IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION

LORI MORRISON & TIMOTHY MORRISON	§	
	§	
	§	
VS.	§	C.A. NO._____
	§	
EXACTECH, INC. & EXACTECH US, INC., both dba "EXACTECH"	§	
	§	

PLAINTIFFS' ORIGINAL COMPLAINT

Plaintiffs LORI AND TIMOTHY MORRISON file this Plaintiffs' Original Complaint, complaining of Defendants EXACTECH, INC. & EXACTECH US, INC., both dba "EXACTECH," and for cause of action, state the following:

A. JURY DEMAND

1. Pursuant to Rules 38 and 39 of the Federal Rules of Civil Procedure, Plaintiffs request a jury trial of this matter. Accordingly, Plaintiffs tendered the proper jury fee with the filing of Plaintiffs' Original Complaint.

B. PARTIES

2. Plaintiffs LORI and TIMOTHY MORRISON are married individuals residing in the state of Texas, in the Northern District of Texas.

3. Defendant EXACTECH, INC. is a Florida Corporation, doing business in the State of Texas, with its principal place of business in Florida. It does business in Texas and elsewhere as "Exactech." It has no designated agent for service of process in Texas. Service of process therefore may be accomplished under the Texas Long Arm Statute, Sections 17.041 et. seq. of the Texas Civil Practice and Remedies Code, by serving duplicate copies of process upon the Texas Secretary of State as follows:

The Secretary of the State of Texas
P.O. Box 12887
Austin, Texas 78711-2887

The Secretary of State will then mail a copy of the process by registered or certified mail, return receipt requested, to the President/Chief Executive Officer or officer or agent for service of Defendant EXACTECH, INC. at its home office address:

Exactech, Inc.
2320 NW 66th Court
Gainesville, FL 32653

4. Defendant EXACTECH US, INC. is a Florida Corporation, doing business in the State of Texas, with its principal place of business in Florida. It does business in Texas and elsewhere as "Exactech." It has no designated agent for service of process in Texas. Service of process therefore may be accomplished under the Texas Long Arm Statute, Sections 17.041 et. seq. of the Texas Civil Practice and Remedies Code, by serving duplicate copies of process upon the Texas Secretary of State as follows:

The Secretary of the State of Texas
P.O. Box 12887
Austin, Texas 78711-2887

The Secretary of State will then mail a copy of the process by registered or certified mail, return receipt requested, to the President/Chief Executive Officer or officer or agent for service of Defendant EXACTECH US, INC. at its home office address:

Exactech US, Inc.
2320 NW 66th Court
Gainesville, FL 32653

C. JURISDICTION AND VENUE

5. The court has jurisdiction over the lawsuit under section 1332(a)(1) of Title 28 of the United States Code because the Plaintiffs and the Defendants are citizens of different states and the amount in controversy exceeds $75,000, exclusive of interest and costs.

6. Venue is proper in this district because a substantial part of the events or omissions giving rise to the claim occurred in this district.

7. At all times relevant to these causes of action, Defendants had continuing and systematic contacts with the State of Texas and this judicial district by delivering their products into the stream of commerce with the expectation that they would reach the State of Texas and this judicial district. Further, Defendants had minimum contacts with Texas and this judicial district and were doing business in Texas and this judicial district by, among other things, distributing, marketing and selling their products to residents of the State of Texas and this judicial district. Plaintiffs' causes of action arise out of such contacts and business.

D. CONDITIONS PRECEDENT

8. All conditions precedent to Plaintiffs' right to recover the relief sought herein have occurred or have been performed.

E. FACTS

9. This lawsuit arises out of the implantation of an Exactech Connexion GXL Liner Hip Implant ("the Defective Device") during a left total hip arthroplasty surgical procedure performed on Plaintiff Lori Morrison by Dr. Jay Mabry at Baylor Medical Center in Dallas, Texas, in the Northern District of Texas on November 11, 2013 ("the Surgery").

10. Dr. Joel Wells removed the Defective Device during a revision left arthroplasty surgery at UT Southwestern Medical Center in Dallas, Texas on May 14, 2020. Dr. Wells determined that the Defective Device sustained "catastrophic poly wear" and "metallosis." He noted in his operative report that Plaintiff Lori Morrison had "significant metallosis throughout her hip" and the "head [of the Defective Device] had completely worn out the poly[ethylene]."

11. Dr. Jay Mabry performed the Surgery in November of 2013 in accordance with all applicable standards of medical care, and the Defective Device did not fail because of any breach of medical care on the part of Dr. Mabry or any other healthcare provider.

12. The Defective Device was subjected to no trauma during the time it was implanted, and the Defective Device did not fail because of any exposure to trauma.

13. The loading applied to the Defective Device during the time it was implanted was within the expected range, and the loading was insufficient to cause the Defective Device to fail.

14. Plaintiff Lori Morrison had no comorbidities or biological conditions that caused, or contributed to cause the Defective Device to fail.

15. The Defective Device failed catastrophically in approximately 6 years due to significant polyethylene wear and osteolysis.

16. Total hip arthroplasty (THA) typically is one of the most successful surgical device implant interventions, with a 25 year survivorship rate of near 58 percent. The primary reasons for THA revisions are instability, infections, and loosening. Early failures of THAs in the short-term and medium-term due to significant polyethylene wear and osteolysis are relatively rare in comparison to failures caused by other factors.

17. The Defective Device was prone to a high rate of early failure from normal wear and severe secondary osteolysis due to a combination of defective implant material and defective design.

18. On June 24, 2021, Defendants Exactech, Inc. & Exactech, US, Inc. ("the Exactech Defendants") provided doctors with a "Frequently Asked Questions" document indicating that Exactech was aware of a "higher risk of premature wear" with its GXL liners. But Exactech told doctors it was "not recalling the GXL liner because they claimed it "is considered safe and effective and performs as intended." The Exactech Defendants left it to the surgeons to contact the patients directly. The Exactech defendants did not contact patients who received the implants directly.

19. Five days later, on June 29, 2021, the Exactech Defendants initiated a Class II recall for Connexion GXL acetabular polyethylene liner components used in many of Exactech's hip replacement implant systems. This recall included the Defective Device. Exactech initiated the recall because Exactech became aware that its hip implants with the Connexion GXL liners were displaying unexpectedly high rates of early failure. A defect in the polyethylene Connexion GXL liner components was causing higher than normal early failure rates in Exactech implants incorporating the Connexion GXL liner components.

20. Medical device manufacturers such as the Exactech defendants have a legal duty to ensure that their products are safe and free of design, marketing, and manufacturing defects that could cause harm to patients who use the devices. The Exactech Defendants breached that duty in this case.

CAUSES OF ACTION

Count 1: Strict Products Liability

21. At all times material to this action, "the Exactech Defendants" were in the business of designing, testing, approving, manufacturing, marketing, distributing, selling and/or supplying devices, such as the Defective Device, for use in Texas and elsewhere throughout the United States.

22. At the time the Defective Device left the control of Exactech Defendants, it was defectively designed and unreasonably dangerous to a person who might reasonably be expected to use it. Specifically, the Defective Device was defective because the design of the device permitted premature, accelerated failure of the device due to wear and damage to the polyethylene acetabular liner of the device. There were safer alternative designs to eliminate or significantly reduce such a possibility. These alternatives were safer because the risks of injury from the device would be eliminated or significantly reduced in relation to the risk with the use of the device. These alternatives would have prevented or significantly reduced the risk of injury without impairing the device's utility. These alternatives were technologically-feasible and economically-feasible alternatives.

23. Further, the Defective Device was defectively marketed and unreasonably dangerous to a person who might reasonably be expected to use it because it lacked adequate, sufficient, conspicuous, and unambiguous warnings and instructions concerning the risks, dangers, hazards, and harms presented by premature failures of the device due to the failure of the polyethylene acetabular liner of the device, and a reasonable means to reduce such risks, dangers, hazards, and harms.

24. The Defective Device was expected to reach, and did reach the user and/or consumer without substantial change to the condition in which it was sold. The Defective Device was

in substantially the same defective condition on the date of the incident, as it was when it was placed in the stream of commerce by the Exactech Defendants.

25. It was foreseeable to the Exactech Defendants the Defective Device could, and would be used in the manner that it was being used at the time of the incident at issue.

26. The design and marketing defects discussed above were a proximate and/or producing cause of the incident and the severe injuries suffered by Plaintiffs.

27. The Defective Device was dangerous to an extent beyond that which would have been contemplated by the ordinary user of the product, with the ordinary knowledge common to the relevant community of users as to the product's characteristics.

28. The Exactech Defendants knew, or should have known, of the dangers of a defectively designed and marketed hip implant, such as the device in question. The Exactech Defendants, among other acts, did not adequately design the Defective Device, did not adequately test to determine whether design and marketing defects existed, and did not adequately warn end users, and intermediary users of the device, such as surgeons of the potential existence and dangers of such defects.

29. The design and marketing defects of the Defective Device, as described above, rendered it unreasonably dangerous and prevented it from functioning as it was intended because the dangers arising out of premature failures of the device were not safely and adequately reduced or eliminated.

Count 2: Negligence

30. Plaintiffs incorporate their "Strict Products Liability" allegations against the Exactech Defendants from above. The Exactech Defendants had a duty to act reasonably and prudently in the design, marketing, and/or sale of the Defective Device. The Exactech

Defendants breached this duty by, among other acts and/or omissions, designing, marketing and/or selling the device in question, with design and marketing defects, as described above, that rendered the device unreasonably dangerous and prevented the device from functioning as it was intended.

31. The Exactech Defendants knew, or should have known, of the dangers of a defectively designed and/or marketed hip implant. These dangers included, but were not limited to, premature catastrophic failures of implants, necessitating painful debilitating revision surgeries, and reduced success rates in subsequent revision surgeries. The Exactech Defendants, among other negligent acts, did not adequately design the device to reduce or eliminate these dangers, did not adequately test to determine whether design and marketing defects existed in the device, and did not adequately warn end users and intermediary users, including surgeons of the device of the potential existence and danger of such defects. The Exactech Defendants' negligence was a proximate cause of damages to Plaintiffs.

32. Each of the foregoing acts or omissions, singularly or in combination with others, constituted negligence, which proximately caused the above-referenced occurrence and Plaintiffs' injuries and damages.

Count 3: Breach of Express and Implied Warranties

33. Plaintiffs incorporate their "Strict Products Liability" allegations against the Exactech Defendants from above. The Exactech Defendants expressly and impliedly represented to Plaintiffs, Plaintiffs' physicians and the medical community, by and through written statements, materials, advertising, labelling, and marketing disseminated by Defendants and their authorized agents and sales representatives, that the Defective Device: 1) was

safe and fit for its intended purposes, 2) was of merchantable quality, and 3) had been completely tested and found to be safe and effective for implantation.

34. The Defective Device does not conform to Defendants' express and implied representations because it was not safe or effective, it was not of merchantable quality, and it did not have the implantation life expressly and impliedly warranted by Defendants.

35. Neither the Plaintiffs nor their physicians had knowledge of the falsity or incompleteness of Defendants' statements and representations concerning the Defective Device.

36. Plaintiffs, other consumers, Plaintiffs' physicians, and the medical community justifiably and detrimentally relied upon Defendants' implied and express warranties when recommending and approving the implantation of the Defective Device.

37. As a foreseeable, direct, producing and proximate cause of Defendants' actions, omissions and misrepresentations, Plaintiffs suffered injuries and damages.

Joint Enterprise

38. Alternatively, the Exactech Defendants are liable for the negligence of each other under a theory of joint enterprise because: 1) an express or implied agreement among these defendants existed, 2) a common purpose was to be carried out by these defendants, 3) a common pecuniary interest in that purpose existed among these defendants, and 4) an equal right to control the enterprise by these defendants existed.

G. PERSONAL INJURIES AND DAMAGES

39. As a result of Defendants' actions, Plaintiffs suffered severe bodily, economic, and mental injuries. Consequently, Plaintiffs seek the following damages:

1. Medical Expenses: Plaintiff Lori Morrison has sustained bodily injuries which were caused by the incident in question. Plaintiffs have incurred medical expenses in the past and will continue to incur them in the future.

2. Physical Pain: Plaintiff Lori Morrison has endured physical pain in the past and will endure pain in the future.

3. Mental Anguish: Plaintiffs have endured mental anguish in the past and will endure mental anguish in the future.

4. Loss of Earning Capacity: Plaintiffs have suffered a loss of earnings in the past, and they will continue to suffer a loss of earning capacity in the future.

5. Disfigurement: Plaintiff Lori Morrison has endured disfigurement in the past, and she will continue to suffer the effects in the future.

6. Impairment: Plaintiff Lori Morrison has endured physical impairment in the past, and she will continue to suffer the effects in the future.

7. Loss of Consortium: Plaintiffs have sustained loss of consortium in the past, and Plaintiffs will continue to suffer the effects in the future.

40. In all reasonable probability, Plaintiffs will continue to suffer from these injuries for the rest of their lives, and Plaintiffs seek compensation for such future damages.

Exemplary Damages

41. Plaintiffs are entitled to exemplary damages under Chapter 41 of the Texas Civil Practice and Remedies Code from the Exactech Defendants because the Exactech Defendants' acts and/or omissions, when viewed objectively from the standpoint of the Exactech Defendants at the time of the occurrence, involved an extreme degree of risk, considering the probability and magnitude of the potential harm to others, and the Exactech Defendants had actual, subjective awareness of the risk involved, but nevertheless proceeded with conscious indifference to the rights, safety and welfare of others.

H. RELIEF SOUGHT

42. Plaintiffs request that Defendants be cited to appear and answer, and that this case be tried, after which Plaintiffs recover:

1. Judgment against Defendants for a sum within the jurisdictional limits of this Court for the damages indicated above;

2. Pre-judgment and post-judgment interest at the maximum amount allowed by law;
3. Costs of suit; and
4. Such other and further relief to which Plaintiffs may be justly entitled.

Respectfully submitted,