reasonably safe as manufactured, packaged, distributed, marketed and/or sold by the Defendants.

100. The defects in the manufacture of the Optetrak Device were a substantial factor in causing Plaintiff's injuries.

101. 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 in manufacture include but are not limited to:

a. failure to package the polyethylene component 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;

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

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

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

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

f. 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;

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

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

i. that Defendants failed to exercise sufficient quality control to ensure the polyethylene insert in the Optetrak Device was safe for implantation in users and patients and would not degrade abnormally under average and regular use; and

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

102. Defendants knew or reasonably should have known and been aware that the Optetrak Device was defectively manufactured.

103. The manufacturing defects in the Optetrak Device existed when the device left

the Defendants' control.

104. 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.

105. 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 condition.

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

107. 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.

108. 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 in a manner that was foreseeable to Defendants.

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

110. 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.

111. 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.

112. 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.

113. As a direct, proximate, and legal consequence of the defective nature of the Optetrak Device as described herein Plaintiff DAVID J. CAPUTO 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, which all require ongoing medical care.

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

115. 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 and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

SECOND CAUSE OF ACTION
STRICT LIABILITY – DESIGN DEFECT

116. Plaintiffs hereby incorporate by reference all previous paragraphs of this Complaint

as if fully set forth herein and further allege as follows:

117. 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.

118. Defendants had a duty to design and package the Optetrak Device in a manner that did not present an unreasonable risk of harm or injury to users and patients exposed its danger, including Plaintiff.

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

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

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

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

123. 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 in design. The defects in the design include but are not limited to:

a. that the Optetrak Device has a propensity to undergo substantial early

polyethylene wear, component loosening and/or other failure causing serious complications including tissue damage, osteolysis, and other injuries as well as the need for revision surgery in patients;

b. failure to design the packaging for the polyethylene component 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 Device and packaging were of an inferior grade or quality than advertised and promoted by Defendants;

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

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

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

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

126. 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.

127. 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 condition.

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

129. 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 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 was in a condition not suitable for proper and intended use.

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

131. 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.

132. 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.

133. 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.

134. 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 in a manner that was foreseeable to Defendants.

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

136. 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.

137. 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.

138. 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.

139. As a direct, proximate, and legal consequence of the defective nature of the Optetrak Device as described herein, Plaintiff DAVID J. CAPUTO 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, which all require ongoing medical care.

140. As a further direct, proximate, and legal consequence of the defective nature of the Optetrak Device, Plaintiff has sustained and will sustain future damages, including but not limited to

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

141. 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 and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

THIRD CAUSE OF ACTION
STRICT LIABILITY – FAILURE TO WARN

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

143. 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.

144. 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 its danger, including Plaintiff.

145. 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 its danger, including Plaintiff.

146. 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.

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

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

149. 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.

150. 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 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.

151. In particular, Defendants failed to adequately disclose the Devices' 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.

152. 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.

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

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

155. 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.

156. 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 condition.

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

158. 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.

159. 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.

160. 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 in a manner that was foreseeable to Defendants.

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

162. 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.

163. 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.

164. 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.

165. 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.

166. As a direct, proximate, and legal consequence of the defective nature of the Optetrak Device as described herein, Plaintiff DAVID J. CAPUTO 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, which all require ongoing medical care.

167. As a further direct, proximate, and legal consequence of the defective nature of the Optetrak Device, Plaintiff has sustained and will sustain future damages, including but not limited to cost of medical care; rehabilitation; home health care; loss of earning capacity; mental and

emotional distress; and pain and suffering.

168. 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 and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

FOURTH CAUSE OF ACTION
NEGLIGENCE

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

170. 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.

171. 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.

172. 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.

173. 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.

174. 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.

175. 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.

176. 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.

177. 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.

178. 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.

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

a. Negligently failing to properly package the polyethylene component of the

Optetrak Device;

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

c. Negligently failing to properly supervise and monitor the packaging of the polyethylene insert 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 its attendant parts before releasing the device 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 Devices;

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 Devices 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.

180. 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 implant, and otherwise distributing the Optetrak Device.

181. 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.

182. 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.

183. 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 DAVID J. CAPUTO 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.

184. 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, Plaintiff has 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; and pain and suffering.

185. 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 and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

FIFTH CAUSE OF ACTION
NEGLIGENT MISREPRESENTATION

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

187. 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.

188. 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 Devices' propensity to undergo substantial early polyethylene wear, component loosening, and/or other failure causing serious complications

including tissue damage, osteolysis, and other injuries as well as the need for revision surgery in patients, which Defendants knew, or in the exercise of diligence should have known.

189. 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.

190. 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.

191. 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.

192. 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.

193. Despite their knowledge of serious problems with the Optetrak Devices, Defendants

urged their sales representatives to continue marketing the Optetrak Devices, 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 Devices and instead create the image and impression that the Optetrak Device was safe.

194. 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.

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

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

197. 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/

198. 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.

199. 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.

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

201. 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.

202. 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.

203. As a direct and proximate result of Defendants' acts and omissions, including Defendants' negligent misrepresentations regarding the Optetrak Device, Plaintiff DAVID J. CAPUTO 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.

204. As a further direct, proximate, and legal consequence of Defendants' acts and omissions, including Defendants' negligent misrepresentations regarding the Optetrak Device, Plaintiff has 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; and pain and suffering.

205. 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 and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

SIXTH CAUSE OF ACTION
BREACH OF EXPRESS WARRANTY

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

207. 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.

208. Defendants expressly warranted the Optetrak Devices, including the Optetrak Comprehensive Total Knee System and the Optetrak Logic Comprehensive Knee System, were safe and effective orthopedic devices.

209. 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."

210. 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.

211. 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.

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

213. The Optetrak Device did not conform to these express representations as demonstrated by the fact that Plaintiff's implants failed prematurely due to polyethylene wear of the tibial insert which necessitated revision surgery.

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

215. Plaintiff DAVID J. CAPUTO and his implanting physician reasonably relied upon Defendants' express warranties.

216. Plaintiff DAVID J. CAPUTO used the Optetrak Device for its intended purpose and in a reasonably foreseeable manner.

217. The Optetrak Device 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.

218. As a direct and proximate result of Defendants' acts and omissions, including breach of express warranty, Plaintiff DAVID J. CAPUTO 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.

219. As a further direct, proximate, and legal consequence of Defendants' acts and omissions, including breach of express warranty, Plaintiff has 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; and pain and suffering.

220. 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 and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

SEVENTH CAUSE OF ACTION
BREACH OF IMPLIED WARRANTY

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

222. 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.

223. 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.

224. 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.

225. The Optetrak Device manufactured and supplied by Defendants was not of merchantable quality nor fit for the ordinary and/or particular purpose for which it was intended as physicians and patients would expect the component to be properly packaged and stored as to avoid premature degradation of component materials.

226. Plaintiff DAVID J. CAPUTO 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.

227. Contrary to such implied warranties, the Optetrak Device was not of merchantable quality nor safe for its intended and particular use and purpose, because Defendants failed to package the polyethylene component of the Optetrak Device in vacuum bags containing a secondary barrier layer containing ethylene vinyl alcohol (EVOH) as to prevent the component 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.

228. As a direct and proximate result of Defendants' acts and omissions, including breach of implied warranties, Plaintiff DAVID J. CAPUTO 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.

229. As a further direct, proximate, and legal consequence of Defendants' acts and omissions, including breach of implied warranties, Plaintiff has 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; and pain and suffering.

230. 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 and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

EIGHTH CAUSE OF ACTION
LOSS OF CONSORTIUM AND SERVICES

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

232. At all relevant times, Plaintiff JEAN ABBRIANO-CAPUTO was and is the lawfully wedded wife of Plaintiff DAVID J. CAPUTO, and as such, was and is entitled to the services, consortium, and society of DAVID J. CAPUTO.

233. As a result of the foregoing, Plaintiff JEAN ABBRIANO-CAPUTO was deprived of the services, consortium, and society of DAVID J. CAPUTO.

234. As a direct, proximate, and legal consequences of Defendants' wrongful conduct described herein, Plaintiff JEAN ABBRIANO-CAPUTO 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 JEAN ABBRIANO-CAPUTO is entitled to compensatory and equitable damages in an amount to be proven at trial.

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.

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, disfigurement, pain and suffering, mental anguish, loss of consortium 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.

Dated: March 13, 2023

Respectfully Submitted,

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DEMAND FOR JURY TRIAL

Plaintiffs demand trial by jury.

Dated: March 13, 2023

Respectfully Submitted,

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Attorneys for Plaintiffs

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