**UNITED STATES DISTRICT COURT**

**EASTERN DISTRICT OF LOUISIANA**

| | | |
|---|---|---|
| **GARY J. CHERAMIE,** | * | **CIVIL ACTION NO.** |
| | * | |
| **Plaintiff,** | * | |
| | * | **SECTION " "** |
| **VERSUS** | * | |
| | * | |
| **EXACTECH, INC. and EXACTECH US, INC.** | * | **MAG. DIV.** |
| | * | |
| | * | |
| **Defendant.** | * | |

* * * * * * * * * * * * * * * * * * * * * * * * * * *

## COMPLAINT

**NOW INTO COURT**, through undersigned counsel, comes plaintiff Gary J. Cheramie, who respectfully represents the following to this Honorable Court:

## PARTIES

1.

Plaintiff Gary J. Cheramie is an individual of the full age of majority, who resides and is domiciled in the Parish of Orleans, State of Louisiana.

2.

Defendant Exactech, Inc. is a Florida corporation with its principal place of business at 2320 NW 6th Court, Gainesville, Florida 32653.

3.

Defendant Exactech US, Inc., a subsidiary of Defendant Exactech, Inc., is a Florida corporation with its principal place of business at 2320 NW 6th Court, Gainesville, Florida 32653.

## JURISDICTION AND VENUE

4.

This Honorable Court has jurisdiction over this civil action pursuant to 28 U.S.C. § 1332, in that this matter in controversy exceeds the sum or value of $75,000, exclusive of interest and costs, and there is complete diversity between the parties.

5.

Venue is proper in this judicial district under 28 U.S.C. § 1391(b), in that a substantial part of the events or omissions giving rise to this claim occurred in this district. Venue is also proper in this Court pursuant to 28 U.S.C. § 1391 because Defendant has sufficient minimum contacts with the State of Louisiana and intentionally availed themselves of the market within Louisiana through the promotion, sale, marketing, and distribution of its products.

## NATURE OF THE CASE

6.

Plaintiff, Gary Cheramie, files this Complaint against Exactech, Inc. and its subsidiary, Exactech US, Inc. (collectively, "Exactech" or "Defendant"), for damages deemed just and proper arising from the injuries Plaintiff suffered and continues to suffer as a direct and proximate result of Defendant's manufacturing, designing, testing, assembling, device packaging, quality control, storing, distributing, supplying, warranting and/or unfair and deceptive marketing, advertising and selling the Truliant Total Knee System ("Truliant Device"), containing a defective polyethylene tibial insert packaged in a non-conforming bag, hereinafter referred to as the "defective insert".

7.

Defendant, directly or through its agent, distributor and/or employees designed, assembled, manufactured, packaged, labeled, distributed, marketed, warranted, and sold the defective insert for use as components of the Truliant Device throughout the United States and, specifically, Louisiana.

8.

The Truliant Device was manufactured, marketed, and sold by Defendant during the years 2017 to 2022, containing defective inserts stored in out-of-specification, non-conforming bags, which lacked a protective barrier necessary to prevent air from reaching the insert during storage, thereby causing premature wear, and resulting in the necessity for surgical revisions.

9.

Although Defendant obtained FDA 510(k) clearance under the Medical Device Amendments of 1976 to the Food Device Cosmetic Act (MDA) for sale and distribution of the Truliant Device during the years 2017-2022, this type of clearance did not involve clinical testing by the FDA for safety and effectiveness or quality control of the Truliant Device or any of its components.

10.

Exactech retained sole responsibility for safety and effectiveness of the Truliant Device, specifically during the times when it was marketed and sold with the defective insert, including quality control procedures.

11.

Exactech touted the Truliant Device as being high performance in its product brochues and promised that it had longevity such that patients can have every confidence in the Truliant Device.

**FACTUAL BACKGROUND**

12.

Beginning in or about 2019, Plaintiff sought treatment for pain in his left knee at the Bone & Joint Clinic in Gretna, Louisiana and was advised by his physician that he would need a total knee replacement.

13.

On June 1, 2021, Plaintiff underwent knee replacement surgery on his left knee at the Bone & Joint Clinic and received a Truliant Tibial Insert Posterior Stabilized (Serial No. S093050), which included the defective insert.

14.

Although he initially appeared to recover after the knee replacement surgery, Plaintiff began developing significant pain in his left knee and apparent loosening of the device within only a few weeks of the surgery, and his pain continued to increase over the next several months despite following the physical therapy routine recommended by his doctor.

15.

Over a year after his surgery, Plaintiff continues to have significant pain and instability in his left knee due to the Truliant Device and has had worsening pain, instability and swelling, is unable to bear weight on his knee, and cannot walk or exercise without pain and assistance.

16.

Recently, Plaintiff was informed by his physician that the only way to correct the problem and potentially alleviate the pain in his left knee is to have revision surgery, which Plaintiff intends to have done.

## THE DEFECTIVE INSERT

17.

On August 30, 2021, Exactech issued a partial recall of the Truliant polyethylene inserts implanted between 2017 and 2022, labeled with a certain limited shelf life. That partial recall stated that "inserts were packaged in vacuum bags that lacked an additional oxygen barrier layer." See, https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?ID+189266

18.

Then, on February 7, 2022, Defendant expanded its recall, regardless of shelf-life, and issued an "Urgent Medical Device Correction" which informed health care professionals that:

> After extensive testing, we have confirmed that most of our inserts manufactured since 2004 were packaged in out-of-specification (referred to hereafter as "nonconforming") vacuum bags that are oxygen resistant but do not contain a secondary barrier layer containing ethylene vinyl alcohol (EVOH) that further augments oxygen resistance. **The use of these non-conforming bags may enable increased oxygen diffusion to the UHMWPE (ultra-high molecular weight polyethylene) insert, resulting in increased oxidation of the material relative to inserts packaged with the specified additional oxygen barrier layer. Over time, oxidation can severely degrade the mechanical properties of conventional UHMWPE, which, in conjunction with other surgical factors, can lead to both accelerated wear debris production and bone loss, and/or component fatigue cracking/fracture, all leading to corrective revision surgery.**

See, https://www.exac.com/wp-content/uploads/2022/04/Exactech-DHCP-letter.4.6.2022.pdf

19.

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

20.

Exactech also advised surgeons that revision surgery should be considered for patients who exhibit premature polyethylene wear and reported in its notification letter that:

> Premature wear of the plastic insert of your knee replacement can lead to the need for additional surgery (also known as revision surgery). *Id.*

21.

Upon information and belief, Defendant knew, or should have known, that between 2017 and 2022, when Plaintiff underwent implant surgery, the defective insert in the Truliant Device was being packaged in bags that did not comply with its own specifications for protection. This defective packaging caused increased release of tibia-femoral wear debris from the polyethylene inserts implanted in Plaintiff. This, in turn, increased the particle burden, which contributed to loosening and bone loss documented in her successive failed knee replacement procedures.

22.

Furthermore, upon information and belief, Defendant knew, or should have known, of the premature wear of the defective inserts based on patient complaints reported in the Australian Orthopaedic Association National Joint Replacement Registry demonstrating significantly higher overall revision rates due to loosening, bone loss and pain occurring with Exactech's Optetrak tibial inserts, which utilized the same defective packaging as the Truliant Devices.

23.

Plaintiff could not, by the exercise of reasonable care, have discovered the dangers related to the defective tibial insert prior to February 7, 2022, when Defendant issued a recall of the defective insert and notified the healthcare providers and patients.

24.

Defendant designed, marketed, advertised, and sold the defective tibial insert to the Bone & Joint Clinic in Gretna, Louisiana for implantation in Plaintiff's right knee replacement surgery on June 1, 2021.

## EXACTECH VIOLATIONS

25.

Upon information and belief, Defendant received numerous reports of adverse events relating to injuries caused by the defective tibial insert but failed to report these events in violation of FDA's requirements in reporting adverse events. 21 U.S.C. § 352(t).

26.

Upon information and belief, Defendant engaged in a campaign of misinformation wherein any incidents of early failures were blamed on surgeons or patients rather than the defective tibial insert.

27.

Based on information and belief, Defendant's Truliant Devices with their defective inserts are considered adulterated pursuant to 21 U.S.C. § 351 because, among other things, they failed to meet established performance standards, and/or methods, facilities, or controls used for their manufacture, packaging, storage, or installation, and are not in conformity with federal requirements in accordance with Current Good Manufacturing Practices ("cGMP") for medical devices. *See* 21 U.S.C. § 351; 21 C.F.R. § 820, et seq.

28.

Based on information and belief, Defendant's Truliant Devices with a defective insert are considered 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.

29.

If Defendant complied with the federal requirements regarding cGMP, Defendant's knee implant devices would have been manufactured properly and would not have resulted in injuries to Plaintiff.

## CAUSES OF ACTION

### COUNT I – STRICT LIABILITY – UNREASONABLY DANGEROUS IN COMPOSITION

30.

The Truliant Knee Implant System containing the defective insert was unreasonably dangerous as manufactured, packaged, distributed, marketed and/or sold by Defendant, as defined in the Louisiana Products Liability Act ("LPLA"), Louisiana Revised Statute 9:2800.55.

31.

The defective components in the Truliant Device were and continue to be a substantial factor in causing Plaintiff's injuries.

32.

Defendant is strictly liable for the defective condition of the Truliant Device; the distribution, marketing, and/or sale of the defective insert; and the injuries sustained by Plaintiff.

### COUNT II – STRICT LIABILITY – UNREASONABLY DANGEROUS IN DESIGN

33.

Defendant had a duty to design and package the defective insert for the Truliant Device in a manner that did not present an unreasonable risk of harm or injury to users and patients exposed to their danger, including Plaintiff.

34.

The designs of the packaging of the defective insert for the Truliant Device were unreasonably dangerous for its expected, intended, and/or foreseeable uses, functions, and purposes, as defined in the Louisiana Products Liability Act, Louisiana Revised Statute 9:200.56.

35.

The defective tibial insert for the Truliant Device was not reasonably safe as designed, distributed, marketed, delivered and/or sold by Defendant.

36.

The design defects in the defective tibial insert for the Truliant Device and its packaging existed when the device left the Defendant's control.

37.

Plaintiff's physicians implanted the defective tibial insert for the Truliant Device in the manner in which they were intended and recommended to be used, making such use reasonably foreseeable to Defendant.

38.

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

39.

Feasible, safer, alternative designs and packaging providing the same functional purpose were available to Defendant at the time the defective tibial insert for the Truliant Device was designed, packaged, and offered for sale in the market.

**COUNT III – STRICT LIABILITY –**
**UNREASONABLY DANGEROUS BECAUSE OF INADEQUATE WARNING**

40.

Defendant failed to provide adequate warnings with reasonable care regarding dangers in the use and handling of the Truliant Device, as defined in the Louisiana Products Liability Act, Louisiana Revised Statute 9:2800.57.

41.

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

42.

The warnings that accompanied the Truliant Device, with the defective tibial insert, and its packaging were inadequate, thereby making the product not reasonably safe for its expected, intended, and/or foreseeable uses, functions, and purposes.

43.

In particular, Defendant failed to adequately disclose the danger of the defective tibial insert, particularly when used with a size four femur in combination with a size four tray, as in Plaintiff's implant surgery, given its propensity to undergo substantial early failure due to component loosening, tissue damage, bone loss, osteolysis, other complications, as well as the need for revision surgery.

44.

Defendant knew of the defective insert's increased risk of harm to Plaintiff and other consumers and that warnings would have been feasible and effective in preventing Plaintiff's injuries.

**COUNT IV – UNREASONABLY DANGEROUS BECAUSE OF NON-CONFORMITY TO EXPRESS WARRANTY**

45.

At the time Defendant applied for the 510(k) premarket approval of its Truliant Device with the defective insert, Defendant warranted that all components would be supplied, properly packaged according to specifications, and Defendant would conduct package validation testing. Defendant failed to perform the package testing over the course of sales from 2017 through 2022.

46.

Defendant warranted that it would comply with 21 CFR Part 820 of the FDA regulations for Current Good Manufacturing Practice (cGMP) requirements to ensure safety and effectiveness of its medical devices, including packaging of finished devices under subpart K and L (subsection 130, 140, 150 of part 820). Defendant violated this warranty.

47.

Defendant, in its marketing and advertising, warranted less polyethylene wear from the Truliant Device as compared to other manufacturers' devices. Defendant breached this warranty.

48.

Defendant was both manufacturer and seller of the Truliant Device and warranted against redhibitory defects regarding defective components when used. Because Defendant was in bad

faith and failed to reveal the defects, Defendant is liable for reimbursement of the expenses, damage, and attorneys' fees under Louisiana Civil Code Article 2345.

**COUNT V – VIOLATION OF LOUISIANA UNFAIR TRADE PRACTICE AND CONSUMER PROTECTION LA. R. S. 51:1401 *ET SEQ***

49.

In order to obtain a commercial advantage, Defendant was engaged in disseminating inaccurate, false, and/or misleading information about the Truliant Device to health care professionals in the State of Louisiana, including Plaintiff's physicians and medical providers, with a reasonable expectation that such information would be used and relied upon by physicians and medical providers throughout the State of Louisiana, including but not limited to:

a. false representations regarding the duration and survival of the components lasting longer than other knee implants because of proprietary use of materials and processes to give superior wear characteristics; and

b. promotional materials of successful outcomes with survival rates of 15 to 20 years despite adverse event reports.

50.

Plaintiff was a consumer of Defendant's defective insert in the Truliant Device and was wrongfully billed and charged as a result.

**DAMAGES**

51.

By reason of the foregoing acts, omissions and conduct committed by Defendant, Plaintiff sustained and continues to sustain serious personal injuries, severe pain and suffering, physical disability, mental anguish, emotional distress, fear, loss of enjoyment of life, medical expenses,

and financial losses. Plaintiff will also sustain future damages, including but not limited to cost of medical care; rehabilitation; home health care; loss of earning capacity; mental and emotional distress and pain and suffering. Accordingly, Plaintiff is seeking compensatory and special damages, including attorneys' fees and costs, and all other available remedies under the law.

**JURY DEMAND**

52.

Plaintiff respectfully demands a trial by jury of all claims that are so triable.

**PRAYER**

**WHEREFORE**, Plaintiff, Gary J. Cheramie, respectfully prays that, after all due proceedings, judgment be entered in his favor and against Defendants, Exactech, Inc. and Exactech US, Inc., for all available damages, together with attorney's fees, costs, judicial interest and all other legal and equitable relief to which Plaintiff may be entitled.

Respectfully submitted,

**ANDREW L. KRAMER, T.A. (Bar No. 23817)**
201 St. Charles Avenue, Suite 2504
New Orleans, Louisiana 70170
Telephone: (504) 599-5623
Facsimile: (866) 667-3890

/and/

**Eberhard D. Garrison (LA No. 22058)**
BARTLETT & GARRISON, L.L.C.
855 Baronne Street
New Orleans, Louisiana 70113
Telephone: (504) 354-2104
Facsimile: (844) 424-3864
garrison@bartlettgarrison.com

**Counsel for Plaintiff**