IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

KEVIN MCGUIRE 4133 W. 58th Street Cleveland, OH 44144 and DENISE MCGUIRE 4133 W. 58th Street Cleveland, OH 44144 *Plaintiffs* vs. EXACTECH, INC. 2320 NW 66th Court Gainesville, FL 32653 and EXACTECH US, INC. 2320 NW 66th Court Gainesville, FL 32653 *Defendants*	:	CASE NO.: JUDGE **COMPLAINT** **(Jury Demand Endorsed Hereon)**

COMPLAINT AND JURY DEMAND

Now come the Plaintiffs, by and through undersigned counsel and submit this Complaint and Jury Demand against Exactech, Inc. ("Exactech") and Exactech US, Inc. ("Exactech US") (collectively "Defendants") for compensatory and punitive damages, equitable relief, and such other relief deemed just and proper arising from the injuries to Plaintiff Kevin McGuire as a result of his injuries suffered as direct and proximate result of Defendants' designing, developing, testing, assembling, manufacturing, packaging, labeling, preparing, distributing, marketing, supplying, warranting and/or selling the defective device sold under the name "Optetrak" total knee

replacement system (hereinafter "Optetrak" or "Defective Device"). In support, Plaintiffs allege the following:

NATURE OF THE ACTION

1. Defendants, directly or through their agents, apparent agents, servants, and/or employees designed, developed, tested, assembled, manufactured, packaged, labeled, prepared, distributed, marketed, supplied, warranted and/or sold the Defective Device for the use as a total knee replacement.

2. Defendants concealed, and continue to conceal, their knowledge of the Defective Device's unreasonably dangerous risks from Plaintiff Kevin McGuire, his medical providers, other consumers, and the medical community at large.

3. As a result of the defective nature of the Optetrak knee replacement procedure, persons who were implanted with a Defective Device, including Plaintiff, Kevin McGuire, have suffered, and may continue to suffer, severe and permanent personal injuries, including painful knee revision surgery to remove or revise the Defective Device, continued rehabilitation, medical care, and possible additional surgeries.

4. This is a product liability action for failure to warn, negligence, fraud, misrepresentation, breach of warranties, and product defect.

THE PARTIES

5. Plaintiffs, Kevin McGuire and Denise McGuire, are and, at all times relevant, were residents of Cleveland, Ohio.

6. In 2020, Plaintiff, Kevin McGuire, underwent a right-sided total knee replacement surgery, employing an Optetrak knee implant, which was manufactured and distributed throughout the United States by the Defendants.

7. In April of 2022, Plaintiff Kevin McGuire required removal and revision of the Optetrak knee implant.

8. Defendant Exactech, Inc. is a for-profit Florida corporation with its principal place of business at 2320 NW 66th CT, Gainesville, Florida, 32653. Exactech's stated business purpose is to "develop, manufacture, market, distribute and sell orthopaedic implant devices, related surgical instrumentation and biologic services to hospitals and physicians in the United States and internationally"[1] and to introduce its products, including the Defective Device, into interstate commerce, either directly or indirectly through third parties or related entities.

9. Exactech US, Inc., a wholly owned subsidiary of Defendant Exactech, Inc., is a for-profit Florida corporation with its principal place of business at 2320 NW 66th CT, Gainesville, Florida, 32653. Defendant Exactech Inc.'s "U.S. sales and distribution activities are conducted by [its] wholly owned subsidiary Exactech US, Inc."[2] and 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 Defective Device, into interstate commerce, either directly or indirectly through third parties or related entities. Collectively, Exactech, Inc. and Exactech US, Inc. are referred to in this pleading as "Exactech" or "Defendants."

JURISDICTION AND VENUE

10. This Court has jurisdiction over Defendants in this action pursuant to 28 U.S.C. § 1332 because there is complete diversity of citizenship between Plaintiffs and Defendants and because the amount in controversy exceeds $75,000 exclusive of interest and costs, and because, among other reasons, Defendants have significant contacts with this district by virtue of doing business within this judicial district.

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[1] Exactech 2015 Form 10-k, p. 2. https://www.exac.com/resource-library/investors/recent-filings/10-k-annual-report-1

[2] *Id.*

11. At all times relevant to this action, Defendants engaged, either directly or indirectly, in the business of designing, developing, testing, assembling, manufacturing, packaging, labeling, preparing, distributing, marketing, supplying, warranting, selling, and introducing into interstate commerce, either directly or indirectly through third parties or related entities, its products, including the Defective Device, within the State of Ohio with a reasonable expectation that the products would be used or consumed in this state, and thus regularly solicited or transacted business in this state.

12. At all times relevant to this action, Defendants were engaged in disseminating inaccurate, false, and/or misleading information about the Defective Device to health care professionals in the State of Ohio, including Plaintiff's health care professionals, with a reasonable expectation that such information would be used and relied upon by health care professionals throughout the State of Ohio.

13. Defendants engaged in substantial business activities in the State of Ohio. At all relevant times, Defendants transacted, solicited, and conducted business in Ohio through their employees, agents, and/or sales representatives and derived substantial revenue from such business in Ohio. Said activities including for the promotion, sale, and use of the Defective Device.

14. Further, Defendants committed torts in whole or in part against Plaintiffs in the State of Ohio. As such, this Court has personal jurisdiction over all named Defendants.

15. Venue is proper within this district pursuant to 28 U.S.C. § 1391 because Plaintiffs reside in this district and because a substantial part of the acts and/or omissions giving rise to these claims occurred within this district.

FACTUAL BACKGROUND

16. At all times material hereto, Defendants designed, developed, tested, assembled, manufactured, packaged, labeled, prepared, distributed, marketed, supplied, warranted and/or sold the Defective Device under various versions of the name "Optetrak."

17. Upon information and belief the first Optetrak knee device was implanted in 1994.

18. Since 1994, Defendants have obtained 510(k) clearance for various Optetrak devices and tibal inserts including the Optetrak PS, Optetrak Hi-Flex PS, Optetrak Finned Tibial Tray, Optetrak Offset Tibial Tray, Optetrak RBK Tibial Insert, Optetrak RBK Tibial Tray, Optetrak CR Slope, and Optetrak Logic.

19. A typical knee replacement surgery, referred to as a total knee arthroplasty ("TKA"), is performed under general anesthesia. The primary indication for TKA is to relieve severe pain associated with arthritis and may also be used to correct knee trauma or minor knee deformities.

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

21. The allegations in this Complaint relate to the early failure of the Defective Device and its tibial tray.

22. Defendants designed, developed, tested, assembled, manufactured, packaged, labeled, prepared, distributed, marketed, supplied, warranted and/or sold Optetrak tibial trays with a design Defendants referred to as "finned."

23. Upon information and belief Defendants became aware of a high rate of early failures with the "finned" Optetrak products.

24. By 2012, Defendants had notice that Optetrak knee implants were failing at a rate higher than promoted. Reports in the Manufacturer and User Facility Device Experience (MAUDE) indicate instances of revision due to "loose tibial component", "aseptic loosening", "pain and visible loosening", 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.

25. In 2013 complaints continued to be reported. Examples of just some of the complaints made 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."

26. The complaints of early onset failures continued in 2014. Some examples include "revision due to tibial loosening", revision of "finned tibial tray 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".

27. Upon information and belief, instead of warning consumers and the medical community about the increased failure rates with its finned Optetrak devices, Defendants engaged in a "silent recall" campaign where it slowly replaced all finned tibial trays with a new, more substantial design, referred to as "fit" trays. Concurrent with this strategy of product replacement, Defendants also engaged in a campaign of misinformation where any incidents of early onset failure were blamed on surgeon specific factors instead of admitting to any issues with the finned product itself.

28. In the year 2015, Defendants did over $241 million in sales across all product lines.[3] Further, Defendants state in the 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."[4]

29. Of the more than $241 million in sales, knee device sales accounted for over $70 million in sales, or 29.3% of all Defendants' sales in 2015.[5]

30. In 2016, Defendants' revenue increased by 7%, up to $257.6 million with knee device sales increasing 4%.[6] Knee device sales for the fourth quarter of 2016 were $19.8 million.[7]

31. According to Exactech CEO 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 anticipates the "revision knee rollout in the fourth quarter" of 2016 will "carry momentum into 2017."[8]

32. Despite Defendants' claims in its promotional materials of over 30 years of successful outcomes with knee devices, Defendants knew of an unacceptably high early failure rate of its Optetrak knee implants.

33. In 2020, Plaintiff, Kevin McGuire, underwent a right knee replacement using Optetrak knee implant manufactured by Defendants.

34. Thereafter, Plaintiff experienced pain and discomfort in his right knee.

35. In April of 2022, Plaintiff underwent revision surgery to replace the Optetrak knee implant.

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[3] See Exactech, Inc. Form 10-K for the fiscal year ended December 31, 2015, https://www.exac.com/resource-library/investors/recent-filings/10-k-annual-report-1
[4] *Id.* at p. 4.
[5] *Id.*
[6] See Exactech, Inc. Form 8-K dated February 21, 2017, https://www.exac.com/resource-library/investors/recent-filings/8-k-current-report-12
[7] *Id.*
[8] *Id.*

FIRST THROUGH FOURTH CAUSES OF ACTIONS
(Strict Product Liability)

36. Plaintiffs restate and re-allege each of the previous paragraphs of this Complaint as if fully rewritten.

37. At all times relevant to this action, Defendants were manufacturers and distributors, as defined in Ohio Revised Code § 2307.71 *et seq.*, which designed, produced, created, made, constructed, distributed, sold, and/or assembled the Defective Device that were placed into the stream of commerce.

38. The Defective Devices were expected to and did reach the ultimate users, including Plaintiff, without substantial change in the condition they were sold.

39. The Defective Devices manufactured, designed, sold, distributed, supplied, promoted and/or placed into the stream of commerce by Defendants were defective in their:

a. Manufacture and construction pursuant to the provisions of Ohio Revised Code § 2307.74; and/or

b. Design pursuant to the provisions of Ohio Revised Code § 2307.75; and/or

c. Inadequate warning or instruction pursuant to the provisions of Ohio Revised Code § 2307.76; and/or

d. Failure to conform, when they left the control of the Defendants to their representations, pursuant to the provisions of Ohio Revised Code § 2307.77.

40. Specifically, Defendants' failures include, but are not limited to:

a. Defendants' failure to exercise reasonable care in the manufacture, design and testing of the Defective Devices;

b. Defendants' failure to include adequate warnings that would alert the medical and/or scientific communities and users of the Defective Devices, including Plaintiff, of the substantially increased risk and serious side effects of the Defective Devices;

c. Defendants' failure to adequately and improperly test and inspect the Defective Devices before placing the medical devices on the market and distributing them into the stream of commerce;

d. Defendants' failure to conduct sufficient testing and inspection of the Defective Devices which, if properly performed, would have shown that the medical devices had serious increased side effects;

e. Defendants' failure to adequately warn the medical and/or scientific communities and users of the Defective Devices, including Plaintiff, of the potential risks and other serious side effects associated with the medical devices;

f. Defendants' failure to provide adequate post-marketing warnings or instructions after Defendants knew or should have known of the significant risks associated with the use of the Defective Devices;

g. Defendants' failure to timely and appropriately recall and/or remove the Defective Devices from the stream of commerce when they knew or should have known of the defective and unreasonably dangerous nature of the medical devices; and

h. Defendants' encouragement of misuse and overuse while failing to disclose the side effects of the medical device to the medical and/or scientific communities, and users, including Plaintiff, in order to maximize profit from sales.

41. The Defective Devices were unsafe for normal or reasonably anticipated use.

42. Plaintiff was using the Optetrak knee implant in the manner for which it was intended and/or in a reasonably foreseeable manner.

43. Plaintiff could not, through the exercise of reasonable care, have discovered the defects or perceived the dangers posed by the medical device.

44. As a direct and proximate result of this defective product, Plaintiff sustained serious side effects including, but not limited to, pain, disability, unnecessary and additional surgeries, and other injuries presently undiagnosed.

45. As a further direct and proximate result of the foregoing, Plaintiff suffered severe and permanent injuries, as well as disability.

46. As a further direct and proximate result of Defendants' conduct, as described above, Plaintiff incurred medical and other related expenses.

47. As a further direct and proximate result of Defendants' conduct, as described above, Plaintiff has incurred lost wages and suffered a permanent diminution in earning capacity.

48. As a further direct and proximate result of Defendants' conduct, as described above, Plaintiff has incurred, and will continue to incur, medical, hospital and other related expenses.

49. As a further direct and proximate result of Defendants' conduct, as described above, Plaintiff has experienced, and will continue to experience, great physical pain, suffering and emotional distress.

50. As a further direct and proximate result of Defendants conduct, as described above, Plaintiff has suffered, and continues to suffer, a loss of enjoyment of life.

51. As a further direct and proximate result of Defendants conduct, Plaintiff has suffered a permanent injury, which will require life-long medical care and other related expenses.

FIFTH CAUSE OF ACTION
(Negligence– Design, Manufacture and Sale)

52. Plaintiffs restate and re-allege each of the previous paragraphs of this Complaint as if fully rewritten.

53. Defendants designed, tested, distributed, manufactured, advertised, sold, and marketed the Defective Devices and, specifically, the Optetrak knee, for implantation into consumers, such as Plaintiff, by physicians and surgeons in the United States, including in the City of Cleveland, Ohio and in Cuyahoga County.

54. Defendants were negligent and careless in and about their design, testing, distribution, manufacture, advertising, sales and marketing of the above-described Defective Devices.

55. Defendants performed inadequate evaluation and testing of the Defective Devices where such evaluation and testing would have revealed the propensity of the Devices to fail and cause pain, inhibition of the ability to walk, and require revision surgery.

56. Prior to, on, and after the dates of Plaintiff's initial knee replacement surgery, the Defendants had received complaints from healthcare providers that the DefectiveeDevice caused serious complications including pain, disability and the need for replacement.

57. Defendants had a duty to and breached their duty to perform further testing of the Defective Devices; investigate the root cause of these complications; suspend sales and distribution; or warn physicians and patients of the propensity of the knee implant to fail and require removal.

58. As a direct and proximate result of the above-described negligence in design, testing, distribution, manufacture, advertising, sales and marketing, Plaintiff suffered the aforementioned injuries.

59. Defendants' negligence in design, testing, distribution, manufacture, advertising, sales, and marketing was a substantial factor in causing Plaintiff's injuries and damages, as described herein.

SIXTH CAUSE OF ACTION
(Negligence– Failure To Recall/Retrofit)

60. Plaintiffs restate and re-allege each of the previous paragraphs of the Complaint as if fully rewritten herein.

61. Prior to, on, and after the dates of Plaintiff's initial knee replacement surgery, and at all relevant times, Defendants designed, tested, distributed, manufactured, advertised, sold,

and marketed the Defective Devices and, specifically, the Optetrak knee implant, for implantation into consumers, such as Plaintiff, by physicians and surgeons in the United States, including in the City of Cleveland, Ohio and in Cuyahoga County.

62. Prior to, on, and after the dates of Plaintiff's initial knee replacement surgery, Defendants knew or reasonably should have known that the Defective Devices were dangerous or were likely to be dangerous when used in a reasonably foreseeable manner.

63. Prior to, on, and after the dates of Plaintiff's initial knee replacement surgery, Defendants became aware of the defects in the Defective Devices, including the propensity to cause pain, injury disability and the need for replacement.

64. Defendants failed to timely and appropriately recall, retrofit, or warn Plaintiff or physicians about the danger of the knee implant prior to purchase and implantation of same.

65. In light of the severity and amount of complaints transmitted to Defendants and the additional available data, reasonable manufacturers and distributors under the same or similar circumstances would have recalled the Defective Devices.

66. As a direct and proximate result of the above-described negligent failure to recall, Plaintiff suffered the injuries herein described.

67. Defendants' negligent failure to timely and appropriately recall the Defective Devices and their warnings prior to, on, or after the dates of Plaintiff's initial knee replacement surgery was a substantial factor in causing Plaintiff's injuries and damages, as described herein.

SEVENTH CAUSE OF ACTION
(Fraud/Deceit by Suppression/ConcealmentMisrepresentation)

68. Plaintiffs restate and re-allege each of the previous paragraphs of this Complaint as if fully rewritten herein

69. Defendants, having undertaken the manufacturing, marketing, dispensing, distribution and promotion of the Defective Devices, owed a duty not to deceive the Plaintiff, health care providers and the public regarding the character, safety, quality and/or effectiveness of their medical devices.

70. Defendants, through studies and reports, received notice that their Optetrak knee implants were prone to premature failure, causing patients to experience additional pain and injury.

71. Despite this knowledge, Defendants continued to manufacture, distribute and promote the sale of their Defective Device and willfully deceived Plaintiff and his medical provider as to the health risks associated with the Defective Device

72. Defendants willfully concealed, misrepresented, suppressed and omitted material scientific and medical information about the risk of the Defective Device with the intent to defraud Plaintiff.

73. Plaintiff was unaware and ignorant of the falsity and/or incompleteness of the statements made by Defendants and reasonably relied upon them to be true.

74. Plaintiff directly and/or indirectly reasonably relied upon Defendants' deceptive, inaccurate and fraudulent misrepresentations.

75. As a direct and proximate result of Defendants' fraudulent misrepresentations, Plaintiff sustained the injuries and damages heretofore alleged.

76. Defendants' conduct was malicious and a deliberate disregard for the rights and safety of others, including Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish Defendants and deter them from similar conduct in the future.

EIGHTH CAUSE OF ACTION
(Loss of Consortium)

77. Plaintiff, Denise McGuire, wife of Plaintiff, Kevin McGuire, incorporates herein by reference all of the statements and allegations made and contained in Counts I-VII as if the same were fully rewritten herein.

78. By reasons of the foregoing, Plaintiff, Denise McGuire, lost the services, companionship and consortium of her husband and she will lose the services, companionship and consortium of her husband in the indefinite future.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment against the Defendants, individually and collectively, jointly and severally, as follows:

a. For an award of compensatory damages in excess of Seventy-Five Thousand Dollars ($75,000.00);

b. For an award of punitive or exemplary damages against Defendants in excess of Seventy-Five Thousand Dollars ($75,000.00);

c. For reasonable attorney fees and costs;

d. For pre-judgment interest; and

d. For such further and other relief this Court deems just and equitable.

Respectfully submitted,

/s/R. Eric Kennedy
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JURY DEMAND

Plaintiffs demand a trial by jury on all issues so triable with the maximum number of jurors permitted by law.

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