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

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| **CHRISTOPHER MATCHETT and REBECCA MATCHETT,**<br><br>**Plaintiffs,**<br><br>**v.**<br><br>**EXACTECH, INC. and EXACTECH US, INC.**<br><br>**Defendants.** | **CASE NO: 1:22-cv-5864**<br><br>**COMPLAINT AND JURY DEMAND** |

COMES NOW, the plaintiffs, CHRISTOPHER MATCHETT and REBECCA MATCHETT, by and through undersigned counsel and submits this Complaint and Jury Demand against EXACTECH, INC. ("Exactech") and EXACTECH US, INC. ("Exactech US") for compensatory and punitive damages, equitable relief, and such other relief deemed just and proper arising from the injuries to plaintiffs CHRISTOPHER MATCHETT and REBECCA MATCHETT, suffered as a direct and proximate result of Defendants' designing, testing, assembling, selecting, manufacturing, packaging, labeling, preparing, distributing, marketing, supplying, warranting, and/or selling the defective device sold under the name "Optetrak Logic" Total Knee System and its component parts. In support, Plaintiffs allege the following:

## NATURE OF THE ACTION

1. This case involves claims of strict product liability, failure to warn, negligence, fraudulent concealment, breach of warranties, deceptive trade practices, among others, in the designing, testing, assembling, selecting, manufacturing, packaging, labeling, preparing, distributing, marketing, supplying, warranting, and/or selling of a defective device sold under the

name "Optetrak Logic" Total Knee System and its component parts by the Defendants directly or through their agents, apparent agents, servants, and/or employees.

2. The Defendants touted their Optetrak Logic Total Knee System as being first-class and comprised primarily of proprietary polyethylene materials, thus being a quality product with a long device lifetime.

3. On January 21, 2014, the Defendants' Optetrak Logic Total Knee System was implanted into Plaintiff CHRISTOPHER MATCHETT's left knee. The expected lifetime for his knee implant was approximately twenty years. Four years later, in or around 2018, the knee implant caused him substantial pain and stiffness. A 2018 MRI showed that Plaintiff was suffering from debris synovitis due to fraying of the original implant's plastic components, namely the tibial insert. On April 17, 2018, doctors performed a revision surgery of his left knee and replaced the Exactech Optetrak Logic polyethylene plastic tibial insert with another Optetrak Logic polyethylene plastic tibial insert from the Defendants. Not only had the original implant failed very prematurely, but upon explantation, it was confirmed that the implant's polyethylene components had severely degraded, releasing pieces of polyethylene plastic into his knee cavity and surrounding tissues, and thus triggering inflammation and other phenomenon associated with an immune response in and around the Plaintiff's knee. Furthermore, MRIs performed in May 2022, have now shown that the second polyethylene implant has also failed, further degrading and

damaging the Plaintiff's knee cavity and surrounding tissues and causing a significant degradation in the Plaintiff's health and quality of life.[1]

4. Upon information and belief, the device and component parts implanted into the Plaintiff on two separate occasions were defective and not reasonably fit for their intended and foreseeable purpose and use. Specifically, the polyethylene substance and/or components used in the Defective Implants and surgically implanted into the Plaintiff's body were defective, unreasonably dangerous, packaged in non-conforming bags and of an inferior quality than that of which the Defendants represented their product to be.

5. Prior to Plaintiff CHRISTOPHER MATCHETT's left knee replacement or revision surgeries, the EXACTECH DEFENDANTS knew, based on anecdotal, clinical and scientific research, studies and evidence, that the Optetrak Logic device and its component parts were subject to high failure and revision rates and had the 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 and/or full replacement surgery in patients.

6. The EXACTECH DEFENDANTS concealed, failed to disclose, misstated, downplayed and understated the risks associated with the use of the defective knee devices and their component parts. They intentionally continued to market and sell the devices to consumers

[1] Plaintiff's January 21, 2014 Total Replacement Implant and the April 17, 2018 revised polyethylene implant tibial insert implant are referred to herein collectively as the "Defective Implants."

and physicians as safe, long-lasting, top-of-the-line, innovative and high performing devices with a low failure rate.

7. On February 7, 2022, the EXACTECH DEFENDANTS issued a recall of the subject knee device's polyethylene tibial inserts due to Defendants' use of non-conforming bags in the packaging of the plastic inserts which caused a substantially heightened risk of oxidation of the subject device's plastic components, namely the tibial insert. Oxidation severely degrades the mechanical properties of the Ultra High Molecular Weight Polyethylene (UHMWP) plastic found in the tibial component leading to accelerated wear debris production, bone loss, component fatigue, cracking, and fracture, and the increased need for revision surgery. Plaintiff received recalled plastic components during both the replacement and revision surgeries.

8. As a direct and proximate result of the defective nature of the EXACTECH DEFENDANTS' total knee system and its component parts being surgically implanted in his knee twice, Plaintiff CHRISTOPHER MATCHETT suffered and will continue to suffer serious personal injuries, including a painful knee revision surgery, anticipated surgery in the future, continued rehabilitation, medical care, medical expenses, loss of enjoyment of life, psychological and emotional distress, and other medical and non-medical sequelae. His wife, REBECCA MATCHETT, has likewise suffered injury including the loss of consortium, society and services of her husband as a result of his injuries from the defective device.

9. Plaintiffs bring this action for personal injuries suffered as a proximate result of CHRISTOPHER MATCHETT being implanted with the Defective Implants. Plaintiffs accordingly seek compensatory and punitive damages, monetary restitution, and all other available

remedies provided to Plaintiffs under equity and law as a result of injuries CHRISTOPHER MATCHETT and REBECCA MATCHETT sustained due to the EXACTECH DEFENDANTS' conduct.

**PARTIES**

10. At all times relevant hereto, Plaintiff CHRISTOPHER MATCHETT was and is a resident and citizen of New York, New York.

11. At all times relevant hereto, Plaintiff REBECCA MATCHETT was and is a resident and citizen of New York, New York.

12. Plaintiffs CHRISTOPHER MATCHETT and REBECCA MATCHETT have been legally married since August 27, 2005 and have continuously resided together since that time.

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

14. Defendant EXACTECH, INC. develops, manufactures, markets and sells orthopedic implant devices and related surgical instrumentation throughout the United States, including in and throughout the Southern District of New York (hereinafter "the District").

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

16. Defendant EXACTECH US, INC., a wholly owned subsidiary of Defendant Exactech, Inc., is a for-profit Florida corporation with its principal place of business located at 2320 NW 66th Court, Gainesville, Florida 32653.

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

18. EXACTECH US, 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 Defective Implants, into commerce throughout the United States and the District.

19. EXACTECH US, INC. is thus also an agent, representative, joint venturer, partner and/or alter ego of Defendant Exactech, Inc.

20. Collectively, Exactech, Inc. and Exactech US, Inc. are referred to in this pleading as "EXACTECH DEFENDANTS" or "Defendants."

## JURISDICTION AND VENUE

21. This Court has jurisdiction over Defendants in this action pursuant to 28 U.S.C. § 1332 because there is complete diversity of citizenship between Plaintiff and Defendants and because the amount in controversy exceeds $75,000 exclusive of interest and costs. Defendants have significant contacts with this District by virtue of doing substantial business within this judicial district, and specifically as a result of their long-term relationship selling and providing total knee replacement devices, including the Defective Implants, to the Hospital of Special Surgery for implantation into patients such as and including Plaintiff CHRISTOPHER MATCHETT.

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

23. The Court maintains general personal jurisdiction over Defendants as they purposely engaged in the business of designing, developing, selecting, testing, assembling, manufacturing, packaging, labeling, preparing, distributing, marketing, supplying, warranting, selling, and introducing into interstate commerce, their products, including the Defective Implants, within the State of New York and specifically the District, with a reasonable expectation that the products would be used within this District.

24. The Court maintains specific personal jurisdiction over Defendants as they purposely solicited and transacted business on a prolonged and consistent basis with the Hospital of Special Surgery (hereinafter HSS) located at 535 East 70th Street, New York, New York 10021, where plaintiff had the Defective Implants inserted and where he suffered injury by said product.

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

26. Further, Defendants also engaged in making false representations and statements to health care professionals in the State of New York and within the District, including specifically those medical professionals employed at HSS, about the nature, durability and quality of the materials used in their implants.

27. Defendants derived substantial revenue and benefit from their business activities within the District and specifically as a result of their relationship with HSS. These activities included the promotion, sale and use of the Optetrak Logic Total Knee System, including the Defective Implants.

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

29. Venue is proper within this district pursuant to 28 U.S.C. § 1391(b)(2) because a substantial part of the acts and/or omissions giving rise to these claims occurred within this District.

## FACTUAL BACKGROUND

*a. HISTORY OF THE DEFECTIVE OPTETRAK IMPLANTS*

30. The original Exactech Optetrak Posterior Stabilized (PS) knee system was introduced on the market in 1994. This system is also known as the "PS Classic".

31. The Exactech Optetrak Posterior Stabilized (PS) knee system is a mixed polyethylene and metal-based system in which the tibial tray and articulating femoral cap are made of metal while the patellar cap and tibial insert are made of molded polyethylene.

32. In 2009, the EXACTECH DEFENDANTS introduced the Optetrak Logic PS Total Knee System into the marketplace for medical use in patients. This system is also known as the PS Evolution (PSE).

33. The Optetrak PS Classic served as the reference implant for the Optetrak Logic.

34. According to the Defendants, the differences in the design between the Optetrak PS System and Optetrak Logic were limited to the following: 1) the intercondylar femoral box was modified to preserve more bone during implantation; 2) increased flexion to 145°; 3) articulation between the anterior face of the post and the anterior surface of the intercondylar box was modified to reduce the contact stress and edge loading in the polyethylene of the tibial post; and 4) the

creation of "half sizes" that would purportedly allow for better fit. Upon information and belief, no other changes were made in the design.

35. According to the Defendants' marketing materials, "Optetrak Logic 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."

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

37. Defendants obtained fast tracked 510(k) clearance from the Food and Drug Administration ("FDA") for the Optetrak Logic Total Knee System on January 11, 2010, based on the Logic purportedly being directly derived from the Optetrak PS knee device and materials and manufacturing processes were to remain the same.

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

*b. THE OPTETRAK LOGIC TOTAL KNEE SYSTEM*

39. At all times material hereto, Defendants designed, developed, tested, assembled, selected, manufactured, packaged, labeled, prepared, distributed, marketed, supplied, warranted, and/or sold the Optetrak Logic Total Knee System, including the Defective Implants.

40. The Optetrak Logic Device is classified as a knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis. Like its predecessor the Optetrak PS Classic, it features a mix of polyethylene and metal-based components.

41. The Optetrak Logic Total Knee System, including the Defective Implants, is comprised of the following parts: a plastic patellar cap, femoral cap, plastic tibial insert and tibial tray.

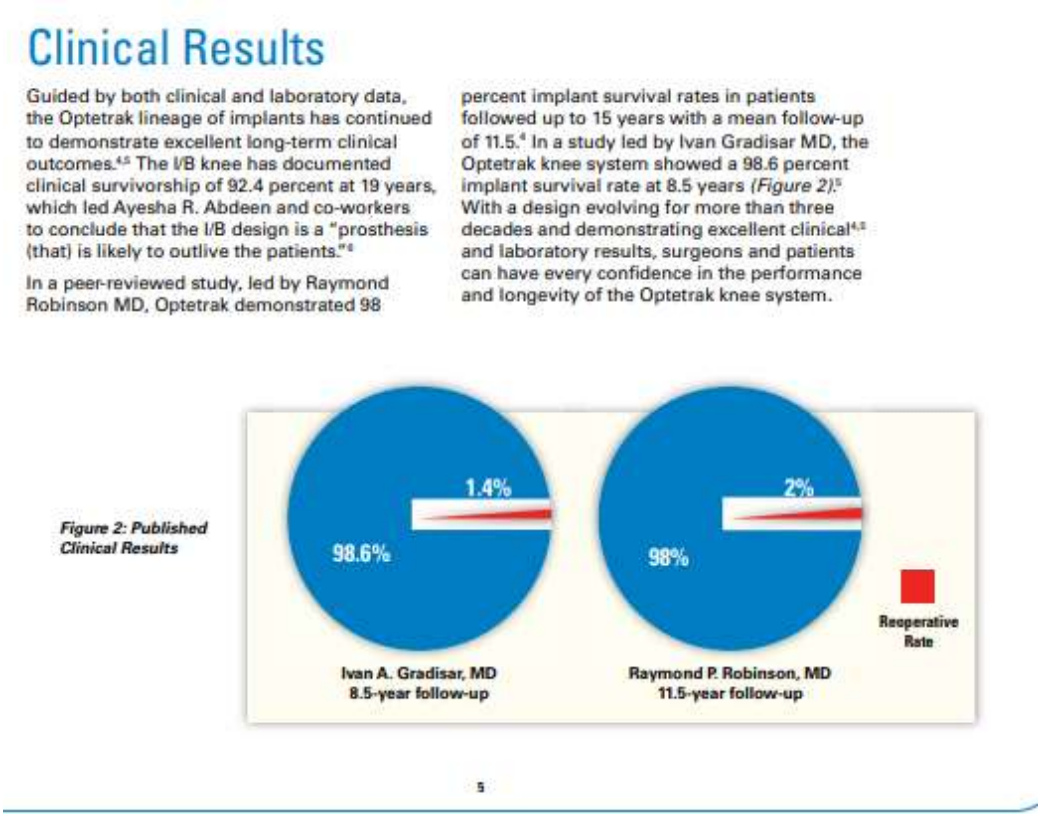

*Optetrak Logic Primary System Knee Implant*

42. The patellar cap and tibial insert are made of Ultra High Molecular Weight Polyethylene (UHMWPE) plastic.

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

44. In their marketing materials, the Defendants promised that, "[i]n clinical and laboratory data, the Optetrak Logic implants demonstrate excellent long-term clinical outcomes"

and "surgeons and patients can have every confidence in the performance and longevity of the Optetrak knee system."



## Clinical Results

Guided by both clinical and laboratory data, the Optetrak lineage of implants has continued to demonstrate excellent long-term clinical outcomes.[4,5] The I/B knee has documented clinical survivorship of 92.4 percent at 19 years, which led Ayesha R. Abdeen and co-workers to conclude that the I/B design is a "prosthesis (that) is likely to outlive the patients."[4]

In a peer-reviewed study, led by Raymond Robinson MD, Optetrak demonstrated 98 percent implant survival rates in patients followed up to 15 years with a mean follow-up of 11.5.[4] In a study led by Ivan Gradisar MD, the Optetrak knee system showed a 98.6 percent implant survival rate at 8.5 years *(Figure 2)*.[5] With a design evolving for more than three decades and demonstrating excellent clinical[4,5] and laboratory results, surgeons and patients can have every confidence in the performance and longevity of the Optetrak knee system.

***Figure 2: Published Clinical Results***



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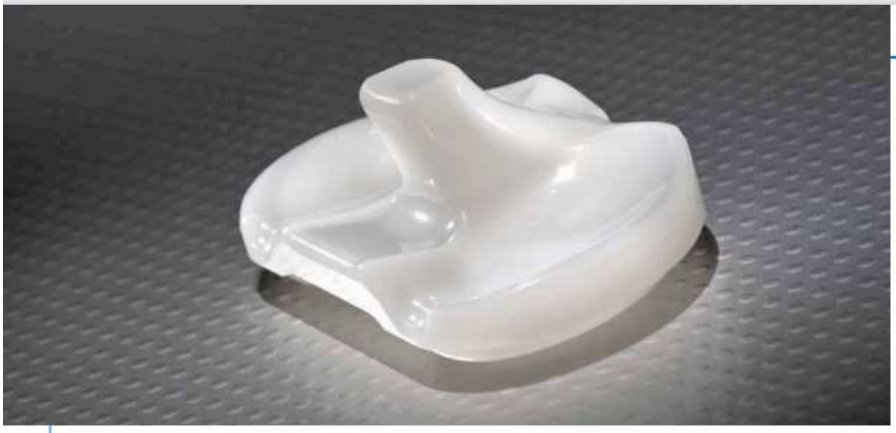
*2011 Exactech Optetrak Logic "Design Rationale" Brochure*

45. The Defendants claim that the Optetrak Logic's longevity is a function of using proprietary Net Compression Molded Polyethylene ("NCM") inserts in the total knee system. According to the Defendants, the surface of the Optetrak Logic's NCM inserts are never machined. In addition, according to the Defendants, the NCM inserts do not require the need for post-consolidation treatments to improve their wear characteristics.



## Net Compression Molded Polyethylene

Total knee replacement longevity is a function of excellent design and proven materials. Optetrak Logic's articular geometry and net compression molded polyethylene inserts are designed to minimize surface damage and wear, ultimately improving the longevity of the knee prosthesis.

**DESIGN**

Wear can occur at the articulating surface between the femur and polyethylene insert (topside wear) and between the polyethylene insert and tibial tray (backside wear). It is important to recognize that topside and backside wear are different. Pitting and delamination are prevalent on the topside and abrasive wear on the backside. The relatively large topside wear particles are not as biologically reactive as the smaller backside wear particles that may increase the potential for osteolysis. Minimizing topside and backside wear is critical to increasing the longevity of the total knee prosthesis.

Optetrak Logic's wear performance is a result of controlling the implant design and managing the material properties of the polyethylene. The 0.96 congruency between the femur and insert and the minimum polyethylene thickness of 6.5mm are design elements that are optimized to reduce contact stress and minimize the potential for topside wear. Additionally, the three-part tibial locking mechanism is designed to eliminate micro motion and backside wear.

**MATERIALS**

Ultra high molecular weight polyethylene (UHMWPE) is the tibial bearing material used for most total knee replacement applications. The manufacturing, packaging and sterilization processes have a significant impact on the resulting properties of the final polyethylene component. Variations in consolidation, oxidation level, amount of cross-linking and mechanical properties can have a pronounced effect on the wear performance and longevity of the implant.

Consolidation is the process of converting polyethylene powder under controlled time, temperature and pressure, into a uniform solid. There are three methods for consolidation: ram extrusion, sheet compression molding and net compression molding (NCM).

The first two processes produce bar stock that is then machined into the final component. The third process, net compression molding, produces one insert at a time, with the articulation surface molded into the component. Exactech chooses the net compression molding to produce the Optetrak Logic tibial inserts because this process is proven to yield the most consistent consolidation, resulting in uniform material properties and oxidation resistance *(Figure 12)*.

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*2011 Exactech Optetrak Logic "Design Rationale" Brochure*

The resulting articular surface of Optetrak Logic's NCM insert is never machined, creating a smooth finish free of machine lines. Precise machining is performed only on the non-articulating surface to create the overall thickness and precise details of the locking mechanism.

The properties of polyethylene can be manipulated through several post consolidation treatments, such as radiation, annealing and re-melting. These treatments have been used to improve the wear characteristics of some designs. The Optetrak lineage of implants, incorporating NCM, has demonstrated excellent wear characteristics through in vivo studies without requiring the need for post-consolidation treatments.[12]

The NCM inserts are sterilized in a vacuum package with gamma irradiation at 2.5-4 Mrad. At this sterilization dose, the level of cross-linking is limited. Although highly cross-linked polyethylene has been shown to increase abrasive wear resistance, it is documented to decrease fracture toughness.[13] Since the Optetrak tibial locking mechanism is proven to resist micro-motion and abrasive backside wear,[14] a high level of cross-linking is not necessary. By avoiding a high level of cross-linking, Optetrak Logic's NCM polyethylene tibial inserts retain oxidation resistance and fracture toughness, which, when combined with the articular design, has demonstrated excellent wear resistance on both the topside and backside.[15]

Extensive testing and clinical results demonstrate Optetrak's continued success in balancing the design and material properties to achieve optimized kinematics and wear characteristics. Optetrak has documented volumetric wear of 1.46 mg/MC.[11] This corresponds to an 83 percent reduction in wear rates and 52 percent less damaged area than the I/B II.[11] This is approximately six times less wear achieved without manipulating the properties of the clinically proven NCM polyethylene *(Figure 13)*.


***FIGURE 12: Manufacturing Process for NCM Polyethylene Inserts***

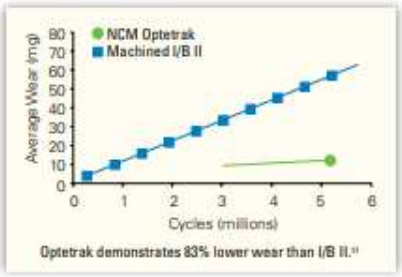


***FIGURE 13: Low Wear Rates***

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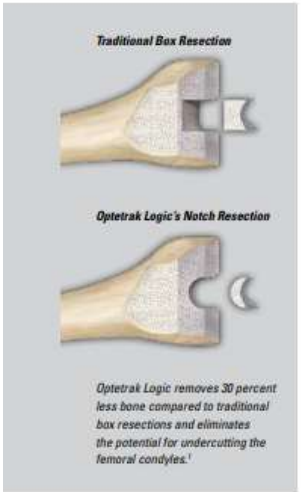
*2011 Exactech Optetrak Logic "Design Rationale" Brochure*

46. Marketing information about the Exactech Optetrak Logic PS tibial inserts boasts exceptional UHMWPE wear performance but cites Optetrak PS data.

47. Product brochures and circulars published by the company prior to the date of Plaintiff's implant and/or revision surgery make representations to the public that the Optetrak Logic devices have key benefits including "long-term implant survivorship"


Developed for excellent long-term implant survivorship, the Optetrak Logic® system of implants uses time-tested patented design and proprietary materials for bone preservation, proper kinematics and wear management in total knee replacement. Optetrak Logic PS is an approach to total knee arthroplasty that just makes sense. From simplified, bone-preserving technique to efficient, tissue-sparing instrumentation, Logic PS streamlines efficiency in the O.R. and provides reproducible outcomes.




**KEY BENEFITS**

- **Long-term Clinical Outcomes:** The Exactech Knee system has documented 98 percent long-term implant survivorship by several peer-reviewed publications.[1]
- **Bone Preservation:** The system's proportional cylindrical resection removes 30 percent less bone compared to traditional box resections.[1]
- **Patient Satisfaction:** Maximizes range of motion through its proportional spine/cam mechanism to improve joint stability, dislocation resistance.[1]
- **OR Efficiency:** Cylindrical notch cutter simplifies notch preparation and standardizes the technique for more reproducible outcomes and efficiency in the O.R.

**SYSTEM FEATURES**

- **Patented design:** Hi-Flex® design, optimized femoral/tibial congruency, deep, wide femoral groove and three-part tibial locking mechanism[1]
- **Proprietary materials:** Net compression molded tibial inserts for superior wear resistance[1]

**References**

1. Data on file at Exactech.

*Logic PS Product Sheet – 712-25-10 Rev A*

48. Defendants also purportedly used a sterilization process in which they sterilized the Optetrak Logic PS Tibial inserts using gamma irradiation in vacuum, a method often referred to as gamma-inert sterilization.

49. During the process of gamma-inert sterilization, the tibial insert is expected to be sealed in barrier packaging. Specifically, the insert should first be packaged in a vacuum bag, after which several other layers of packaging are added. The packaged tibial insert should then be exposed to 25 kGy gamma irradiation.

50. The intended purpose of proper barrier packaging is to avoid exposure of the gamma-inert-sterilized UHMWPE tibial insert to oxygen while on the shelf because gamma sterilization creates highly-reactive macroradicals in the UHMWPE material that attempt to bond to oxygen atoms.[2]

51. Macroradicals are macromolecules that are also free radicals, i.e., these molecules contain one or more unpaired electrons and, thus, are highly reactive. When exposed to air, the free radical will attempt to bond with oxygen atoms.

52. Exposure to oxygen can oxidize and age the tibial insert prior to implanting it in the patient. Oxidation negatively affects the mechanical properties of UHMWPE;[3] in particular, it reduces its resistance to fatigue failure.[4] The cyclic in-vivo loading during gait causes fatigue

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[2] S.M. Kurtz, UHMWPE Biomaterials Handbook: Ultra High Molecular Weight Polyethylene in Total Joint Replacement and Medical Devices, Academic Press, 2nd edition (2009)

[3] Ibid.; *see also* F.J. Medel, S.M. Kurtz, W.J Hozack, et al. Gamma inert sterilization: a solution to polyethylene oxidation? J. Bone Joint Surg Am., Vol. 91(4), pp. 839-849 (2009).

[4] B.H. Currier, J.H. Currier, M.B. Mayor, K.A. Lyford, D.W. Van Citters, J.P. Collier, In vivo oxidation of γ-barrier–sterilized ultra–high-molecular-weight polyethylene bearings, J. Arthroplasty, Vol. 22(5), pp. 721-731 (2007); *see also* F.J. Medel, S.M. Kurtz, J. Parvizi, G.R.

failure of the UHMWPE tibial insert in prosthetic knee implants. Fatigue failure occurs as sub-surface cracking, which eventually can lead to delamination of the UHMWPE.[5]

53. The Optetrak Defendants' marketing brochures for the Optetrak Logic PS, incorrectly states that vacuum gamma-inert sterilization does not generate free radicals and thus reduces UHMWPE wear by preventing shelf and in-vivo oxidation. Vacuum gamma sterilization still creates free radicals, which is why appropriate and conforming barrier packaging is necessary to avoid exposure of the polyethylene insert to oxygen atoms which bond with the free radicals while the inserts are on the shelf.

54. Moreover, the presence of macroradicals in UHMWPE from gamma-inert sterilization still renders the Optetrak Logic polyethylene inserts susceptible to in-vivo oxidation after implantation in patients because oxygen exists in body fluids such as synovial fluid and blood.

55. Prior to 2014, alternative sterilization methods, including both Ethylene Oxide (EtO) gas or low-temperature gas plasma (GP) sterilization methods, were well-known and used in the orthopedic implant industry as economical alternatives to gamma-inert sterilization. For instance, EtO and GP sterilization do not create highly reactive macroradicals that cause oxidation and degradation of the UHMWPE mechanical properties.

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Klein, M.J. Kraay, C.M. Rimnac, In vivo oxidation contributes to delamination but not pitting in polyethylene components for total knee arthroplasty, J. Arthroplasty, Vol. 26(5), pp. 802-810 (2011).

[5] C.A. Lockard, A.P. Sanders, B. Raeymaekers, An experimental approach to determining fatigue crack size in polyethylene tibial inserts, J. Mech. Behavior Biomed. Mats., Vol. 54, pp. 106-114 (2016).

56. Studies also show that EtO sterilization substantially reduces oxidation in UHMWPE compared to gamma-sterilization and can potentially eliminate the in-vivo oxidation of UHMWPE that causes UHMWPE delamination and fatigue failure, which eventually leads to revision surgery.

57. Defendants did not utilize Ethylene Oxide (EtO) gas or low-temperature gas plasma (GP) sterilization methods in their designing and/or manufacturing of the subject Optetrak Devices and their components, including the Defective Implants.

58. Further, Defendants failed to package the polyethylene tibial inserts of the Subject Defective Optetrak devices in vacuum bags with a secondary barrier layer containing ethylene vinyl alcohol (EVOH) that further augments the inserts' oxygen resistance. Consequently, such bags were out-of-specification and non-conforming.

59. Upon information and belief, Defendants have never conducted a clinical trial on the Optetrak devices, including on the Optetrak Logic after modifications to the design of the reference Optetrak Classic implant were made.

60. Had Defendants conducted clinical trials of the Optetrak Logic before the device was first released on the market, they would have discovered at that time the device's propensity to undergo substantial early polyethylene wear, component loosening and/or other failure causing serious complications including tissue damage, osteolysis, and other injuries as well as the need for revision and/or full replacement surgery in patients.

*c. DEFENDANTS HAD KNOWLEDGE OF THE HIGHER THAN ANTICIPATED REVISION RATES OF THE OPTETRAK PS DEVICES AT ALL RELEVANT TIMES.*

61. For many years prior to Plaintiff CHRISTOPHER MATCHETT'S first total knee replacement and/or revision procedure and, at all relevant times, Defendants were aware that the Optetrak total knee system had higher than anticipated revision rates when compared to its competitors, which required Patients to undergo revision surgeries to remove or revise the defective devices.

62. In a study published in 2012, the Optetrak total knee system performed poorly when compared to its competitors.[6]

63. The Australian Registry, a preeminent, internationally recognized resource for evaluating orthopedic implants, identified the Logic's reference implant the Optetrak PS Classic as an implant with a higher-than-expected rate of revision in their 2007, 2008, 2009, 2010, 2011, 2012, 2013, 2014, 2015, 2016, 2017, 2018, 2019, 2020, and 2021 annual reports.

64. The Australian Registry reported that ***every*** Exactech Optetrak Total Knee Replacement ("TKR") polyethylene component combination demonstrated ***statistically significant*** increased revision rates compared to other TKR systems (N=668,852) with at least one and a half years of follow-up with hazard ratios ranging from 1.84 to 5.85 ($p<0.001$).[7]

65. The United Kingdom Registry reported that the Exactech Optetrak TKR System utilizing the cruciate retaining femoral component (N=1,638) had statistically significant increased

[6] See Thelu, C. et al., "Poor results of the Optetrak cemented posterior stabilized knee prosthesis after a mean 25-month follow-up:Analysis of 110 protheses", Orthopedics and Traumatology 2012; 98:413-420.

[7] See Exactech February 7, 2022 Urgent Medical Device Correction Letter (emphasis added).

cumulative revision rates compared to all TKRs (N=1,145,052) at the 3, 5, 10, 13 and 15-year timepoints.[8]

66. The New Zealand Registry reported a total of 63 TKR revision procedures among 661 primary Optetrak TKRs. The Optetrak TKR revision rate was 1.015/100 component years compared to all other primary TKRs (N=118,430) which had a revision rate of 0.48/100 component years and represented a ***statistically significant*** value greater than a two-fold increased revision rate.[9]

67. The Federal Drug Administration's Manufacturer and User Facility Device Experience ("MAUDE") database records complaints submitted to the FDA by mandatory reporters, including manufacturers, importers and device user facilities, and voluntary reporters such as health care professionals, patients and consumers.

68. There are over 500 reports in the MAUDE database related to problems with the Optetrak PS and Optetrak Logic devices which include the following complaints, without limit:

- Loosening of Implant
- Worn Implant
- Adverse events
- Fracture
- Instability
- Degradation
- Failure of Implant
- Pain
- Migration
- Osteolysis
- Edema
- Audible noises from Implant
- Delamination

[8] Ibid.
[9] Ibid. (emphasis added)

- Joint Disorder
- Cracking
- Collapse
- Loss of Osseointegration
- Disability
- Debris
- Swelling
- Bone shedding
- Tissue Damage

*d. FEBRUARY 7, 2022 RECALL*

69. On August 30, 2021, Defendants initiated a partial recall of their Optetrak Comprehensive Knee System because these devices were packaged improperly without an additional oxygen barrier layer, which can lead to expedited wear and minimized longevity. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRes/res.cfm?ID=189266.

70. On February 7, 2022, the recall was expanded to include "all knee and ankle arthroplasty polyethylene inserts packaged in non-conforming bags" since 2004.

71. On February 7, 2022, Defendants sent an Urgent Medical Device Correction letter to surgeons indicating that their Optetrak Logic Polyethylene Inserts, including the Defective Implants, were packaged in out-of-specification vacuum bags.

72. In their February 7, 2022 Urgent Medical Device Correction letter ("Recall Letter"), Defendants initiated an expanded recall to include all knee and ankle arthroplasty polyethylene inserts packaged in non-conforming bags regardless of label or shelf life.

73. Specifically, the Defendants wrote in the February 7, 2022 Recall letter 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

74. At all times relevant to this action, Defendants were aware of the problems with the Optetrak and Optetrak Logic's design and their 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 and/or full replacement surgery in patients. Nonetheless, Defendants still did not adequately warn patients, the medical community, or the public about these risks, and continued to promote, market, sell and defend the Optetrak devices without limitation until February 7, 2022.

75. Despite Defendants' knowledge of early onset failures of the Optetrak and Optetrak Logic devices, including the devices and components implanted in Plaintiff CHRISTOPHER MATCHETT, Defendants continued to manufacture, package, promote, and distribute the devices and their defective component parts without alerting surgeons of the potential increased risks of early onset failures of the devices.

76. Despite Defendants' knowledge of early onset failures of the Optetrak and Optetrak Logic devices, including the devices and components implanted in Plaintiff CHRISTOPHER MATCHETT, Defendants continued to manufacture, package, promote, and distribute the devices and their defective component parts without changing, modifying, or improving the device or its packaging to address the increased risk of early failure.

77. Despite Defendants' knowledge of early onset failures of the Optetrak and Optetrak Logic devices, including the devices and components implanted in Plaintiff CHRISTOPHER MATCHETT, Defendants did not change the labeling, marketing materials or product inserts to adequately and accurately warn patients or physicians of the associated increased risks, longevity, and alternative product options manufactured by Defendants or other companies with lesser risks and rates of early failure.

78. Despite knowledge that the Optetrak and Optetrak Logic devices, including the devices and components implanted in Plaintiff CHRISTOPHER MATCHETT, were defective and resulted in premature failures and accompanying complications, Defendants continued to aggressively market and sell the devices and their defective component parts, all the while maintaining that they were safe and effective for use in total knee replacements and revisions and concealing the true safety information related to these devices.

79. Despite Defendants' knowledge of early onset failures of the Optetrak and Optetrak Logic devices, including the devices and components implanted in Plaintiff CHRISTOPHER MATCHETT, Defendants did not partially alert the FDA of the known increased risks until August 30, 2021, and did not more fully alert the FDA until February 7, 2022.

80. Defendants concealed their knowledge of the Optetrak and Optetrak Logic devices', including the devices and components implanted in Plaintiff CHRISTOPHER MATCHETT, unreasonably dangerous risks, including an increased risk of early failure, from Plaintiff, Plaintiff's medical providers, other consumers, and the medical community at large.

*e. PLAINTIFF CHRISTOPHER MATCHETT RECEIVES DEFECTIVE IMPLANTS*

81. Plaintiff, CHRISTOPHER MATCHETT, is a 58-year-old citizen and resident of New York.

82. Plaintiff CHRISTOPHER MATCHETT is of a healthy weight for a man of his age and height.

83. Plaintiff, CHRISTOPHER MATCHETT, does not suffer from or have a family history of any bone disorders or diseases.

84. On January 21, 2014, Plaintiff CHRISTOPHER MATCHETT underwent a total knee replacement at HSS in New York, New York during which the defective Exactech Optetrak Logic Total Knee System was implanted into the Plaintiff's left knee cavity (hereinafter the "2014 Defective Implant").

85. The January 21, 2014 total knee replacement included the following parts: Exactech Patella Three Peg 35MM (Lot # 200-02-35, Serial No. 2858707); Exactech Optetrak Logic Femoral PS Cen Sz 5 Lft (Lot # 02-010-01-0250, Serial No. 2774881); Exactech Optetrak Logic Tibia Tray Cem Sz 5F/4T (Lot # 02-012-41-5040, Serial No. 2795886); Exactech Optetrak Logic Tibia Insert PSC 5 9MM (Lot # 02-012-44-5009, Serial No. 2724610).

86. The January 21, 2014 knee replacement was done correctly and did not deviate from accepted medical custom and practice with regards to the implantation of an Optetrak Logic Total Knee System.

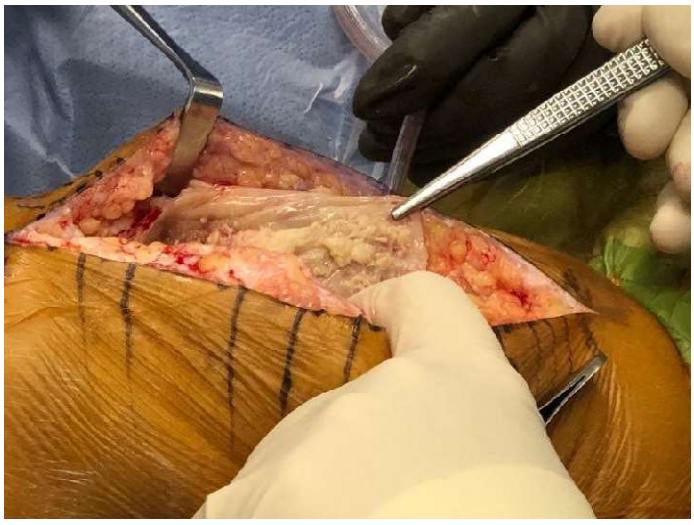
87. In or around 2018, Plaintiff CHRISTOPHER MATCHETT experienced pain, discomfort and stiffening in his left knee.

88. In or around 2018, an MRI of Plaintiff CHRISTOPHER MATCHETT's left knee showed debris synovitis.

89. In or around 2018, Plaintiff CHRISTOPHER MATCHETT required a revision procedure after it was discovered that the plastic tibial insert of the defective Optetrak Logic Total Knee System implant had failed and was fraying, resulting in plastic fragments in his left knee.

90. On April 17, 2018, Plaintiff CHRISTOPHER MATCHETT had an arthrotomy and partial synovectomy operation performed at HSS, during which the prior left knee surgery was revised and the plastic tibial insert was replaced with the Optetrak Logic PSC Tibial Insert Posterior Stabilized Size 5, 11mm (Lot 02-012-44-5011, Serial No. 4908393) (the replaced polyethylene tibial insert hereinafter will be referred to as the "2018 Defective Implant").

91. Upon revision of the failed parts of the original defective Optetrak Logic Total Knee System implant, doctors observed that substantial degradation and systemic inflammation had occurred from the patellar component and tibial insert as shown in the picture below:

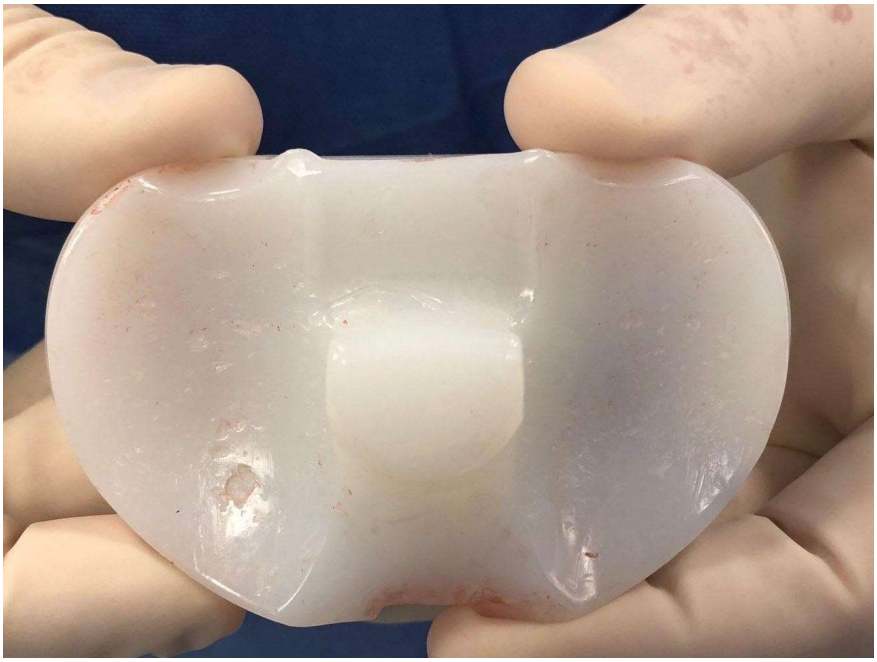


*Debris Removal during April 17, 2018 Surgery at HSS*

92. Plaintiff CHRISTOPHER MATCHETT had extensive debris synovitis.

93. The amount, type and appearance of the polyethylene degradation observed by the operating surgeons was abnormal.

94. Explantation of the failed polyethylene components of the 2014 Defective Implant, revealed damage, including pitting, fracture, surface fatigue and cracking to the plastic tibial insert, which was visible to the naked eye, as shown below.



*Observable Pitting in CHRISTOPHER MATCHETT's Explanted Tibial Tray*

95. Upon information and belief, the April 17, 2018 left knee revision was done correctly and did not deviate from accepted medical custom and practice with regards to a revision of an Exactech Optetrak Logic knee and its component parts.

96. On May 3, 2018, Plaintiff CHRISTOPHER MATCHETT submitted a web e-mail to Exactech in which he provided the following comments and information to the company: "I had

a knee replacement at HSS in NYC about 4 years ago and had to have a replacement of my patella spacer on April 17, as the spacer was fraying, resulting in plastic fragments in my knee…"

97. Upon information and belief, his report did not prompt an investigation into the cause of the failure of his knee replacement and/or any action by the company to warn of problems of the polyethylene inserts in the 2014 Defective Implant and the 2018 Defective Implant and/or any efforts by the company to improve the quality and durability of the plastic components of the Defective Implants.

98. Plaintiff CHRISTOPHER MATCHETT required and continues to require medical treatment, care and follow-up, including extensive physical therapy, after the April 17, 2018 revision procedure.

99. Upon information and belief, the 2014 Defective Implant failed prematurely, especially in light of the Plaintiff's body mass index and lifestyle.

100. The 2014 and 2018 Defective Implants contain polyethylene plastic inserts that are subject to the February 7, 2022 recall initiated by the Defendants.

101. The 2018 Defective Implant remains in Plaintiff's body and contains defective, recalled plastic components.

102. The 2018 Defective Implant contains plastic components that are defective, unfit for use and/or unreasonably dangerous.

103. The 2018 Defective Implant continues to cause Plaintiff CHRISTOPHER MATCHETT pain, stiffness and discomfort requiring medical treatment, monitoring and care.

104. Plaintiff CHRISTOPHER MATCHETT is receiving medical treatment, management and care of the 2018 Defective Implant from a revision specialist.

105. An MRI taken in or around May 2022 shows that Plaintiff CHRISTOPHER MATCHETT will more likely than not require a second revision surgery or full revision total knee replacement due to defects and failures of the plastic tibial insert components used in the 2018 revision procedure.

106. Defendants designed, developed, tested, assembled, manufactured, packaged, labeled, prepared, distributed, marketed, supplied, warranted and/or sold the Defective Implants.

107. Upon information and belief, the polyethylene substance used in the Defective Implants was defectively made and/or designed, of an inferior quality, improperly selected and/or improperly packaged.

108. Upon information and belief, the defective polyethylene substance used in the Defective Implants caused and/or contributed to the premature failure of the 2014 Defective Implant, only four years after it was implanted into Plaintiff's knee, causing injury to Plaintiff, CHRISTOPHER MATCHETT.

109. Upon information and belief, the defective polyethylene substance used in the Defective Implants caused and/or contributed to the current failure of the 2018 Defective Implant, causing injury to Plaintiff, CHRISTOPHER MATCHETT.

110. Upon information and belief, the Defective Implants were defective in their design, manufacturing and materials at the time they left the Defendants' hands and were delivered into the stream of commerce in their defective condition.

111. It was foreseeable, expected and intended by the Defendants for the Defective Implants to be used in a knee arthroplasty and knee revision patient, such as Plaintiff CHRISTOPHER MATCHETT.

112. Defendants allowed the Defective Implants to be implanted during Plaintiff's total knee replacement and revision procedures in said condition.

113. Defendants failed with respect to the selection, processes, testing, quality audits, supervision for their knee implant devices and their component parts, including the Defective Implants.

114. As a direct and proximate result of the deficiencies in the Defective Implants and the Defendants' failures, the Plaintiff has suffered and continues to suffer injuries and damages, including without limit was caused to undergo a painful revision surgery, has required and will continue to require additional medical care and treatment, including extensive physical therapy, pain management and surgery, and has experienced and will continue to experience prolonged and lasting pain and suffering and loss of enjoyment of life.

*f. DEFENDANTS VIOLATED FEDERAL REQUIREMENTS*

115. Upon information and belief, Defendants' violated federal and state laws and regulations regarding the design, selection, testing, manufacturing, packaging, storage, selling, and/or distribution of medical knee implant devices, including without limit the following: 21 U.S.C. § 351, *et seq*. and 21 C.F.R. § 820 *et seq*. regarding federal regulations for medical devices and Current Good Manufacturing Practices; as well as 15 U.S.C. § 2051, *et seq*. and 16 C.F.R. § 1101, *et seq*. regarding the Consumer Product Safety Act. Moreover, upon information and belief,

the EXACTECH DEFENDANTS violated one or more of the following federal laws and regulations.

116. Pursuant to federal law, a device is deemed to be adulterated if, among other things, it fails to meet established performance standards, or if the methods, facilities or controls used for its manufacture, packing, storage or installation are not in conformity with federal requirements. See 21 U.S.C. §351. 95.

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

118. Pursuant to federal law, manufacturers are required to comply with FDA regulation of medical devices, including FDA requirements for records and reports, in order to prohibit introduction of medical devices that are adulterated or misbranded, and to assure the safety and effectiveness of medical devices. See 21 U.S.C. §360(i). 97.

119. Pursuant to federal law, manufacturers must keep records and make reports of any medical device that may have caused or contributed to death or serious injury, or if the device has malfunctioned in a manner likely to cause or contribute to death or serious injury. See 21 U.S.C. §360(i). 97.

120. Federal law mandates that the FDA establish regulations requiring a manufacturer of a medical device to report promptly to FDA any correction or removal of a device undertaken to reduce a risk to health posed by the device, or to remedy a violation of federal law by which a device may present a risk to health. See 21 U.S.C. §360(i).

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

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

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

124. Pursuant to federal regulation, manufacturers must report to FDA within five (5) business days after becoming aware of any reportable MDR event or events, including a trend analysis that necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health. See 21 CFR §803.53. 101.

125. Pursuant to federal regulation, device manufacturers must report promptly to FDA any device corrections and removals and maintain records of device corrections and removals. FDA regulations require submission of a written report within ten (10) working days of any correction or removal of a device initiated by the manufacturer to reduce a risk to health posed by the device, or to remedy a violation of the Act caused by the device, which may present a risk to health. The written submission must contain, among other things, a description of the event giving rise to the information reported and the corrective or removal actions taken, and any illness or injuries that have occurred with the use of the device, including reference to any device report numbers. Manufacturers must also indicate the total number of devices manufactured or distributed which are subject to the correction or removal and provide a copy of all communications regarding the correction or removal. See 21 CFR §806. 102.

126. Pursuant to federal regulation, manufacturers must comply with specific quality system requirements promulgated by FDA. These regulations require manufacturers to meet design control requirements, including but not limited to conducting design validation to ensure that devices conform to define user needs and intended uses. Manufacturers must also meet quality standards in manufacture and production. Manufacturers must establish and maintain procedures for implementing corrective actions and preventive actions and investigate the cause of

nonconforming products and take corrective action to prevent recurrence. Manufacturers are also required to review and evaluate all complaints and determine whether an investigation is necessary. Manufacturers are also required to use statistical techniques where necessary to evaluate product performance. See 21 CFR §820.

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

128. Pursuant to 21 CFR §820.1 (c), the failure to comply with any applicable provision in Part 820 renders a device adulterated under section 501(h) of the Federal Food Drug & Cosmetic Act ("the Act") (21 U.S.C. § 351). 105. Pursuant to 21 CFR §820.5, each manufacturer shall establish and maintain a quality system that is appropriate for the specific medical device designed or manufactured. "Quality system" means the organizations structure, responsibilities, procedures, processes and resources for implementing quality management. See 21 CFR §820.3(v).

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

130. Pursuant to 21 CFR §820.30(a), each manufacturer shall establish and maintain procedures to control the design of the device in order to ensure that specified design requirements are met. 108. Pursuant to 21 CFR §820.30(d), each manufacturer shall establish and maintain procedures for defining and documenting design output in terms that allow an adequate evaluation of conformance to design input requirements.

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

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

133. Pursuant to 21 CFR §820.30(g), each manufacturer shall establish and maintain procedures for validating the device design. Design validation shall be performed under defined operating conditions on initial production units, lots, or batches, or their equivalents. Design validations shall ensure that devices conform to defined user needs and intended uses and shall include testing of production units under actual or simulated use conditions.

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

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

136. Pursuant to 21 CFR §820.70(a), each manufacturer shall develop, conduct, control, and monitor production processes to ensure that a device conforms to its specifications. Where deviations from device specifications could occur as a result of the manufacturing process, the manufacturer shall establish and maintain process control procedures that describe any process controls necessary to ensure conformance to specifications. Such process controls shall include: a) Documented instructions, standard operating procedures (SOP's), and methods that define and control the manner of production; b) Monitoring and control of process parameters and component and device characteristics during production; c) Compliance with specified reference standards or codes; d) The approval of processes and process equipment; and e) Criteria for workmanship which shall be expressed in documented standards or by other equivalent means.

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

138. Pursuant to 21 CFR §820.70(c), each manufacturer shall establish and maintain procedures to adequately control environmental conditions that could reasonably be expected to have an adverse effect on product quality, including periodic inspection of environmental control system(s) to verify that the system, including necessary equipment, is adequate and functioning properly.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

148. Upon information and belief, Defendants' Subject Defective Optetrak devices also violated the FDA 510(k) approval process. See U.S.C. §360 et seq.

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

150. Upon information and belief, Defendants' Subject Defective Optetrak devices are adulterated pursuant to 21 U.S.C. §351 because, among other things, they failed to meet established performance standards, and/or the methods, facilities, or controls used for their manufacture, packing, storage or installation are not in conformity with federal requirements. See 21 U.S.C. §351. 129.

151. Upon information and belief, Defendants' Subject Defective Optetrak devices are misbranded because, among other things, they are dangerous to health when used in the manner prescribed, recommended or suggested in the labeling thereof. See 21 U.S.C. §352.

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

153. Upon information and belief, Defendants failed to establish and maintain CGMP with respect to the quality audits, quality testing and process validation for their Subject Defective Optetrak devices, including the Defective Implants.

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

*g. Fraudulent Concealment*

155. The EXACTECH DEFENDANTS, through their affirmative misrepresentations and omissions actively concealed from Plaintiff and Plaintiff's healthcare providers the true and significant risks associated with the Subject Defective Optetrak devices claiming any failures were due to surgical technique, positioning or patient characteristics. [10]

156. At the time of implantation and revision of the defective devices, Plaintiff and Plaintiff's healthcare providers relied on Defendants' continued representations that the Subject Defective Optetrak devices had excellent long-term clinical outcomes.

157. The EXACTECH DEFENDANTS made these representations with knowledge of their falsity given their knowledge of reports and studies of high failure rates.

[10] Hereinafter, the term "Subject Defective Optetrak Devices" refers generally to the Optetrak PS and Optetrak Logic devices and their component parts, and includes the devices' defective polyethylene tibial inserts as well as Plaintiff's Defective Implants.

158. Although clinical evidence demonstrated that the Subject Defective Optetrak devices were failing at a rate higher than promoted, Defendants failed to initiate a recall earlier or issue any communications to healthcare providers that patients should not have these devices implanted, should be monitored, and/or should have revisions and/replacements done with alternative devices.

159. Earlier disclosure of the Subject Defective Optetrak devices true failure rates could have impacted the sale of the company to private equity investors.

160. Had Defendants not actively concealed evidence of growing reports of premature device failures, Plaintiff would have opted to have a different device initially implanted; would have opted to have different components implanted during the revision; would have opted for a complete replacement with a different device at the time of revision; and/or would have obtained radiological intervention at an earlier time that would have led to an earlier diagnosis of bone loss and earlier removal of the Defective Implants, thereby reducing damage to bone and tissue.

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

162. Accordingly, no limitations period ought to accrue until such time as Plaintiff knew or reasonably should have known of some causal connection between Plaintiff being implanted with the Defective Implants, and the resulting harm later suffered by Plaintiff as a result of Defendants' fraudulent concealment.

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

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

## CAUSES OF ACTION

### COUNT I
### STRICT LIABILITY: MANUFACTURING DEFECT
### AGAINST ALL DEFENDANTS

165. Plaintiffs repeat and reallege the allegations of the paragraphs above as if fully stated herein.

166. The EXACTECH DEFENDANTS had a duty to manufacture the Subject Defective Optetrak devices in a manner that prevents unreasonable risk of harm or injury to users and patients, including Plaintiff CHRISTOPHER MATCHETT.

167. The EXACTECH DEFENDANTS had a duty to distribute, market, and/or sell the Subject Defective Optetrak devices without manufacturing defects to prevent an unreasonable risk of harm or injury to users and patients, including Plaintiff CHRISTOPHER MATCHETT.

168. The Subject Defective Optetrak devices manufactured by the EXACTECH DEFENDANTS were not reasonably safe for their expected, intended, and/or foreseeable uses, functions and purposes.

169. The Subject Defective Optetrak devices were not reasonably safe as manufactured, distributed, marketed and/or sold by the EXACTECH DEFENDANTS.

170. The Subject Defective Optetrak devices were defectively manufactured for a multitude of reasons, including but not limited to the following:

a) The polyethylene substance used within the devices was of an inferior grade or quality than that advertised and promoted by the EXACTECH DEFENDANTS;

b) Defendants packaged the Subject Defective Optetrak devices, and specifically the polyethylene plastic tibial inserts, in out-of-specification or non-conforming vacuum bags that did not contain a secondary barrier layer containing ethylene vinyl alcohol (EVOH) that further prevents oxidation and/or promotes oxygen resistance;

c) Defendants' method of sterilizing the defective polyethylene inserts increased the risk of users and patients suffering from pain, discomfort, injury and the need for revision surgery;

d) Defendants' use of the gamma-inert sterilization method rendered the polyethylene plastic components in the Subject Defective Optetrak devices, susceptible to oxidation either while in the packaging and/or following implantation in the patient;

e) Defendants utilized and/or selected barrier packaging which was not sufficient to prevent the polyethylene plastic components in the Subject Defective Optetrak devices from being exposed to oxidation while on the shelf;

f) Defendants manufactured a product with polyethylene plastic components that created highly-reactive macroradicals in the UHMWPE material, which attempt

to bond to oxygen atoms and degrade the Subject Defective Optetrak devices' polyethylene plastic components;

g) Defendants failed to package polyethylene plastic components in barrier packaging with sufficient layers to prevent oxidation of the Subject Defective Optetrak devices' polyethylene plastic components while on the shelf;

h) The sterilization method used by Defendants did not utilize feasible alternative sterilization methods, such as EtO and/or GP sterilization, and, thereby, failed to eliminate the creation and/or substantial risk of the creation of highly reactive macroradicals that caused oxidation and degradation of the Subject Defective Optetrak devices polyethylene plastic components;

i) The sterilization method used by Defendants did not utilize feasible alternative sterilization methods, such as EtO and/or GP sterilization, and, thereby, failed to substantially reduce and/or eliminate the risk of oxidation;

j) The EXACTECH DEFENDANTS failed to exercise sufficient quality control to ensure the polyethylene inserts were safe for implantation in users and patients and would not degrade abnormally under average and regular use;

k) The polyethylene substance within the Subject Defective Optetrak devices did not comply with the required specifications for the polyethylene inserts that should be used in the devices;

l) The EXACTECH DEFENDANTS failed to perform quality control or other such testing on the polyethylene inserts used in the Subject Defective Optetrak devices to ensure they complied with required specifications;

m) The EXACTECH DEFENDANTS violated applicable state and federal laws and regulations;

n) and in all other ways.

171. The Exactech Defendants knew or should have known and been aware that the Subject Defective Optetrak devices were defectively manufactured.

172. The Subject Defective Optetrak devices were defective in their manufacturing and materials at the time they left the Defendants' hands and were delivered into the stream of commerce in their defective condition.

173. The Subject Defective Optetrak devices should not have been distributed, marketed, and/or sold by Defendants in a defectively manufactured condition.

174. It was foreseeable, expected and intended by the Defendants for the Subject Defective Optetrak devices to be used in a knee arthroplasty and revision patient, such as Plaintiff CHRISTOPHER MATCHETT.

175. The manufacturing defects of the Subject Defective Optetrak devices presented an unreasonable risk of harm to users and patients exposed to their danger, including Plaintiff CHRISTOPHER MATCHETT, when they were used and operated for the purposes intended by Defendants.

176. The manufacturing defects of the Subject Defective Optetrak devices presented an unreasonable risk of harm to users and patients exposed to their danger, including Plaintiff CHRISTOPHER MATCHETT, when they were used and operated in a manner that was foreseeable to Defendants.

177. The EXACTECH DEFENDANTS breached their duty to manufacture the Subject Defective 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 CHRISTOPHER MATCHETT.

178. The EXACTECH DEFENDANTS breached their duty to distribute, market, and/or sell the Subject Defective Optetrak devices without manufacturing defects to eliminate or prevent an unreasonable risk of harm or injury to users and patients exposed to their danger, including Plaintiff CHRISTOPHER MATCHETT.

179. Plaintiff CHRISTOPHER MATCHETT was seriously injured as a direct and proximate result of the manufacturing defects in the Defective Implants, caused by Defendants.

180. The EXACTECH DEFENDANTS are strictly liable for the defective manufacture of the Subject Defective Optetrak devices, including the Defective Implants; the distribution, marketing, and/or sale of the defectively manufactured Subject Defective Optetrak devices; and the injuries sustained by Plaintiff CHRISTOPHER MATCHETT.

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

183. By reason of the foregoing acts, omissions and conduct committed by the EXACTECH DEFENDANTS, Plaintiff CHRISTOPHER MATCHETT was caused to sustain and will continue to sustain disabilities in activities of daily living.

184. By reason of the foregoing acts, omissions and conduct committed by the EXACTECH DEFENDANTS, Plaintiff CHRISTOPHER MATCHETT has sustained and will sustain medical expenses and related economic losses.

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

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

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

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

COUNT II
STRICT LIABILITY: DESIGN DEFECT
AGAINST ALL DEFENDANTS

188. Plaintiffs repeat and reallege the allegations of the paragraphs above as if fully stated herein.

189. Exactech had a duty to design the Subject Defective Optetrak devices in a manner that did not present an unreasonable risk of harm or injury to users and patients exposed to their danger, including Plaintiff CHRISTOPHER MATCHETT.

190. The EXACTECH DEFENDANTS each had a duty to distribute, market, and/or sell the Subject Defective Optetrak devices with a design that did not present an unreasonable risk of harm or injury to users and patients exposed to their danger, including Plaintiff CHRISTOPHER MATCHETT.

191. The design of the Optetrak Logic Total Knee System by Exactech is defective and not reasonably safe.

192. The Subject Defective Optetrak devices are not reasonably safe as designed, distributed, marketed, delivered and/or sold by Defendants.

193. The Subject Defective Optetrak devices are defectively designed for a multitude of reasons, including but not limited to the following:

a) Defendants' method of sterilizing the polyethylene plastic insert pursuant to their design increased the risk of users and patients suffering from pain, discomfort, injury and the need for revision and/or full replacement surgery;

b) Defendants' design of the defective polyethylene plastic components caused them to have the 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 and/or full replacement surgery in patients;

c) Defendants' use of the gamma-inert sterilization method pursuant to their design rendered the Subject Defective Optetrak devices' polyethylene plastic components susceptible to in-vivo oxidation either while in the packaging and/or following implantation in the patient;

d) Defendants utilized barrier packaging pursuant to their design which was not sufficient to prevent the polyethylene plastic components from being exposed to oxidation while on the shelf;

e) Defendants designed a product with polyethylene plastic that created highly-reactive macroradicals in the UHMWPE material, which attempt to bond to oxygen atoms and degrade the polyethylene plastic components;

f) Defendants failed to utilize a design that required sufficient layers in the barrier packaging to prevent oxidation of the polyethylene plastic components while on the shelf;

g) Defendants packaged the polyethylene plastic components in improperly designed vacuum bags that did not contain a secondary barrier layer containing ethylene vinyl alcohol (EVOH) to prevent oxidation;

h) The sterilization method used by Defendants pursuant to their design did not utilize feasible alternative sterilization methods, such as EtO and/or GP sterilization, and, thereby, failed to eliminate the creation and/or substantial risk of the creation of highly reactive macroradicals that caused oxidation and degradation of the polyethylene plastic components;

i) The sterilization method used by Defendants pursuant to their design did not utilize feasible alternative sterilization methods, such as EtO and/or GP sterilization, and, thereby, failed to substantially reduce and/or eliminate the risk of oxidation;

j) Defendants failed to perform adequate quality assurance testing and validation before and after sterilization;

k) The Subject Defective Optetrak devices as designed had a propensity to sustain substantial early polyethylene wear component, loosening and/or other failures causing serious complications including tissue damage, osteolysis, and other injuries as well as the need for revision and/or full replacement surgery in patients;

l) The Net Compression Molding process and/or system as designed allowed for or contributed to effusions of polyethylene material from the device greater in

size and quantity than other polyethylene inserts available at the time the Subject Defective Optetrak devices were put on the market;

m) The polyethylene material used in the Subject Defective Optetrak devices caused and/or contributed to the device having a higher failure rate than other similar devices available at the time the devices were put on the market;

n) The polyethylene material caused and/or contributed to the device having a shorter effective lifetime than other similar devices available at the time the Subject Defective Optetrak devices were put on the market;

o) The Defendants' method of forming the polyethylene insert increased the risk of users and patients suffering from pain, discomfort, injury and the need for revision surgery;

p) The angles at which the other components were extended relative to the polyethylene inserts increased the risk of users and patients suffering from pain, discomfort, injury and the need for revision surgery;

q) Defendants failed to conduct adequate mechanical testing, including wear or other testing, on components, subassemblies and/or the finished Subject Defective Optetrak devices, including the Defective Implants;

r) Defendants failed to test an adequate number of samples of Subject Defective Optetrak devices and/or their component parts on an ongoing basis;

s) Defendants failed to take adequate steps to specifically identify failure modes with clarity and to suggest methods to monitor, avoid, and/or prevent further failures;

t) Defendants failed to identify and/or note the significance of any testing that resulted in failure of the Subject Defective Optetrak devices;

u) Defendants failed to perform adequate testing in an environment that adequately simulated in vivo conditions;

v) Defendants failed to perform adequate testing of the Defective Implants, including their components and subassemblies, to ensure that the Subject Defective Optetrak devices functioned properly during and after implantation;

w) Defendants failed to properly record in-field failures and maintain an adequate feedback loop in order to identify and correct failure modes;

x) The EXACTECH DEFENDANTS violated applicable state and federal laws and regulations;

y) and in all other ways.

194. The EXACTECH DEFENDANTS knew or reasonably should have known and been aware that the Subject Defective Optetrak devices were defectively designed.

195. The Optetrak devices, including the Defective Implants, were defective in their design at the time they left the Defendants' hands, and they were delivered into the stream of commerce in their defective condition.

196. The Subject Defective Optetrak devices should not have been sold, marketed, distributed, and/or delivered by Defendants in a defectively designed condition.

197. It was foreseeable, expected and intended by the Defendants for the Subject Defective Optetrak devices to be used in a knee arthroplasty and revision patient, such as Plaintiff CHRISTOPHER MATCHETT.

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

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

200. Pre-existing feasible safer alternative designs providing the same functional purpose were available to the Defendants at the time the Subject Defective Optetrak devices were designed and offered for sale in the market.

201. The EXACTECH DEFENDANTS failed to balance the feasibility of safer alternative designs for the Subject Defective Optetrak devices against existing risks of injury.

202. The EXACTECH DEFENDANTS failed to use pre-existing feasible safer alternative designs providing the same functional purpose.

203. The EXACTECH DEFENDANTS failed to use their own pre-existing feasible safer alternative designs providing the same functional purpose.

204. The EXACTECH DEFENDANTS failed to take into account the reasonable cost of feasible safer alternative designs.

205. The EXACTECH DEFENDANTS failed to balance the risks of injury against the utility and costs of feasible safer alternative designs.

206. The EXACTECH DEFENDANTS failed to develop feasible safer alternative designs providing the same functional purpose with reasonable price adjustments.

207. The EXACTECH DEFENDANTS failed to take into account improvements related to safety and injury prevention presented by feasible safer alternative designs.

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

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

210. Defendants breached their duty to distribute, market, and/or sell the Subject Defective Optetrak devices with a design that eliminated or prevented an unreasonable risk of harm or injury.

211. Plaintiff CHRISTOPHER MATCHETT was seriously injured as a direct and proximate result of the design defects in the Subject Defective Optetrak devices caused by Defendants.

212. The EXACTECH DEFENDANTS are strictly liable for the defective design of the Subject Defective Optetrak devices, including the Defective Implants; the distribution, marketing,

and/or sale of the defectively designed Subject Defective Optetrak devices; and the injuries sustained by Plaintiff CHRISTOPHER MATCHETT as a result thereof.

213. By reason of the foregoing acts, omissions, and conduct committed by the EXACTECH DEFENDANTS, Plaintiff CHRISTOPHER MATCHETT was caused to sustain and will continue 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.

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

215. By reason of the foregoing acts, omissions and conduct committed by the EXACTECH DEFENDANTS, Plaintiff CHRISTOPHER MATCHETT was caused to sustain and will continue to sustain disabilities in activities of daily living.

216. By reason of the foregoing acts, omissions and conduct committed by the EXACTECH DEFENDANTS, Plaintiff CHRISTOPHER MATCHETT has sustained and will sustain medical expenses and related economic losses.

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

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

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

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

## COUNT III
## STRICT LIABILITY: FAILURE TO WARN
## AGAINST ALL DEFENDANTS

220. Plaintiffs repeat and reallege the allegations of the paragraphs above as if fully stated herein.

221. The EXACTECH DEFENDANTS had a duty to provide proper and adequate safety warnings to doctors, users and patients concerning the Subject Defective Optetrak devices, including to Plaintiff CHRISTOPHER MATCHETT.

222. The EXACTECH DEFENDANTS had a duty to provide proper and adequate safety warnings to ensure that doctors, users and patients possessed detailed, unequivocal and unambiguous information about the Subject Defective Optetrak devices' health and safety risks so that doctors, users and patients could make informed decisions about whether to use the Subject Defective Optetrak devices, including the Defective Implants.

223. The EXACTECH DEFENDANTS had a duty to provide proper and adequate safety warnings about potential safety hazards, dangers and serious health risks presented by the Subject Defective Optetrak devices' expected, intended and foreseeable uses.

224. The EXACTECH DEFENDANTS breached their duty and failed to exercise ordinary care in the labeling of the Optetrak Logic system and failed to issue adequate pre-marketing or post-marketing warnings to doctors and the general public, including Plaintiff CHRISTOPHER MATCHETT, regarding the risk of serious injury, including premature polyethylene wear and risk of early revision surgery.

225. The EXACTECH DEFENDANTS knew or should have known that Plaintiff could suffer injury as a result of Defendants' failure to exercise ordinary care as described above.

226. Despite the fact that the EXACTECH DEFENDANTS knew or should have known that the Subject Defective Optetrak devices posed a serious risk of bodily harm to consumers, Defendants continued to manufacture and market the Subject Defective Optetrak devices for implantation into consumers without appropriate and adequate labels and warnings.

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

a) Designing, manufacturing, marketing, advertising, distributing, and selling the Subject Defective Optetrak devices to consumers, including Plaintiff CHRISTOPHER MATCHETT, without an adequate warning of the dangerous risks of the devices;

b) Negligently failing to notify and warn the public including Plaintiff

CHRISTOPHER MATCHETT and his doctors of reported incidents involving injury and the negative health effects attendant to the use of the Subject Defective Optetrak devices;

c) Negligently failing to notify and warn the public including Plaintiff CHRISTOPHER MATCHETT and his doctors of the risk of oxidation of the polyethylene plastic components in the Subject Defective Optetrak devices;

d) Negligently failing to notify and warn the public including Plaintiff CHRISTOPHER MATCHETT and his doctors that they were using a sterilization method for the polyethylene plastic components which created highly-reactive macroradicals which can cause the plastic components to oxidize and age when exposed to oxygen atoms, thereby, causing device fatigue and failure;

e) Negligently failing to notify and warn the public including Plaintiff CHRISTOPHER MATCHETT and his doctors that they were not using alternative state-of-the art sterilization methods, including EtO and/or GP sterilization, which were available during the relevant time period, and would not create highly reactive macroradicals that cause oxidation and degradation of the polyethylene plastic components in the Subject Defective Optetrak devices, including the Defective Implants;

f) Negligently failing to notify and warn the public including Plaintiff CHRISTOPHER MATCHETT and his doctors that the polyethylene plastic components were packaged in non-conforming barrier packaging;

g) Negligently misrepresenting the safety of the Subject Defective Optetrak devices, including the Defective Implants;

h) Negligently failing to provide warnings, instructions or other information that accurately reflected the risks of early failure of the Subject Defective Optetrak devices, including the Defective Implants;

i) Negligently failing to provide warnings, instructions or other information that accurately reflected the risks of early degradation of the polyethylene substance in the Subject Defective Optetrak devices, including the Defective Implants;

j) Negligently failing to provide warnings, instructions or other information to the public including Plaintiff CHRISTOPHER MATCHETT and his doctors of adequate precautions that could be taken to avoid fatigue and failure of the Subject Defective Optetrak devices, including the Defective Implants;

k) Negligently failing to exercise due care in the advertisement and promotion of the Subject Defective Optetrak devices, including the

Defective Implants;

l) 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 Subject Defective Optetrak devices, including the Defective Implants;

m) Aggressively promoting the Defective Implants without proper warnings of the risk of early failure or material degradation in the average user;

n) Aggressively promoting the Subject Defective Optetrak devices even after Defendants knew or should have known of the unreasonable risks from implantation;

o) Negligently diminishing or hiding the risks associated with the implantation of the Subject Defective Optetrak devices;

p) Negligently failing to provide warnings in accordance with applicable state and federal laws and regulations;

q) and in all other ways.

228. The EXACTECH DEFENDANTS knew or reasonably should have known that they failed to provide proper and adequate safety warnings to consumers, users, doctors and patients that were sufficient for users to make informed decisions about implantation.

229. The EXACTECH DEFENDANTS knew or reasonably should have known that they failed to provide proper and adequate safety warnings to consumers, users, doctors and patients that were sufficient for the Subject Defective Optetrak devices' expected, intended and foreseeable uses.

230. The Subject Defective Optetrak devices should not have been designed, manufactured, distributed, marketed, and/or sold by Defendants without proper and adequate safety warnings to consumers, users, doctors and patients about the potential health and safety risks of the product.

231. The EXACTECH DEFENDANTS breached their duty to provide proper and adequate safety warnings to consumers, users, doctors and patients to make informed decisions about implantation and product use.

232. The EXACTECH DEFENDANTS breached their duty to design, manufacture, distribute, market, and/or sell the Subject Defective Optetrak devices with proper and adequate safety warnings to consumers, users, doctors and patients to make informed decisions about implantation and product use.

233. Plaintiff CHRISTOPHER MATCHETT was seriously injured by Defendants' failure to provide proper and adequate safety warnings to consumers, users, doctors and patients.

234. As a direct and proximate result of Defendants' acts and omissions, including their failure to provide proper and adequate safety warnings to consumers, users, doctors and patients regarding the Defective Opterak Devices, Plaintiff CHRISTOPHER MATCHETT was implanted with the Defective Implants.

235. By reason of the foregoing acts, omissions and conduct committed by the EXACTECH DEFENDANTS, Plaintiff CHRISTOPHER MATCHETT was caused to sustain and will continue to sustain serious personal injuries, conscious pain and suffering, mental anguish, emotional distress, fear, loss of enjoyment of life and physical disability that will require continued and additional medical treatment.

236. By reason of the foregoing acts, omissions and conduct committed by the EXACTECH DEFENDANTS, Plaintiff CHRISTOPHER MATCHETT was caused to sustain and will continue to sustain disabilities in activities of daily living.

237. By reason of the foregoing acts, omissions and conduct committed by the EXACTECH DEFENDANTS, Plaintiff CHRISTOPHER MATCHETT has sustained and will sustain medical expenses and related economic losses.

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

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

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

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, treble

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

COUNT IV
NEGLIGENCE
AGAINST ALL DEFENDANTS

241. Plaintiffs repeat and reallege the allegations of the paragraphs above as if fully stated herein.

242. The EXACTECH DEFENDANTS had a duty to exercise reasonable care in the design, development, selection, formulation, testing, manufacture, marketing, sale and distribution of the Subject Defective Optetrak devices into the stream of commerce, including a duty to assure that their products did not pose a significantly increased risk of physical bodily harm and adverse events to users and patients.

243. The EXACTECH DEFENDANTS had an obligation to follow the law in the manufacture, design, selecting, testing, assembly, inspection, labeling, packaging, supplying, marketing, selling, advertising, post market surveillance, preparing for use and otherwise distributing the Subject Defective Optetrak devices, including the Defective Implants.

244. The EXACTECH DEFENDANTS had a duty to warn Plaintiff CHRISTOPHER MATCHETT and other consumers of the risks and dangers associated with the Subject Defective Optetrak devices that were known or should have been known to Defendants at the time of the sale to the Plaintiff.

245. The EXACTECH DEFENDANTS' acts and omissions constitute a breach of duty, subjecting Defendants to civil liability for all damages arising therefrom.

246. The EXACTECH DEFENDANTS owed Plaintiff CHRISTOPHER MATCHETT a duty to exercise reasonable care when designing, manufacturing, selecting marketing, advertising, distributing, and selling the Subject Defective Optetrak devices, including the duty to take all reasonable steps necessary to ensure the product was not unreasonably dangerous to their consumers and users.

247. At all times material hereto, the EXACTECH DEFENDANTS had actual knowledge, or in the alternative, should have known through the exercise of reasonable and prudent care, of the hazards and dangers of the Subject Defective Optetrak devices, including the Defective Implants.

248. The EXACTECH DEFENDANTS breached their duty and failed to exercise ordinary care and/or were negligent, reckless and/or wanton in the design, formulation, manufacture, sale, testing, quality assurance, quality control, labeling, marketing, promotion and distribution of the Subject Defective Optetrak devices into interstate commerce because Defendants knew or should have known that these products would cause significant bodily harm and were not safe for use by consumers.

249. The EXACTECH DEFENDANTS knew or should have known that Plaintiff could suffer injury as a result of Defendants' failure to exercise ordinary care as described above.

250. Despite the fact that the EXACTECH DEFENDANTS knew or should have known that the Subject Defective Optetrak devices posed a serious risk of bodily harm to consumers, Defendants continued to manufacture and market the Subject Defective Optetrak devices for implantation into consumers, such as the Plaintiff.

251. The EXACTECH DEFENDANTS failed to exercise due care under the circumstances, and their negligence and recklessness includes the following acts and omissions:

a) Negligently failing to properly and thoroughly select the material that would be used in the Subject Defective Optetrak devices, including the Defective Implants;

b) Negligently failing to properly and adequately test the Subject Defective Optetrak devices and their attendant parts before releasing the devices to market;

c) Negligently failing to properly and adequately package the polyethylene plastic components used in the Subject Defective Optetrak devices in packaging with sufficient barrier layers and/or a second barrier layer containing EVOH;

d) Negligently failing to properly and adequately test the barrier packaging used to package the Subject Defective Optetrak devices' polyethylene plastic component parts;

e) Negligently failing to properly manage, supervise and monitor the production of the polyethylene plastic components used in the Subject Defective Optetrak devices;

f) Negligently failing to conduct sufficient post-market testing and surveillance of the Subject Defective Optetrak devices;

g) Negligently utilizing an outdated, improper and/or ineffective sterilization method for the Subject Defective Optetrak devices' polyethylene plastic

components when other feasible, alternative methods were available and could prevent and/or substantially reduce the risk of the plastic oxidizing, breaking down, fatiguing and/or failing;

h) Negligently failed to utilize feasible, economical alternatives to gamma inert sterilization which would have prevented and/or substantially reduced the risk of oxidation, fatigue and premature failure of the Subject Defective Optetrak devices;

i) Negligently failing to stay apprised of the scientific research and advances of the time which dictated that there were feasible, economical alternatives to gamma inert sterilization and would have prevented and/or substantially reduced the risk of oxidation, fatigue and premature failure of the Subject Defective Optetrak devices;

j) Negligently failing to identify, investigate and/or respond to reports by the Public, Patients and/or surgeons, including Plaintiff CHRISTOPHER MATCHETT, regarding fatigue and failure of the polyethylene plastic components found in the Subject Defective Optetrak devices;

k) Negligently failing to establish a proper, appropriate and effective feedback loop mechanism in order to identify, investigate and/or respond to reports by the Public, Patients and/or surgeons, including Plaintiff CHRISTOPHER MATCHETT, regarding fatigue and failure of the polyethylene plastic

components found in the Subject Defective Optetrak devices so that such reported defects could be remedied;

l) Negligently failing to adequately prevent, identify, mitigate, and fix defective designs and hazards associated with the Subject Defective Optetrak devices in accordance with good practices;

m) Negligently manufacturing, designing, selecting, testing, assembling, inspecting, labeling, packaging, supplying, marketing, selling, advertising, and surveilling the Subject Defective Optetrak devices and their attendant parts;

n) Continuing to negligently manufacture, and distribute the Subject Defective Optetrak devices after the Defendants knew or should have known of their adverse effects and/or the increased early onset failure rates;

o) Negligently failing to select appropriate third-parties to produce the polyethylene inserts used in the Subject Defective Optetrak devices;

p) Negligently failing to properly supervise and monitor the production of the polyethylene plastic components and inserts used in the Subject Defective Optetrak devices;

q) Negligently failing to select appropriate third-parties to produce the barrier packaging used to package the Subject Defective Optetrak devices and/or their polyethylene plastic components and inserts;

r) Negligently failing to properly supervise and monitor the production of the barrier packaging used to package the Subject Defective Optetrak devices and/or their polyethylene plastic components and inserts;

s) Negligently violating applicable state and federal laws and regulations;

t) and in all other ways.

252. 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 Subject Defective Optetrak devices, and otherwise distributing the Subject Defective Optetrak devices.

253. As a direct and proximate result of Defendants' acts and omissions, including their failure to exercise ordinary care in the design, formulation, testing, manufacture, sale, and distribution of the Subject Defective Optetrak devices, Plaintiff CHRISTOPHER MATCHETT was implanted with the Defective Implants and was caused to sustain and will continue 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.

254. By reason of the foregoing acts, omissions and conduct committed by the EXACTECH DEFENDANTS, Plaintiff CHRISTOPHER MATCHETT was caused to sustain and will continue to sustain serious personal injuries, conscious pain and suffering, mental anguish, emotional distress, fear, loss of enjoyment of life and physical disability that will require continued and additional medical treatment.

255. By reason of the foregoing acts, omissions and conduct committed by the EXACTECH DEFENDANTS, Plaintiff CHRISTOPHER MATCHETT was caused to sustain and will continue to sustain disabilities in activities of daily living.

256. By reason of the foregoing acts, omissions and conduct committed by the EXACTECH DEFENDANTS, Plaintiff CHRISTOPHER MATCHETT has sustained and will sustain medical expenses and related economic losses.

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

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

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

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

COUNT V
NEGLIGENT MISREPRESENTATION
AGAINST ALL DEFENDANTS

260. Plaintiffs repeat and reallege the allegations of the paragraphs above as if fully stated herein.

261. The EXACTECH DEFENDANTS owed a duty in all of their undertakings, including the dissemination of information concerning the Subject Defective Optetrak devices to exercise reasonable care to ensure they did not create unreasonable risks of personal injury to others.

262. The EXACTECH DEFENDANTS disseminated to health care professionals and consumers, through published labels, marketing materials, direct communications, and otherwise, information that misrepresented the quality and longevity of the Subject Defective Optetrak devices with the intention that health care professionals and consumers would rely upon that information in their decisions concerning whether to implant the Subject Defective Optetrak devices.

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

264. The EXACTECH 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 Subject Defective Optetrak devices 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.

265. The EXACTECH DEFENDANTS, as designers, manufacturers, sellers, promoters, and/or distributors of the Subject Defective Optetrak devices, knew or reasonably should have known that surgeons would implant the Subject Defective Optetrak devices in reliance on the information disseminated by Defendants, and that the patients implanted with the Subject Defective Optetrak devices would suffer early failure and require revision and/or full replacement surgery because the information disseminated by Defendants and relied upon by health care professionals and consumers, including Plaintiff CHRISTOPHER MATCHETT, was materially inaccurate, misleading, or otherwise false.

266. The EXACTECH DEFENDANTS made material misrepresentations to Plaintiff, Plaintiff's health care professionals, the healthcare community, and the general public, about the Subject Defective Optetrak devices including without limit:

a) Negligently misrepresenting the Subject Defective Optetrak devices' safety risks, including risk of dangerous early failure; polyethylene degradation, fatigue and failure; and increased rate of wear;

b) Negligently representing that their polyethylene plastic components were top-quality or of superior quality than competitors' polyethylene inserts;

c) Negligently representing that the Subject Defective Optetrak devices have lower wear propensities than comparable products;

d) Negligently representing that the Subject Defective Optetrak devices have greater longevity than comparable products;

e) Negligently failing to disclose that the Subject Defective Optetrak devices were failing at a high rate, despite knowledge of same;

f) Negligently failing to disclose that recipients of the Subject Defective Optetrak devices were experiencing problems including osteolysis, loosening of the components, deterioration of the polyethylene, and significant swelling, stiffness and pain, and failing to disclose same;

g) Negligently representing that the Subject Defective Optetrak devices were safe to be used for their intended purposes;

h) Negligently representing that the polyethylene inserts selected for the Subject Defective Optetrak devices were of the same quality as that described in promotion and marketing materials and brochures;

i) Negligently representing that the Subject Defective Optetrak devices had been adequately tested;

j) Negligently representing that the polyethylene inserts selected for the Subject Defective Optetrak devices were developed from the same processes as that described in promotion and marketing materials and brochures;

k) Overstating and or mispresenting the success rate of the Subject Defective Optetrak devices;

l) Overstating the benefits of the proprietary Net Compression Molding system;

m) Negligently failing to comply with applicable state and federal laws and regulations regarding the promotion and advertisement of orthopedic devices;

n) and in all other ways.

267. These representations were made directly by Defendants, their sales representatives, and other authorized agents, and in publications and other written materials directed to health care professionals, medical patients, and the public, including Plaintiff CHRISTOPHER MATCHETT and Plaintiff's physicians.

268. Defendants made these representations with the intent to induce reliance thereon, and to encourage purchase and implantation of the Subject Defective Optetrak devices.

269. Defendants made these representations without any reasonable ground for believing them to be true.

270. Defendants had a duty to accurately and truthfully represent to medical professionals and consumers, including Plaintiff CHRISTOPHER MATCHETT the truth regarding Defendants' claims that the Subject Defective Optetrak devices contained parts and materials that were of the quality and grade that the Defendants represented they were.

271. Defendants had a duty to accurately and truthfully represent to medical professionals and consumers, including Plaintiff CHRISTOPHER MATCHETT the truth regarding Defendants' claims that the Subject Defective Optetrak devices contained parts and materials that had been adequately tested and approved by the Defendants.

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

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

274. Defendants engaged in a nationwide marketing campaign, over-promoting the Subject Defective Optetrak devices in written marketing literature, in written product packaging, and in direct-to-consumer advertising via print and internet advertisements and television commercial ads. Defendants' over-promotion was undertaken by touting the safety, quality and longevity of the Subject Defective Optetrak devices while concealing, misrepresenting, and actively downplaying the serious, severe, and life-threatening risks of harm to patients implanted with the Subject Defective Optetrak devices, when compared to comparable alternative implant options.

275. Defendants negligently misrepresented the Subject Defective Optetrak devices' safety, quality and longevity.

276. As a direct and proximate result of Defendants' acts and omissions, including their failure to provide proper and adequate safety warnings to consumers, users, doctors and patients regarding the Subject Defective Optetrak devices, Plaintiff CHRISTOPHER MATCHETT was implanted with the Defective Implants and was caused to sustain and will continue 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.

277. By reason of the foregoing acts, omissions and conduct committed by the EXACTECH DEFENDANTS, Plaintiff CHRISTOPHER MATCHETT was caused to sustain and will continue to sustain serious personal injuries, conscious pain and suffering, mental anguish, emotional distress, fear, loss of enjoyment of life and physical disability that will require continued and additional medical treatment.

278. By reason of the foregoing acts, omissions and conduct committed by the EXACTECH DEFENDANTS, Plaintiff CHRISTOPHER MATCHETT was caused to sustain and will continue to sustain disabilities in activities of daily living.

279. By reason of the foregoing acts, omissions and conduct committed by the EXACTECH DEFENDANTS, Plaintiff CHRISTOPHER MATCHETT has sustained and will sustain medical expenses and related economic losses.

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

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

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

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

COUNT VI
FRAUDULENT INDUCEMENT
AGAINST ALL DEFENDANTS

283. Plaintiffs repeat and reallege the allegations of the paragraphs above as if fully stated herein.

284. The EXACTECH DEFENDANTS having undertaken to test, study, research, design, formulate, manufacture, inspect, label, package, promote, advertise, market, distribute and sell the Subject Defective Optetrak devices owed a duty to provide accurate and complete information to Plaintiff, his orthopedic surgeon, and the public regarding the safety and efficacy of the devices and their component parts.

285. The EXACTECH DEFENDANTS misled Plaintiff CHRISTOPHER MATCHETT, his medical providers and the public into believing that the Subject Defective Optetrak devices were safe and effective for use in total knee replacement and revision surgeries and engaged in deceptive, misleading and unconscionable promotional, marketing and sales tactics

to convince orthopedic surgeons and patients to use the Subject Defective Optetrak devices even though Defendants knew or should have known that the devices were unreasonably dangerous as alleged herein.

286. The EXACTECH DEFENDANTS failed to warn orthopedic surgeons and the public about the serious risks associated with the use of the Subject Defective Optetrak devices, including their high failure and revision rates and their 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 and/or full replacement surgery in patients.

287. The EXACTECH DEFENDANTS' advertising campaigns, marketing materials and promotional items, by containing affirmative misrepresentations and omissions, falsely and deceptively sought to create the image and impression that the Subject Defective Optetrak devices was safe for human use, had no unacceptable risks and was equivalent to or superior to other similar orthopedic devices on the market.

288. The EXACTECH DEFENDANTS purposefully concealed, failed to disclose, misstated, downplayed and understated the risks associated with the use of the Subject Defective Optetrak devices.

289. The EXACTECH DEFENDANTS, through sales representatives, advertisements, and other marketing and promotional practices and communications as well as through the publication of medical literature including non-peer reviewed studies, deceived orthopedic

surgeons, Plaintiff, other patients, and the public about the true risks of the Subject Defective Optetrak devices.

290. The EXACTECH DEFENDANTS falsely and deceptively kept relevant information from orthopedic surgeons, the FDA and the public, including Plaintiff, regarding the safety of the Subject Defective Optetrak devices.

291. The EXACTECH DEFENDANTS expressly denied that the Subject Defective Optetrak devices created an increased risk of injury and took affirmative steps to prevent the discovery and dissemination of any evidence regarding the increased likelihood of injury from the Subject Defective Optetrak devices including but not limited to the device's high failure and revision rates and 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 and/or full replacement surgery in patients.

292. The EXACTECH DEFENDANTS did not accurately report the results of adverse events by fraudulently and intentionally withholding from the FDA, orthopedic surgeons, Plaintiff, and the public, the truth regarding Subject Defective Optetrak devices' failures for years, all the while undertaking sales, marketing and promotional campaigns to sell the Subject Defective Optetrak devices.

293. The EXACTECH DEFENDANTS received reports of defects in their Subject Defective Optetrak devices from various sources, including those alleged herein, and intentionally withheld this information from the FDA, orthopedic surgeons, Plaintiff, and the public, while

continuing to sell the Subject Defective Optetrak devices for implantation in patients such as Plaintiff.

294. The EXACTECH DEFENDANTS provided disclosures which were inadequate, incomplete, and/or misleading regarding the Optetrak and Optetrak Logic devices' defects.

295. Through the EXACTECH DEFENDANTS' wrongful conduct, Defendants effectively deceived and misled the scientific and medical communities regarding the risks and benefits of the Subject Defective Optetrak devices.

296. The EXACTECH DEFENDANTS failed to fully inform orthopedic surgeons, Plaintiff, other patients, and the public of the true risks associated with the Subject Defective Optetrak devices, which were known to Defendants, and continued to assure orthopedic surgeons and patients that the Subject Defective Optetrak devices were safe and effective device for the purpose of continuing to derive substantial profits from their sale.

297. Through the EXACTECH DEFENDANTS' advertising campaigns, sales and marketing materials and promotional items, Defendants falsely and deceptively misrepresented and omitted numerous material facts regarding the Subject Defective Optetrak devices, including but not limited to the device's high failure and revision rates and 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 and/or full replacement surgery in patients.

298. The EXACTECH DEFENDANTS continued to market the Subject Defective Optetrak devices by providing false and misleading information about the device's safety and

efficacy to Plaintiff and Plaintiff's orthopedic surgeon, despite the fact that possessed reports, clinical information and scientific studies and evidence demonstrating the Optetrak caused serious injuries.

299. Among the EXACTECH DEFENDANTS' numerous misrepresentations and misleading omissions to Plaintiff, Plaintiff's orthopedic surgeon, and the public were Defendants' assurances that the Subject Defective Optetrak devices were a safe device, had a low failure rate; were long-lasting, top-of-the-line, innovative and high performing; and performed as well or better than other similar devices on the market

300. The EXACTECH DEFENDANTS concealed from Plaintiff and Plaintiff's healthcare providers the true and significant risks associated with the Subject Defective Optetrak devices and claimed claiming any failures were due to surgical technique, positioning or patient characteristics, such as body mass index.

301. The EXACTECH DEFENDANTS did not reveal, and in fact concealed, their knowledge of numerous and serious complications and other bad data during their meetings with orthopedic surgeons.

302. Despite their knowledge of the risks with the Subject Defective Optetrak devices, the EXACTECH DEFENDANTS, instructed their sales representatives to continue marketing the Devices for profit.

303. The EXACTECH DEFENDANTS distributed medical literature including non-peer reviewed studies and other communications to orthopedic surgeons which did not adequately

convey the risks of the devices in an effort to mislead them and the public about the serious risks associated with their use.

304. The EXACTECH DEFENDANTS engaged in all the acts and omissions alleged herein with the intent that Plaintiff and Plaintiff's orthopedic surgeon would rely on the misrepresentations, deceptions and concealments in deciding to implant and use the Defective Implants rather than another of product.

305. In addition, the EXACTECH DEFENDANTS engaged in all the acts and omissions alleged herein so that these failure rates would not impact the sale of the company to private equity.

306. Plaintiff and Plaintiff's orthopedic surgeon justifiably relied to their detriment on the Exactech Defendant's intentional and fraudulent misrepresentations in their decision to buy and utilize the Defective Implants and this reliance proximately caused Plaintiff's injuries and damages as alleged herein.

307. Had the EXACTECH DEFENDANTS disclosed accurate, complete and truthful information about the device's high failure and revision rates and 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 and/or full replacement surgery in patients, Plaintiff would not have allowed his orthopedic surgeon to implant the Defective Implants into his body.

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

309. By reason of the foregoing acts, omissions and conduct committed by the EXACTECH DEFENDANTS, Plaintiff CHRISTOPHER MATCHETT was caused to sustain and will continue 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 that will require continued and additional medical treatment.

310. By reason of the foregoing acts, omissions and conduct committed by the EXACTECH DEFENDANTS, Plaintiff CHRISTOPHER MATCHETT was caused to sustain and will continue to sustain disabilities in activities of daily living.

311. By reason of the foregoing acts, omissions and conduct committed by the EXACTECH DEFENDANTS, Plaintiff CHRISTOPHER MATCHETT has sustained and will sustain medical expenses and related economic losses.

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

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

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

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, treble

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

COUNT VII
FRAUDULENT CONCEALMENT
AGAINST ALL DEFENDANTS

315. Plaintiffs repeat and reallege the allegations of the paragraphs above as if fully stated herein.

316. At all times during the course of dealing between the Defendants, Plaintiff, Plaintiff's healthcare providers, and/or the FDA, the Defendants misrepresented the safety of the Subject Defective Optetrak devices for their intended use.

317. In representations to the public, Plaintiff CHRISTOPHER MATCHETT, Plaintiff's healthcare providers, and/or the FDA, the Defendants fraudulently concealed and intentionally omitted material information, including but not limited to the fact that:

a) the subject product was not as safe as other similar devices indicated for knee arthroplasty;

b) that the subject product was manufactured and/or packaged negligently;

c) that the subject product was manufactured and/or packaged defectively;

d) that the subject product was manufactured and/or packaged improperly;

e) that the subject product and/or product packaging was designed negligently;

f) that the subject product and/or product packaging was designed defectively;

g) that the subject product and/or product packaging was designed improperly;

h) that the subject product was packaged in insufficient and/or improper barrier packaging;

i) that the Defendants did not utilize state-of-the-art technology in their design and manufacturing of the Subject Defective Optetrak devices, despite Defendants' representations as to same;

j) that the subject product was defective, and that it caused dangerous side effects, including but not limited to the risks of developing serious and dangerous medical and orthopedic conditions, including but not limited to component loosening, component mal-alignment, substantial early polyethylene wear, pain, irritation and discomfort, as well as the need for additional procedures to remove and replace the device, notwithstanding the Defendants' knowledge of an increased risk of these injuries and side effects over other knee arthroplasty devices; and

k) in all other ways.

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

319. Defendants were under a duty to disclose to the public, Plaintiff CHRISTOPHER MATCHETT, Plaintiff's healthcare providers, and/or the FDA the defective nature of the subject product, including but not limited to the risk of the device's propensity to undergo substantial early polyethylene wear, component loosening and/or other failure causing serious complications including tissue damage, osteolysis, and other injuries, as well as the need for revision and/or full replacement surgery in patients.

320. Defendants had sole access to material facts concerning the defective nature of the subject product and its propensity to cause serious and dangerous side effects, and hence, cause damage to persons who used the Subject Defective Optetrak devices, including the Plaintiff CHRISTOPHER MATCHETT.

321. Defendants' concealment and omissions of material facts concerning, *inter alia*, the safety of the Subject Defective Optetrak devices were made purposefully, willfully, wantonly, and/or recklessly, to mislead the public, Plaintiff CHRISTOPHER MATCHETT and Plaintiff's physicians, hospitals and healthcare providers into reliance on the use of the devices, and to cause them to purchase, prescribe, dispense and/or use the subject product.

322. Defendants knew that the public, Plaintiff CHRISTOPHER MATCHETT, Plaintiff's healthcare providers, and/or the FDA had no way to determine the truth behind the Defendants' concealment and omissions, as set forth herein.

323. Plaintiff, as well as Plaintiff's doctors, healthcare providers, and/or hospitals, reasonably relied on facts revealed which negligently, fraudulently and/or purposefully did not include facts that were concealed and/or omitted by the Defendants.

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

325. By reason of the foregoing acts, omissions and conduct committed by the EXACTECH DEFENDANTS, Plaintiff CHRISTOPHER MATCHETT was caused to sustain and will continue to sustain serious personal injuries, conscious pain and suffering, mental anguish, emotional distress, fear, loss of enjoyment of life and physical disability that will require continued and additional medical treatment.

326. By reason of the foregoing acts, omissions and conduct committed by the EXACTECH DEFENDANTS, Plaintiff CHRISTOPHER MATCHETT was caused to sustain and will continue to sustain disabilities in activities of daily living.

327. By reason of the foregoing acts, omissions and conduct committed by the EXACTECH DEFENDANTS, Plaintiff CHRISTOPHER MATCHETT has sustained and will sustain medical expenses and related economic losses.

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

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

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

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

COUNT VIII
CONSUMER FRAUD AND DECEPTIVE TRADE PRACTICES
VIOLATIONS OF GBL §§ 349 AND 350
AGAINST ALL DEFENDANTS

331. Plaintiffs repeat and reallege the allegations of the paragraphs above as if fully stated herein.

332. The allegations contained in previous paragraphs set forth specific representations the EXACTECH DEFENDANTS have made to consumers, physicians, and other healthcare providers through their advertising and promotional materials (some of which are reproduced above). These representations were made by the EXACTECH DEFENDANTS on an ongoing and repeated basis, and, as specifically relevant here, at various points prior to 2014.

333. The representations made by the EXACTECH DEFENDANTS were materially deceptive in that they asserted that their defective knee implants were equivalent or superior to other similar devices on the market, utilized innovative technologies which resulted in improved outcomes for patients and longevity of the implants, when in fact, the devices had a high failure and revision rates and caused 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.

334. In such representations, the EXACTECH DEFENDANTS willfully ignored or avoided the reports, scientific data and studies concluding that their defective knee implants had high failure and revision rates so that it could continue to sell the Opetrak Logic devices and profit from their sales.

335. The EXACTECH DEFENDANTS willfully failed to take protective measures, such as changing their products, packaging, guidelines, instructions, and/or warnings, which would have prevented Patients such as CHRISTOPHER MATCHETT from being implanted with the defective devices and thereafter developing and suffering long-term medical problems as a result, including early polyethylene wear, component loosening and/or other failure, tissue damage, osteolysis, pain, inflammation, stiffness, and other injuries as well as the need for revision and/or full replacement surgery or surgeries.

336. The acts, omissions, and practices of Defendant ABBOTT alleged herein constitute deceptive trade practices within the meaning of N.Y.GEN.BUS.LAW § 349 and § 350.

337. Plaintiffs have standing to bring these claims because they have been injured in that they suffered and lost money as a result of the EXACTECH DEFENDANTS' deceptive trade practices.

338. The EXACTECH DEFENDANTS engaged in deceptive trade practices by and through the following without limit:

a) Developed a systematic, pervasive, effective, and manipulative marketing scheme designed to make Patients, including Plaintiff, and healthcare providers believe that their Subject Defective Optetrak devices were safe; had a low failure rate; were

long-lasting, top-of-the-line, innovative and high performing; and performed as well or better than other similar devices on the market;

b) Acted, used and employed unconscionable commercial practices, deception, fraud, false pretenses, false promises and misrepresentations;

c) Knowingly concealed, suppressed and omitted material facts with the intent that consumers, including the Plaintiff herein and his physicians and medical providers, rely upon such concealment, suppression and omission, in connection with the sale, advertisement and promotion of Subject Defective Optetrak devices;

d) Representing that the Subject Defective Optetrak devices had characteristics, uses or benefits that they did not have;

e) Engaging in fraudulent or deceptive conduct that creates a likelihood of confusion or misunderstanding;

f) Making monetary contributions to endear itself to the medical profession and win its favor; and

g) In all other ways.

339. The EXACTECH DEFENDANTS intended for Patients like CHRISTOPHER MATCHETT and healthcare providers to rely on their representations and advertisements regarding the Subject Defective Optetrak devices, so that the EXACTECH DEFENDANTS would profit from their sale.

340. The Defendants' deceptive conduct was directed at physicians, healthcare providers, Patients, including Plaintiff, and the public in order to create demand and sell the Optetrak Logic defective devices.

341. Each aspect of the EXACTECH DEFENDANTS' conduct combined to artificially create sales of their Subject Defective Optetrak devices, including the Logic devices and specifically the Defective Implants, and to deceive the public at large and Plaintiff, CHRISTOPHER MATCHETT, in particular.

342. As a result of the deceptive trade practices engaged in by the EXACTECH DEFENDANTS, patients such as Plaintiff paid and will continue to pay large sums of money to care for and treat their injuries, including past and future medical costs and expenses.

343. The EXACTECH DEFENDANTS' intentional, deceptive, unconscionable, immoral, and fraudulent representations and material omissions to Plaintiff CHRISTOPHER MATCHETT, physicians, and consumers constitute deceptive trade practices.

344. Under New York law, the EXACTECH DEFENDANTS are under a duty to not act deceptively in design, labeling, development, manufacture, promotion, and sale of their consumer products including the Subject Defective Optetrak devices.

345. Had the EXACTECH DEFENDANTS not engaged in the deceptive conduct described above, CHRISTOPHER MATCHETT would not have been implanted with the defective and dangerous product and would not have incurred related injuries and damages.

346. The EXACTECH DEFENDANTS had actual knowledge of the defective and dangerous condition of the Subject Defective Optetrak devices, including their defective

polyethylene plastic tibial inserts, and failed to take any action to cure such defective and dangerous conditions.

347. Plaintiff CHRISTOPHER MATCHETT and healthcare providers relied upon the EXACTECH DEFENDANTS misrepresentations and omissions in deciding to purchase and use the Subject Defective Optetrak devices, costs which were passed off to Plaintiff as a patient and consumer.

348. Plaintiff CHRISTOPHER MATCHETT and healthcare providers were misled into not objecting to the use of the Subject Defective Optetrak devices as a direct and proximate result of the EXACTECH DEFENDANTS misrepresentations, omissions, and deceptive marketing campaigns.

349. As a direct and proximate result foregoing acts, omissions, and conduct committed by the EXACTECH DEFENDANTS, Plaintiff CHRISTOPHER MATCHETT was implanted with the Defective Implants and was caused to sustain and will continue to sustain serious personal injuries, conscious pain and suffering, mental anguish, emotional distress, fear, loss of enjoyment of life and physical disability that will require continued and additional medical treatment.

350. By reason of the foregoing acts, omissions, and conduct committed by the EXACTECH DEFENDANTS, Plaintiff CHRISTOPHER MATCHETT was caused to sustain mental anguish, emotional distress, fear, loss of enjoyment of life, medical expenses, and financial losses, in the past and continuing into the future.

351. By reason of the foregoing acts, omissions and conduct committed by the EXACTECH DEFENDANTS, Plaintiff CHRISTOPHER MATCHETT was caused to sustain disabilities in activities of daily living.

352. By reason of the foregoing acts, omissions and conduct committed by the EXACTECH DEFENDANTS, Plaintiff CHRISTOPHER MATCHETT has sustained and will sustain medical expenses and related economic losses.

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

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

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

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

COUNT IX
BREACH OF EXPRESS WARRANTY
AGAINST ALL DEFENDANTS

356. Plaintiffs repeat and reallege the allegations of the paragraphs above as if fully stated herein.

357. At all times herein mentioned, the Defendants manufactured, packaged, distributed, recommended, merchandized, advertised, promoted, and sold the Subject Defective Optetrak devices, including the Defective Implants.

358. Defendants expressly represented and warranted that the Subject Defective Optetrak devices were safe and effective devices for those patients requiring a knee replacement.

359. The Subject Defective Optetrak devices manufactured, packaged, and sold by Defendants did not conform to these express representations and warranties because they caused serious injury to the Plaintiff when used as recommended and directed.

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

361. The Subject Defective Optetrak devices were placed 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.

362. Plaintiff CHRISTOPHER MATCHETT and Plaintiff's surgeon relied on Defendants' express representations and warranties about the safety and efficacy of the Subject

Defective Optetrak devices, including the Defective Implants. Plaintiff and Plaintiff's surgeon reasonably relied upon the skill and judgment of Defendant as to whether the Defective Implants were of merchantable quality and safe and fit for their intended use.

363. The Defendant breached the aforesaid express warranties as the Subject Defective Optetrak devices were not fit for their intended purposes and uses.

364. As a direct and proximate result of Defendants' breach of warranty, Plaintiff CHRISTOPHER MATCHETT was implanted with the Defective Implants and was caused to sustain and will continue 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.

365. By reason of the foregoing acts, omissions and conduct committed by the EXACTECH DEFENDANTS, Plaintiff CHRISTOPHER MATCHETT was caused to sustain and will continue to sustain serious personal injuries, conscious pain and suffering, mental anguish, emotional distress, fear, loss of enjoyment of life and physical disability that will require continued and additional medical treatment.

366. By reason of the foregoing acts, omissions and conduct committed by the EXACTECH DEFENDANTS, Plaintiff CHRISTOPHER MATCHETT was caused to sustain and will continue to sustain disabilities in activities of daily living.

367. By reason of the foregoing acts, omissions and conduct committed by the EXACTECH DEFENDANTS, Plaintiff CHRISTOPHER MATCHETT has sustained and will sustain medical expenses and related economic losses.

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

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

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

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

## COUNT X
## BREACH OF IMPLIED WARRANTY
## AGAINST ALL DEFENDANTS

371. Plaintiffs repeat and reallege the allegations of the paragraphs above as if fully stated herein.

372. Prior to Plaintiff CHRISTOPHER MATCHETT'S 2014 and 2018 surgeries, and at all relevant times in this action, the EXACTECH DEFENDANTS tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold the Subject Defective Optetrak devices for implantation into consumers, such as Plaintiff, by orthopedic surgeons in the United States.

373. EXACTECH DEFENDANTS impliedly warranted, through their marketing, advertising, distributors and sales representatives, that the Subject Defective Optetrak devices were of merchantable quality and fit for the ordinary purposes and uses for which they were sold.

374. The Subject Defective Optetrak devices were not of merchantable quality nor fit for the ordinary purposes and uses for which they were sold and did not meet the expectations of consumers.

375. The Subject Defective Optetrak devices manufactured and supplied by the EXACTECH DEFENDANTS were not of merchantable quality and were not fit for the ordinary and/or particular purpose for which they were intended as physicians and patients would expect the components to be properly manufactured, treated to prevent oxidation, and packaged and stored as to avoid premature degradation of component materials.

376. Plaintiff CHRISTOPHER MATCHETT and/or Plaintiff's physician reasonably relied upon the skill and judgment of the EXACTECH DEFENDANTS as to whether the Subject Defective Optetrak devices were of merchantable quality and safe for their intended and particular use and purpose.

377. Contrary to such implied warranties, the Subject Defective Optetrak devices were not of merchantable quality or safe for their intended and particular use and purpose, because the EXACTECH DEFENDANTS failed 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.

378. As a direct and proximate result of the EXACTECH DEFENDANTS' acts and omissions, including breach of implied warranties, Plaintiff was implanted with a Device and was caused to sustain and will continue 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.

379. By reason of the foregoing acts, omissions and conduct committed by the EXACTECH DEFENDANTS, Plaintiff CHRISTOPHER MATCHETT was caused to sustain and will continue to sustain serious personal injuries, conscious pain and suffering, mental anguish, emotional distress, fear, loss of enjoyment of life and physical disability that will require continued and additional medical treatment.

380. By reason of the foregoing acts, omissions and conduct committed by the EXACTECH DEFENDANTS, Plaintiff CHRISTOPHER MATCHETT was caused to sustain and will continue to sustain disabilities in activities of daily living.

381. By reason of the foregoing acts, omissions and conduct committed by the EXACTECH DEFENDANTS, Plaintiff CHRISTOPHER MATCHETT has sustained and will sustain medical expenses and related economic losses.

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

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

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

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

## COUNT XI
## LOSS OF CONSORTIUM AND SERVICES
## BY PLAINTIFF REBECCA MATCHETT, INDIVIDUALLY,
## AGAINST ALL DEFENDANTS

385. Plaintiffs repeat and reallege the allegations of the paragraphs above as if fully stated herein.

386. At all relevant times, Plaintiff REBECCA MATCHETT was and is the lawfully wedded wife of Plaintiff CHRISTOPHER MATCHETT, and as such, was and is entitled to the services, consortium and society of CHRISTOPHER MATCHETT.

387. As a result of the foregoing strict products liability, negligence, and negligent misrepresentations by the EXACTECH DEFENDANTS, Plaintiff REBECCA MATCHETT was and continues to be deprived of the services, consortium and society of CHRISTOPHER MATCHETT.

388. As a result of the foregoing strict products liability, negligence, and negligent misrepresentations by the EXACTECH DEFENDANTS, Plaintiff REBECCA MATCHETT is entitled to monetary damages for her losses.

389. As a result of the foregoing, Plaintiff REBECCA MATCHETT is entitled to monetary damages for her non-economic and economic injuries.

390. As a result of the foregoing, Plaintiff REBECCA MATCHETT demands judgment in an amount that exceeds the jurisdictional minimum.

## DEMAND FOR JURY TRIAL

Plaintiffs demand trial by jury pursuant to Rule 38 of the Federal Rules of Civil Procedure and the Seventh Amendment of the U.S. Constitution.

## PRAYER FOR RELIEF

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

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

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

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

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

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

f) For punitive damages on Counts I, II, III, IV, V, VI, VII, VIII, IX, and X in in an amount in excess of any jurisdictional minimum of this Court and in an amount sufficient to deter similar conduct in the future and punish the Defendants for the conduct described herein;

g) For attorneys' fees, expenses and costs of this action; and

h) For such further and other relief as this Court deems necessary, just and proper.

Dated: July 9, 2022

Respectfully submitted,

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