IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO

Civil Action No.

DANIEL E. CARSON,

Plaintiff,

v.

EXACTECH, INC. and
EXACTECH U.S., INC.,

Defendants.

COMPLAINT AND JURY DEMAND

PARTIES

1. Plaintiff Daniel E. Carson resides in Pueblo West, Pueblo County, Colorado, and is a citizen of the state of Colorado.

2. Defendant Exactech, Inc. is a for-profit Florida corporation with its principal place of business at 2320 NW 66th Court, Gainesville, Florida, 32653, and as such is deemed to be a citizen of the state of Florida.

3. Defendant Exactech, Inc., is not registered to do business in the state of Colorado.

4. Defendant Exactech U.S., Inc., is a for-profit Florida corporation with its principal place of business at 2320 NW 66th Court, Gainesville, Florida, 32653, and as such is deemed to be a citizen of the state of Florida.

5. Defendant Exactech U.S., Inc., is registered with the office of the Colorado Secretary of State to do business in the state of Colorado.

6. Defendant Exactech U.S., Inc.'s Registered Agent in the state of Colorado is Corporation Service Company, 1900 West Littleton Boulevard, Littleton, Colorado, 80120.

JURISDICTION AND VENUE

7. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332(a) as the parties are citizens of different states, and the amount in controversy exceeds the sum or value of $75,000, exclusive of interest and costs.

8. Defendant Exactech U.S., Inc. distributed its OPTETRAK® devices used in knee replacement surgery to distributors, hospitals, and surgeons in the state of Colorado for implantation in patients seeking knee replacement surgery.

9. Defendant Exactech U.S., Inc. marketed its OPTETRAK® devices knowing that some of those products would be implanted in patients in the state of Colorado.

10. Defendant Exactech U.S., Inc. distributed its OPTETRAK® devices to one or more distributors located in Colorado, knowing that some of those products would be purchased by, and delivered to, consumers in the state of Colorado.

11. Defendant Exactech U.S., Inc. is subject to the *in personam* jurisdiction of this Court, as it is registered to do business in the state of Colorado, has a registered agent in the state of Colorado, and did and continues to do business within the state of Colorado.

12. Defendant Exactech U.S., Inc. is a corporation and deemed to reside in a judicial district in which it is subject to personal jurisdiction. 28 U.S.C. §1391(c).

13. Venue is proper in this District pursuant to 28 U.S.C. § 1391(a) and (c), as Plaintiff resides in Pueblo County, Colorado, within the jurisdictional boundaries of this United States

District Court, and a substantial part of the events giving rise to this claim occurred in Pueblo County, Colorado.

FACTUAL ALLEGATIONS

14. On December 19, 1995, the Word Mark "OPTETRAK®" [i.e., Trademark] was registered with the United States Patent and Trademark Office, listing Exactech, Inc., as the Owner (Registrant), Registration Number 1942473.

15. The OPTETRAK® brand is the property of Defendant Exactech, Inc.

16. Defendant Exactech, Inc.'s stated business purpose is to "develop, manufacture, market, distribute and sell orthopedic implant devices, related surgical instrumentation and biologic services to hospitals and physicians in the United States and internationally".

17. Defendant Exactech, Inc. has stated in documents filed with the United States Securities and Exchange Commission [SEC], "Exactech Knee Systems provide comprehensive solutions for partial, primary and revision total knee arthroplasty. . . . All of our knee implant systems feature design elements that have been proven for more than four decades, as well as proprietary, net compression molded polyethylene inserts, which are designed to minimize surface damage and wear rates, and ultimately improve the longevity of the knee prosthesis. For primary knee replacement, the OPTETRAK® Logic system offers implant solutions for both posterior stabilized, or PS, and cruciate retaining, or CR, approaches."

18. Defendant Exactech, Inc. has stated in documents filed with SEC, "We market our orthopaedic implant products in the United States through Exactech U.S., Inc., which operates through a network of independent sales agencies and direct sales representatives. These

organizations, along with their independently contracted personnel, serve as our sales representatives."

19. At all times relevant to the issues alleged in this Complaint, Defendant Exactech U.S., Inc., was a wholly owned subsidiary of Exactech, Inc., and is a for-profit Florida corporation with its principal place of business at 2320 NW 66th Court, Gainesville, Florida, 32653.

20. Defendant Exactech U.S., Inc. is engaged in the business of designing, developing, testing, assembling, manufacturing, packaging, labeling, preparing, distributing, marketing, supplying, warranting, selling, and introducing its products, including the OPTETRAK® devices, into interstate commerce, either directly or indirectly through third parties or related entities.

21. Defendant Exactech, Inc. designed the OPTETRAK® devices that are in issue in this civil action.

22. Defendant Exactech, Inc. manufactured the OPTETRAK® devices that are in issue in this civil action.

23. Defendant Exactech, Inc. applied for, and received, clearance from the United States Food and Drug Administration [FDA] to distribute in the United States the OPTETRAK® devices that are in issue in this civil action, including the OPTETRAK® CR Slope Tibial Inserts.

24. Defendant Exactech, Inc. distributed the OPTETRAK® devices that are in issue in this civil action.

25. Defendant Exactech U.S., Inc., distributed the OPTETRAK® devices that are in issue in this civil action for Defendant Exactech, Inc.

26. Defendant Exactech, Inc. marketed the OPTETRAK® devices that are in issue in this civil action.

27. Defendant Exactech U.S., Inc., marketed the OPTETRAK® devices that are in issue in this civil action for Defendant Exactech, Inc.

28. Defendant Exactech, Inc. sold the OPTETRAK® devices that are in issue in this civil action.

29. Defendant Exactech U.S., Inc., sold the OPTETRAK® devices that are in issue in this civil action for Defendant Exactech, Inc.

30. Defendant Exactech, Inc., realized substantial revenue from the sale of the OPTETRAK® devices that are in issue in this civil action.

31. Pursuant to C.R.S. §13-21-401, Defendant Exactech U.S., Inc., is deemed to be the "manufacturer" of the OPTETRAK® devices that are the subject of this civil action.

ACCRUAL OF THIS CAUSE OF ACTION

32. Prior to July 9, 2020, Plaintiff had neither knowledge nor notice that there was any defect in the design, manufacture or labeling of his OPTETRAK® devices.

33. Prior to July 9, 2020, Plaintiff had not suffered any injury from the use of his OPTETRAK® devices.

34. Plaintiff's cause of action against Defendant Exactech, Inc. and Defendant Exactech U.S., Inc., accrued on July 9, 2020.

PLAINTIFF'S OPTETRAK® DEVICES

35. On December 9, 2014, Plaintiff Daniel E. Carson had a surgical procedure generally known as a total knee arthroplasty [TKA] performed on his left knee at St. Thomas More Hospital in Canon City, Colorado.

36. On December 9, 2014, Plaintiff Daniel E. Carson had implanted in his left knee various orthopedic devices, including:

a. OPTETRAK® Asymmetric Femoral
Cruciate Retained, Cemented
Size 4, Left
REF: 230-02-04
SN: 2499009

b. OPTETRAK® Logic Fit Tibial Tray
Cemented
Size 4F/4T
REF: 02-012-45-4040
SN: 3760479

c. OPTETRAK® 1 Peg Patella
Cemented
38mm Diameter
REF: 200-03-8
SN: 2956664

d. OPTETRAK® CR Slope
Cruciate Retained Tibial Insert
Size 4, 9mm, Slope +
REF: 200-64-09
SN: 1758256

37. On July 9, 2020, Plaintiff Daniel E. Carson's OPTETRAK® knee system catastrophically failed.

38. On examination at Centura Health St. Mary Corwin Hospital Emergency Department, in Pueblo Colorado, on July 9, 2020, it was determined that Plaintiff Daniel E. Carson had suffered a periprosthetic fracture of the distal femur, proximal tibia, and fibula.

39. Due to the severity and complexity of Plaintiff's injuries sustained on July 9, 2020, arrangements were made for the immediate transportation by ambulance to Presbyterian St. Luke's Hospital in Denver Colorado.

40. Once at Presbyterian St. Luke's Hospital in Denver, on July 9, 2020, Plaintiff was diagnosed with a failed left total knee arthroplasty with massive osteolysis and periprosthetic tibia fracture with massive bone loss. [Figure 1.]

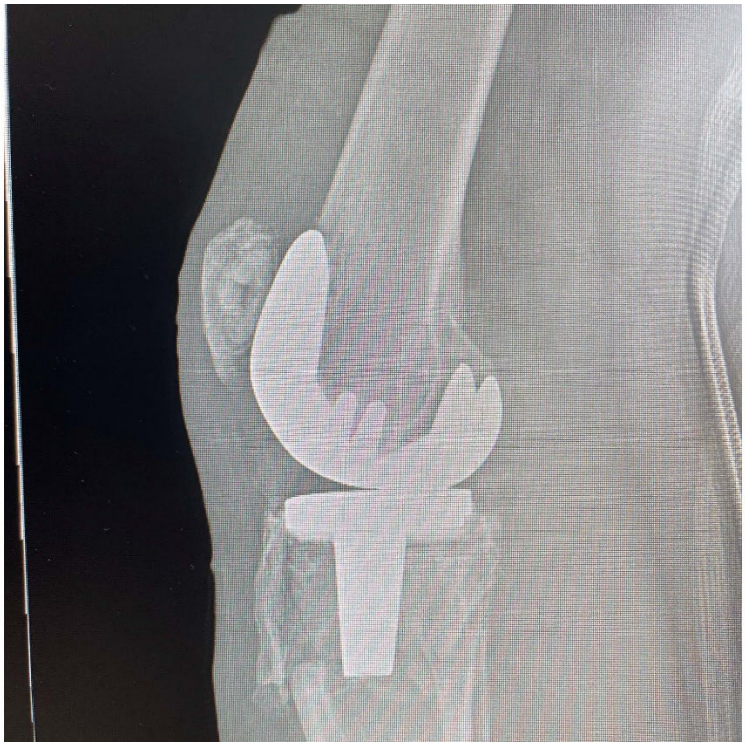

Figure 1

41. On July 10, 2020, Plaintiff had a knee revision surgery performed at Presbyterian St. Luke's Hospital in Denver by orthopedic surgeon Mark S. Tuttle, M.D., which included:

a. Proximal tibia replacement;

b. Hinged prosthesis, left distal femur;

c. 80 cc bone graft to distal femur bone defects;

d. Resection of proximal tibia; and,

e. Repair of extensor mechanism.

42. Plastic and reconstructive surgeon, Karen Lo, M.D., also participated in Plaintiff's July 10, 2020, surgery to perform a left medial gastric flap.

43. Dr. Tuttle's findings in the July 10, 2020, revision surgery included:

a. Massive bone loss, likely secondary to osteolysis with significant polyethylene wear debris and extremely large cysts.

b. Large bone loss around periprosthetic and grossly unstable tibia.

c. No evidence of infection.

d. Incompetent extensor mechanism.

44. In the July 10, 2020, revision surgery a significant amount of Plaintiff's proximal tibia was removed and replaced with a metal tibial device. [Figure 2.]

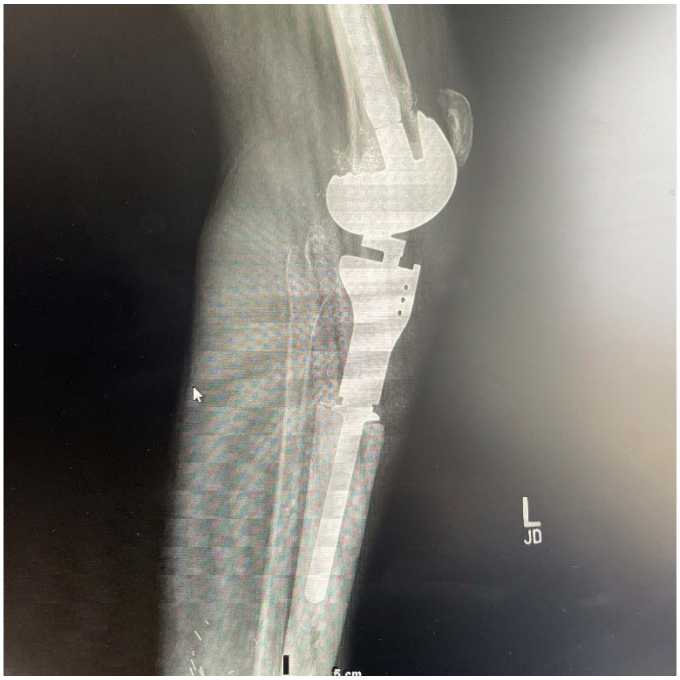

Figure 2

45. While the July 10, 2020, revision surgery was successful, because of the damage that his left leg sustained in the failure of his OPTETRAK® knee system, in the future Plaintiff most probably will need to have an above the knee amputation of his left leg.

DEFECTIVE OPTETRAK® PRODUCTS

46. Exactech OPTETRAK® knee devices have been distributed in the United States since first receiving an FDA 510(k) clearance on February 26, 1996, K954208.

47. On August 30, 2021, Exactech issued a Class 2 Device Recall of the OPTETRAK® Comprehensive Knee System, including all OPTETRAK® All-polyethylene CR Tibial Components. [https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRes/res.cfm?ID=189266]

48. Medical device recalls are classified by a numerical designation (I, II, or III) by the United States Food and Drug administration [FDA] to indicate the relative degree of health hazard presented by the product being recalled.

49. A check of the US Exactech Recall Information web page for the serial number of Plaintiff's OPTETRAK® CR Slope Cruciate Retained Tibial Insert, Serial Number 1758256, nets the following result [Figure 3]:

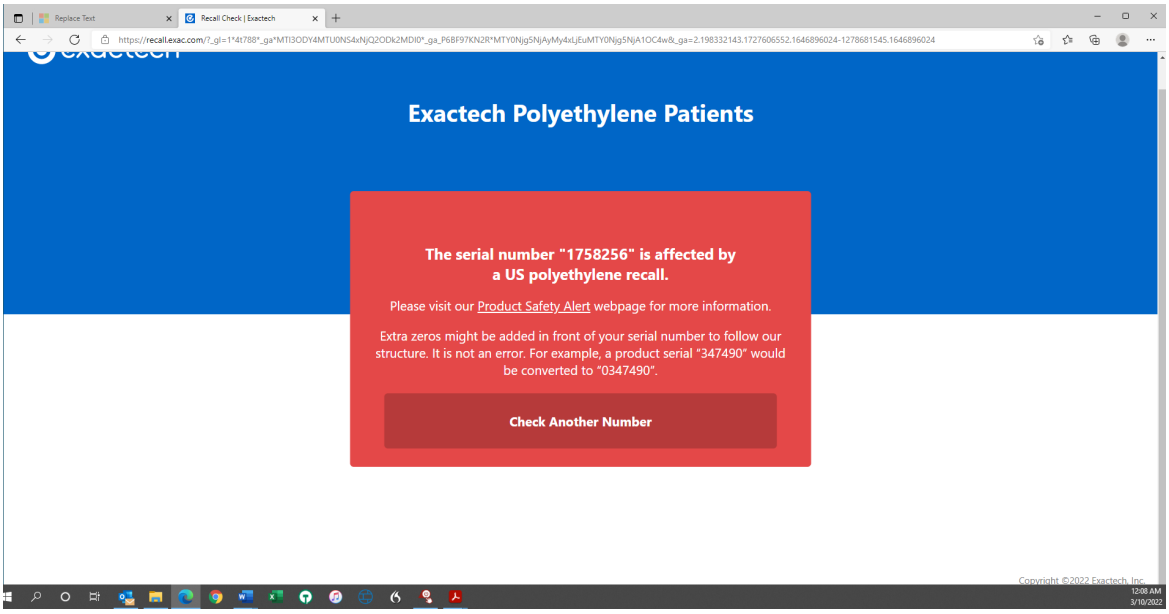

Figure 3

50. On February 7, 2022, Exactech issued an "URGENT MEDICAL DEVICE CORRECTION", to "Exactech Knee and Ankle Surgeons, Hospitals, Health Care Professionals", informing them of "Exactech Ultra-High Molecular Weight Polyethylene (UHMWPE) Knee and Ankle Polyethylene Inserts packaged in out-of-specification vacuum bags."

51. Among the devices included in this Urgent Medical Device Correction were the OPTETRAK® CR Slope Tibial Inserts, "Introduced in the United States in 1994."

52. This Urgent Medical Device Correction was accompanied by a letter addressed to: "Dear Exactech Surgeon". [See Exhibit A to this Complaint.] That letter states, in part:

> The purpose of this letter is to provide an important update on the status of our knee and ankle arthroplasty polyethylene inserts and the recall we initiated on August 31, 2021 and important recommendations for surgeons.
>
> 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.

53. The August 2021 Recall, and the February 7, 2022, Urgent Medical Device Correction, came too late for Plaintiff Daniel Carson, as he had been implanted with his defective OPTETRAK® device on December 9, 2014.

54. As is now acknowledged by Defendants, the OPTETRAK® CR Slope Tibial Inserts have a propensity to undergo substantial early polyethylene wear, causing component loosening, and causing serious complications including tissue damage, osteolysis, and other injuries as well as the need for revision surgery.

55. As is now acknowledged by Defendants, revision surgeries, such as Plaintiff Dan Carson had, are necessitated by the OPTETRAK® CR Slope Tibial Inserts propensity to undergo substantial early polyethylene wear, causing component loosening, and causing serious complications including tissue damage, osteolysis, and other injuries as well as the need for revision surgery.

56. Defendants concealed their knowledge of the OPTETRAK® device's unreasonably dangerous risks, including an increased risk of early failure, from Plaintiff, Plaintiff's medical providers, other consumers, the FDA, and the medical community at large.

57. 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® Device, all the while maintaining that it is safe and effective for use in total knee replacements and concealing the true safety information related to these devices.

58. The OPTETRAK® Device is comprised of a patellar cap, femoral cap, tibial insert, and tibial tray, as shown below. [Figure 4.] The patellar cap and tibial insert are made of polyethylene.

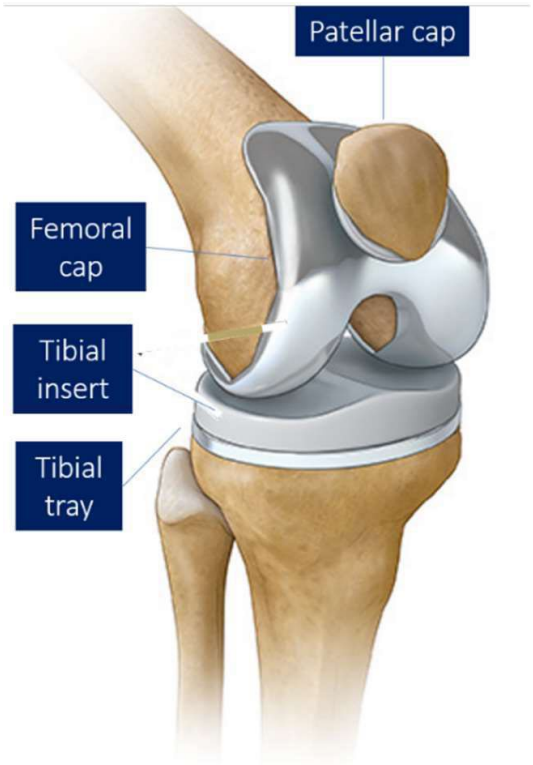

Figure 4

59. As of 2012, Defendants were utilizing a proprietary Net Compression Molded ("NCM") conventional polyethylene rather than cross-linked polyethylene ("XLPE") in the OPTETRAK® Device.

60. Defendants claimed that the OPTETRAK® Device's longevity was a function of using proprietary NCM inserts in the total knee system.

61. Defendants touted the OPTETRAK® Device as being first-in-class in their product brochures.

62. 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."

63. However, in studies published in 2012 and 2016, the OPTETRAK® total knee system performed poorly when compared to its competitors.[1]

64. The reason the OPTETRAK® total knee system performed poorly when compared to its competitors was that its UHMWPE (ultra-high molecular weight polyethylene) inserts manufactured since 2004 were packaged in out-of-specification vacuum bags that did not contain a secondary barrier layer containing ethylene vinyl alcohol (EVOH) that further augments oxygen resistance.

65. The use of these out-of-specification vacuum bags enabled increased oxygen diffusion to the UHMWPE inserts, resulting in increased oxidation of the material relative to inserts packaged with the specified additional oxygen barrier layer.

66. Over time, oxidation severely degraded the mechanical properties of the UHMWPE inserts, which, lead to accelerated wear debris production, bone loss, and/or component fatigue cracking/fracture, all leading to corrective revision surgery.

67. In spite of the UHMWPE inserts having been packaged in out-of-specification bags, Defendants promoted their OPTETRAK® devices as a system with nearly three decades of

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[1] The Australian Registry, a preeminent, internationally recognized orthopedic implant registry, identified the OPTETRAK® as an implant with a higher-than-expected rate of revision.

clinical success and proven outcomes for patients around the world because of an improved articular design resulting in low polyethylene stresses.

68. At all times relevant, Defendants have been aware of a high rate of early failures with OPTETRAK® knee systems which required recipients of the OPTETRAK® Device to undergo revision surgeries to remove the defective device.[2]

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

70. Despite Defendants' knowledge of early onset failures of the OPTETRAK® Device, Defendants continued to manufacture, promote, and distribute the OPTETRAK® Device without alerting surgeons of the potential increased risks of early onset failures of the OPTETRAK® Device.

71. Despite Defendants' knowledge of early onset failures of the OPTETRAK® Device, Defendants continued to manufacture, promote, and distribute the OPTETRAK® Device without changing, modifying, or improving the OPTETRAK® Device to address the increased risk of early failure.

72. Despite Defendants' knowledge of early onset failures of the OPTETRAK® Device, Defendants never changed the labeling, marketing materials or product inserts to

[2] 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.

adequately and accurately warn patients or physicians of the associated increased risks, longevity, and alternative product options manufactured by Defendants or other companies with lesser risks and rates of early failure.

73. Despite Defendants' knowledge of early onset failures of the OPTETRAK® Device, Defendants never alerted the FDA of the known increased risks.

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

75. In 2013, complaints that OPTETRAK® knee implants were failing at a rate higher than promoted continued to be reported. Some examples include revision for "tibial loosening" just two years postoperatively, "revision due to tibial loosening", "during revision, the tibial component was found to be loose and easily removed", "revision of knee component due to loosening", "revision due to pain and loosening."

76. The complaints of early onset failures of the OPTETRAK® knee implants 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".

77. In the year 2015, Defendants did over $241 million in sales across all product lines.

78. 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."

79. 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.

80. 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.

81. 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."

82. On February 23, 2017, Defendants received 510(k) clearance for a new Exactech knee implant, called "Truliant", K170240.

83. Shortly thereafter in 2017, 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.

84. 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.

85. Upon information and belief, Defendants have never conducted a clinical trial on the OPTETRAK® Device.

86. Had Defendants conducted clinical trials of the OPTETRAK® Device 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.

87. At all times relevant to this action, Defendants were aware of the problems with the OPTETRAK® Device's design and its propensity to undergo substantial early polyethylene wear, component loosening and/or other failure causing serious complications including tissue damage, osteolysis, and other injuries as well as the need for revision surgery in patients. Nonetheless, Defendants still did not adequately warn patients, the medical community, or the public about these risks, and continued and continue to present day to promote, market, sell and defend the OPTETRAK® Device.

88. At all times relevant to this action, Defendants failed to recognize the defects in the OPTETRAK® Device due to its failure to package its UHMWPE inserts manufactured since 2004 in vacuum bags that met the required design and/or manufacturing specifications.

89. At all times relevant to this action, Defendants failed to recognize the defects in the OPTETRAK® Device due to poor and inadequate quality assurance procedures, including the failure to implement appropriate physical, manual, x-ray, microscopic and other inspections of the OPTETRAK® Device. Defendants also failed to implement or utilize adequate safeguards, tests,

inspections, validation, monitoring, and quality assessments to ensure the safety of the OPTETRAK® Device.

90. At the time the OPTETRAK® Device was manufactured and sold to patients, including Plaintiff, the device was defectively manufactured, defectively packaged, and unreasonably dangerous, did not conform with the Defendants' own specifications, and did not conform to the federal regulations subjecting patients to unreasonable risks of injury.

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

92. During the course of designing and manufacturing the OPTETRAK® Device, Defendants failed in several ways, including, without limitation, by:

a. Failing to package its UHMWPE inserts manufactured since 2004 in vacuum bags that met the required design and/or manufacturing specifications;

b. Failing to conduct adequate mechanical testing, including fatigue or other wear testing, on components, subassemblies and/or the finished OPTETRAK® Device;

c. Failing to test an adequate number of sample devices on an ongoing basis;

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

e. Failing to identify and/or note the significance of any testing that resulted in failure of the OPTETRAK® Device;

f. Failing to take corrective actions to eliminate or minimize further failures of the OPTETRAK® Device;

g. Failing to adequately explain performance specifications for the components, subassemblies, and/or finished OPTETRAK® Device;

h. Failing to adequately explain or justify all test conditions and acceptance criteria for the OPTETRAK® Device;

i. Failing to perform adequate testing in an environment that adequately simulated in vivo conditions; and,

j. Failing to perform adequate quality assurance testing before and after sterilization.

93. At all times relevant to this action, Defendants failed to perform adequate testing of the OPTETRAK® Device, including its components and subassemblies, to ensure that the OPTETRAK® Device functioned properly during and after implantation.

94. As a result of these manufacturing and quality control problems associated with the manufacture of the OPTETRAK® Device, the device was inadequately and defectively manufactured making it adulterated, and outside of the specifications expressly cleared by the FDA.

95. On or before the date of Plaintiff's initial knee replacement surgery, Defendants knew or should have known that the OPTETRAK® Device was not manufactured and packaged in conformance with its own specifications and 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.

96. Defendants, however, actively concealed the true information and spread false information through, among other things, marketing and promotional materials, advertisements, and communications and meetings with orthopedic surgeons and other healthcare providers.

97. Before the date of Plaintiff's initial knee replacement surgery in December of 2014, 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.

98. Defendants had legal obligations to stop promoting, marketing, selling, and defending the OPTETRAK® Device. Defendants should have taken steps to notify physicians who had implanted and continue to implant the OPTETRAK® Device of its propensity to undergo substantial early polyethylene wear, component loosening and/or other failure causing serious complications including tissue damage, osteolysis, and other injuries as well as the need for revision surgery in patients. Defendants should have attempted to convey this same information to patients who had been implanted with the OPTETRAK® Device. Nevertheless, Defendants did not notify doctors or patients of the risks the OPTETRAK® Device presented. Instead, Defendants

purposefully concealed this material information, while using their sales representatives and other sales, marketing, and promotional employees to market, promote, distribute, sell, and defend the OPTETRAK® Device.

PLAINTIFF'S INJURIES AND DAMAGES

99. As a direct and proximate result of the defects in, and the failure of, the OPTETRAK®, Plaintiff Daniel E. Carson, has sustained injuries and damages including, but not limited to:

a. Past pain and anguish, both in mind and in body;

b. Future pain and anguish, both in mind and in body;

c. Past medical expenses;

d. Future medical expenses, including future surgery for an above the knee amputation of his left leg;

e. Loss of enjoyment of life;

f. Permanent disfigurement; and,

g. Physical impairment.

CAUSES OF ACTION

COUNT I

STRICT PRODUCT LIABILITY

Colorado Product Liability Act, C.R.S. §13-21-401, *et seq.*

100. Plaintiff incorporates by reference the facts and allegations set forth in the paragraphs above of this Complaint.

101. Defendants are subject to the provisions of the Colorado Product Liability Act, C.R.S. §13-21-401, *et. seq.* for products that it manufactured, and which were sold or distributed to citizens of the state of Colorado.

102. The OPTETRAK® purchased by Plaintiff Daniel E. Carson is a "product", as that word is used in the Colorado Product Liability Act.

103. Defendants were the manufacturers of the OPTETRAK® purchased by Plaintiff Daniel E. Carson, as the word "manufacturer" is defined by the Colorado Product Liability Act, C.R.S. §13-21-401 (1).

104. Defendants were the sellers of the OPTETRAK® purchased by Plaintiff Daniel E. Carson, as the word "seller" is defined by the Colorado Product Liability Act, C.R.S. §13-21-401(3).

105. Pursuant to the Colorado Product Liability Act, Defendants owed a duty to Plaintiff to manufacture and sell a product that was reasonably safe, and which did not materially deviate from applicable design and manufacturing specifications.

106. Pursuant to the Colorado Product Liability Act, Defendants owed a duty to Plaintiff to design, manufacture, assemble, test, label, distribute, and sell a product that was not unreasonably dangerous.

107. Pursuant to the Colorado Product Liability Act, Defendants owed a duty to Plaintiff to design, manufacture, assemble, test, label, distribute, and sell a product that conformed to its implied warranties, including, but not limited to, the implied warranty that Defendants' product was reasonably safe for use by consumers.

108. Defendant had a duty to design, manufacture, import, place into the stream of commerce, distribute, market, and sell the OPTETRAK® so that it was neither defective nor unreasonably dangerous when put to the use for which it was designed, manufactured, distributed, marketed, and sold.

109. The OPTETRAK® devices were defectively manufactured and packaged for a multitude of reasons, including but not limited to the following:

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

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

c. The polyethylene substance within the defective OPTETRAK® devices was not made using the Net Compression Molding process as advertised and promoted by Defendants;

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

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

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

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

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

110. In addition to the above, the OPTETRAK® purchased from Defendants and used by Plaintiff was in a defective condition and unreasonably dangerous to the user or consumer at the time the OPTETRAK® left the possession of Defendants, and at the time the device entered the stream of commerce, because of, but not limited to, the followings:

a. The OPTETRAK® was not reasonably safe as intended to be used;

b. The OPTETRAK® contained design defects, including that the UHMWPE insert was prone to oxidation which can severely degrade the mechanical properties of conventional UHMWPE;

c. The OPTETRAK® contained manufacturing defects, including that the UHMWPE insert was not packaged as intended by its specifications, resulting in increased oxidation of the material causing the mechanical properties of the insert to severely degrade, resulting in accelerated wear

debris production, bone loss, and component fatigue cracking/fracture, all leading to corrective revision surgery;

d. The OPTETRAK® contained defects in its warnings, which were inadequate to inform consumers that these defects were known and causing serious injury;

e. The OPTETRAK® was dangerous to an extent beyond which would be contemplated by the ordinary consumer, and did not meet consumer expectations;

f. The OPTETRAK® did not comply with its design specifications;

g. The OPTETRAK® did not comply with its manufacturing and packaging specifications;

h. The OPTETRAK® did not comply with applicable industry standards;

i. A reasonably prudent manufacturer, distributor, or seller, given knowledge of the OPTETRAK®'s condition, would not have marketed, distributed, or sold the device; and,

j. The OPTETRAK® was not appropriately or adequately tested before its distribution or sale.

111. The OPTETRAK® purchased by Plaintiff Daniel E. Carson was expected, and did, reach the consumer without substantial change in the condition in which it was sold.

112. The defects in the OPTETRAK® purchased by Plaintiff Daniel E. Carson caused the injuries to Plaintiff as set forth in this Complaint.

113. Defendants knew or should have known and been aware that the defective OPTETRAK® devices were defectively manufactured and/or packaged.

114. The defective OPTETRAK® devices were defective in their manufacturing, materials, and packaging at the time they left Defendants' hands, and they were delivered into the stream of commerce in their defective condition.

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

116. It was foreseeable, expected and intended by Defendants for the defective OPTETRAK® devices to be used in a knee arthroplasty patient, such as Plaintiff. The manufacturing and packaging defects of the defective OPTETRAK® devices presented an unreasonable risk of harm to users and patients exposed to their danger, including Plaintiff, when used and operated for the purposes intended by Defendants.

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

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

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

120. Pursuant to the provisions of the Colorado Product Liability Act, C.R.S. §13-21-401, et. seq., Defendants are deemed to be the "manufacturer" of products that they designed, manufactured, distributed, or sold, and that were used by citizens of the state of Colorado in the state of Colorado, and are thereby liable to Plaintiff for the claims asserted in this count of this Complaint.

121. Plaintiff was seriously injured as a result of the manufacturing and packaging defects in the OPTETRAK® devices caused by Defendants.

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

123. By reason of the foregoing acts, omissions and conduct committed by 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, and other injuries and damages as set forth in this Complaint.

COUNT II

NEGLIGENCE

124. Plaintiff incorporates by reference the facts and allegations set forth in the paragraphs above of this Complaint.

125. The conduct, actions, and failure to act, of Defendants, as set forth in this Complaint, were negligent.

126. Defendants had a duty to exercise reasonable care in the design, manufacture, packaging, sale and/or distribution of OPTETRAK® devices into the stream of commerce,

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

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

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

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

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

c. Negligently failing to properly supervise and monitor the production and packaging of the polyethylene inserts used in the OPTETRAK® devices;

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

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

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

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

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

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

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

129. In addition to the above alleged negligence, the conduct, actions, and failure to act, of Defendants, were negligent in that:

a. They did not have adequate quality control to assure that the OPTETRAK® UHMWPE insert was packaged in conformance with its intended packaging specifications;

b. They packaged OPTETRAK® UHMWPE inserts in vacuum bags that did not conform with their own specifications, resulting in increased oxidation of the material causing the mechanical properties of the insert to severely degrade, resulting in accelerated wear debris production, bone loss, and component fatigue cracking/fracture, all leading to corrective revision surgery;

c. They distributed OPTETRAK® UHMWPE inserts in vacuum bags that did not conform with their own specifications, resulting in increased

oxidation of the material causing the mechanical properties of the insert to severely degrade, resulting in accelerated wear debris production, bone loss, and component fatigue cracking/fracture, all leading to corrective revision surgery;

d. They sold OPTETRAK® UHMWPE inserts in vacuum bags that did not conform with their own specifications, resulting in increased oxidation of the material causing the mechanical properties of the insert to severely degrade, resulting in accelerated wear debris production, bone loss, and component fatigue cracking/fracture, all leading to corrective revision surgery;

e. The OPTETRAK® as designed contained defects, including that the UHMWPE insert was prone to oxidation which can severely degrade the mechanical properties of conventional UHMWPE;

f. They did not timely discover that the OPTETRAK® UHMWPE insert was not packaged in conformance with its intended packaging specifications;

g. The OPTETRAK® UHMWPE insert was not adequately tested in design to ensure that it would perform as intended;

h. The OPTETRAK® UHMWPE insert as manufactured was not adequately tested to ensure that it would perform as represented;

i. The OPTETRAK® UHMWPE insert did not comply with applicable industry standards;

j. The OPTETRAK® UHMWPE insert did not comply with its design specifications;

k. Once they knew or should have known that the OPTETRAK® UHMWPE insert was not packaged according to its specifications, they failed to timely correct that issue;

l. Once they knew or should have known that the OPTETRAK® UHMWPE insert was not packaged according to its specifications, and knew that could lead to the failure of its devices, they failed to timely warn or inform surgeons using its devices of that fact;

m. Once they knew or should have known that the OPTETRAK® UHMWPE insert was not packaged according to its specifications, and knew that could lead to the failure of its devices, they failed to recall these products from the market; and,

n. Once they knew or should have known that the OPTETRAK® UHMWPE insert was prone to oxidation, which can severely degrade the mechanical properties, they failed to warn of that condition.

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

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

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

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

134. In the exercise of reasonable care, Defendants knew or should have known that the OPTETRAK® was negligently designed, negligently tested, negligently manufactured, packaged, failed to comply with applicable industry standards, contained false and misleading safety warnings and information, misrepresented its safety and safety devices and characteristics, and otherwise was defective and likely to cause serious bodily injury to consumers when being used as reasonably expected.

COUNT III

NEGLIGENT MISREPRESENTATION

135. Plaintiff incorporates by reference the facts and allegations set forth in the paragraphs above of this Complaint.

136. 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.

137. 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.

138. Among Defendants' numerous misrepresentations and misleading omissions are Defendants' assurances that the OPTETRAK® device was safe, had an excellent performance record, and did not have a greater propensity to undergo substantial early polyethylene wear, component loosening and/or other failure causing serious complications including tissue damage, osteolysis, and other injuries as well as the need for revision surgery in patients. Instead, and in Plaintiff's case, Defendants stated or implied to orthopedic surgeons, patients and the FDA that any problem with the OPTETRAK® devices in a particular patient was attributable to "surgical technique" or patient factors such as body mass index, bone composition, and post-implantation

activity level. Defendants made such statements even after they became aware of numerous and serious complications with the OPTETRAK® device. Defendants did not reveal (and instead concealed) their knowledge of numerous and serious complications and other bad data during their meetings with orthopedic surgeons and the FDA.

139. 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.

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

COUNT IV

VIOLATION OF THE COLORADO CONSUMER PROTECTION ACT

C.R.S. §6-1-101, et seq.

141. Plaintiff incorporates by reference the facts and allegations as set forth in the paragraphs above of this Complaint.

142. Pursuant to of the provisions of the Colorado Product Liability Act, C.R.S. §13-21-401, et. seq., Defendants are deemed to be the "manufacturer" of products that they distributed, and that were used by citizens of the state of Colorado in the state of Colorado and are thereby liable to Plaintiff for the claims asserted in this count of this Complaint.

143. The claims and statements made by Defendants regarding the performance and safety features of the OPTETRAK®, as set forth above, were false.

144. The claims and statements made by Defendants regarding the performance and safety features of the OPTETRAK®, as set forth above, were deceptive trade practices, as defined in C.R.S. §6-1-105, including, but not limited to C.R.S. §6-1-105 (e), (g), and (i).

145. As a direct and proximate result of Defendant's deceptive trade practices, Plaintiff is entitled to all of the damages and remedies provided to Colorado consumers pursuant to C.R.S. §6-1-113, including but not limited to treble damages, and the costs of this action, together with reasonable attorney fees as determined by the Court.

COUNT V

BREACH OF IMPLIED WARRANTY

146. Plaintiff incorporates by reference the facts and allegations as set forth in the paragraphs above of this Complaint.

147. Defendants impliedly warranted that the OPTETRAK® was safe, merchantable, and free of defects that would cause injury when being used in a reasonable and expected way.

148. Plaintiff used the OPTETRAK® for its intended purpose, and in a reasonably foreseeable manner.

149. Plaintiff's OPTETRAK® did not conform with the implied warranty of merchantability in that the inserts implanted in Plaintiff were packaged in an out-of-specification ("non-conforming") vacuum bag that did not contain a secondary barrier layer containing ethylene vinyl alcohol (EVOH) that further augments oxygen resistance, which resulted in increased oxidation and degradation of the mechanical properties of the UHMWPE insert, accelerated wear

debris production, and bone loss, and component fatigue cracking/fracture, resulting in severe injury to Plaintiff and the need for a revision surgery.

150. As a direct and proximate result of the breach of the implied warranty of merchantability, as set for the herein, and as set forth above, Plaintiff suffered the injuries and damages set forth in this Complaint.

COUNT VI

BREACH OF EXPRESS WARRANTY

151. Plaintiff incorporates by reference the facts and allegations as set forth in the paragraphs above of this Complaint.

152. At all times herein mentioned, Defendants manufactured, packaged, distributed, recommended, merchandized, advertised, promoted, and sold the OPTETRAK® devices.

153. Defendants expressly represented and warranted that OPTETRAK® Devices were safe and effective devices for those patients requiring a knee replacement.

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

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

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

157. Plaintiff and Plaintiff's surgeon relied on Defendants' express representations and warranties about the safety and efficacy of the OPTETRAK® device.

158. Plaintiff and Plaintiff's surgeon reasonably relied upon the skill and judgment of Defendants as to whether the OPTETRAK® was of merchantable quality and safe and fit for its intended use.

159. Defendants breached the aforesaid express warranties, as its OPTETRAK® device was not fit for its intended purposes and uses.

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

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

162. As a direct and proximate result of the breach of the express warranty of merchantability, as set forth herein, and as set forth above, Plaintiff suffered the injuries and damages set forth in this Complaint.

WANTON AND RECKLESS CONDUCT

C.R.S. § 13-21-102

[Not a cause of action]

163. Plaintiff incorporates by reference the factual background as set forth in the paragraphs above of this Complaint.

164. The acts and conduct of Defendants, set forth above, was attended by circumstances of malice, or willful and wanton conduct, and/or in reckless disregard of the consequences from which malice may be inferred and showed a total disregard for human life and human suffering.

165. The willful and wanton conduct of Defendants was conduct purposefully committed which Defendants must have realized as dangerous, done heedlessly and recklessly, without regard to consequences, or of the rights and safety of others, particularly Plaintiff.

DAMAGES FOR ALL CAUSES OF ACTION

166. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and for his damages for each cause of action further alleges as follows:

167. As a direct and proximate result of the failure of Defendants' OPTETRAK® and the conduct, actions, inactions and omissions of Defendants, Plaintiff Daniel E. Carson sustained injuries and damages, which total in excess of $75,000, exclusive of interest and costs, including, but not limited to:

a. Serious and permanent physical injuries;

b. Past and future pain, suffering, and anguish, both in mind and in body;

c. Physical disability, past and future;

d. Physical impairment;

e. Disfigurement;

f. Loss of enjoyment of life;

g. Past medical bills in excess of $75,000.00;

h. Future medical bills and expenses to be incurred;

i. Exemplary damages in the maximum amount allowed by Colorado law, C.R.S. § 13-21-102;

j. Such other damages as may be allowed by Colorado law, and supported by the evidence;

k. Exemplary damages as may be allowed by Colorado Law; and,

l. Attorneys' fees and the costs and expenses of litigation as may be permitted by Colorado law and the rules of this Court.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Daniel E. Carson, demands judgment against Defendants Exactech, Inc., and Defendant Exactech U.S., Inc., in an amount of compensatory damages to be determined by a jury, in excess of $75,000, exclusive of interest and costs, plus prejudgment interest, post-judgment interest, and taxable costs, exemplary damages in the maximum amount allowed by Colorado law, and any and all other relief available under the law to fully compensate him for his injuries and damages.

PLAINTIFF DEMANDS A TRIAL BY JURY

Respectfully submitted this 15th day of April 2022.

/s/ *George E. McLaughlin*
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