IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF ARKANSAS
CENTRAL DIVISION

GEORGE WILSON and
VALERIE WILSON,

Plaintiffs,

v.

EXACTECH, INC.,

Defendant.

Docket No. 4:22cv136-BRW

This case assigned to District Judge Wilson
and to Magistrate Judge Harris

COMPLAINT FOR DAMAGES

Plaintiffs bring this action for injuries sustained from Defendant's defectively designed and manufactured hip implant that resulted in bodily injury to George Wilson from excessive polyethylene wear and early failure with associated osteolysis from the polyethylene wear particles of Defendant's Connexion GXL Liner.

PARTIES

1. At relevant times hereto, Plaintiffs George Wilson and Valerie Wilson, husband and wife, were and are adult residents and citizens of the State of Arkansas, residing in the County of Pulaski, Sherwood, Arkansas.

2. Defendant ExacTech, Inc. ("Defendant" or "ExacTech") is a Florida corporation with its principal place of business at 2320 NW 66th Court,

Gainesville, Florida 32653, and as such is a citizen of the State of Florida, and at all times relevant hereto did business in the State o Florida and in the State of Arkansas. ExacTech, at all times relevant hereto, did business in the State of Arkansas. ExacTech may be served through its registered agent of service, Corporation Service Company, 1201 Hays Street, Tallahassee, Florida 32301-2525.

JURISDICTION & VENUE

3. This Court has diversity jurisdiction pursuant to 28 U.S.C. §1332. The amount in controversy exceeds the sum of Seventy-Five Thousand Dollars ($75,000), exclusive of interest and costs, as this action involves a products liability claim by a severely injured party. There is complete diversity of citizenship between the parties.

4. Defendant is subject to the *in persona* jurisdiction of this Court, and venue is therefore proper pursuant to 28 U.S.C. §1391, as Defendant did have and continues to do business within the State of Arkansas and has had continuous and systematic contacts with the State of Arkansas, and has consented to jurisdiction in the State of Arkansas. Defendant is a corporation and deemed to reside in a judicial district in which it is subject to personal jurisdiction. 28 U.S.C. §1391(c). As Defendant is subject to personal jurisdiction in Arkansas, and a substantial part

of the events giving rise to this claim occurred in this judicial district, venue is proper in this Court. 28 U.S.C. §1391(a)(1).

5. At all times relevant hereto, Defendant designed, developed, manufactured, advertised, promoted, marketed, sold and/or distributed the defective Novation Total Hip System, including the Novation Crown Cup Connexion GXL Liner throughout the United States, including Arkansas.

FACTUAL ALLEGATIONS

PLAINTIFF GEORGE WILSON'S NOVATION HIP IMPLANT

6. On or about September 26, 2013, Plaintiff George Wilson had an ExacTech artificial hip implanted in his left hip in a procedure known as a total hip arthroplasty (or "THA").

7. Orthopedic surgeon William Bowen, M.D. ("Dr. Bowen") implanted the ExacTech artificial hip in Mr. Wilson.

8. Plaintiff's September 26, 2013 hip implant surgery was performed at the Arkansas Surgical Hospital in North Little Rock, Arkansas.

9. Dr. Bowen did not breach any generally accepted standard of care in the field of orthopedic surgery in his care and treatment of Plaintiff or negligently cause any injury to Plaintiff in any of the following respects:

(a) In the care or treatment that he provided to Plaintiff prior to beginning the hip implant surgery;

(b) in the hip implant surgery he performed on Plaintiff; or

(c) In the care or treatment that he provided to Plaintiff, subsequent to Plaintiff's hip implant surgery.

10. Based upon the patient population that ExacTech intended its Novation artificial hip devices to be implanted in, at the time of implantation of his ExacTech Novation hip device, Plaintiff George Wilson was an appropriate patient to be implanted with the ExacTech Novation hip components he received.

11. Dr. Bowen recommended the ExacTech Novation hip device to Plaintiff and indicated that the ExacTech Novation hip device was appropriate for him.

12. Plaintiff George Wilson reasonably relied upon Dr. Bowen in deciding to proceed with hip replacement surgery and have the ExacTech Novation hip device implanted in him.

13. Before or during the course of the Plaintiff's September 26, 2013 surgery, Defendant arranged for the specific ExacTech hip components that were implanted in Plaintiff to be delivered to the Arkansas Surgical Hospital and/or Dr. Bowen for implantation in the Plaintiff.

14. In his total hip replacement surgery on September 26, 2013, Plaintiff George Wilson had implanted in his left hip the following specific ExacTech artificial components:

(a) Novation Crown Cup
Plasma Coated Shell
Ref: 180-01-56
Size: 56mm O.D.
Lot: 2764125

(b) Novation Element Femoral Stem
HA Coated
Ref: 184-01-14
Size: 14, 160mm
Lot: 2286169

(c) Biolox Delta Femoral Head
Ref: 170-36-00
Size: 36mm
Lot: 2774516

(d) Novation Crown Cup
Connexion GXL Neutral Line
Ref: 130-36-53
Size: 36mm I.D.
Lot: 2594517

15. At the time of implant, each of the components of the Plaintiff's ExacTech hip was in substantially the same condition in all relevant respects as when they left Defendant's control.

16. Subsequent to the date of implantation of his ExacTech artificial hip, Plaintiff used his ExacTech artificial hip in a normal and reasonably foreseeable manner.

17. After initial recovery and for a period of time from implant surgery, Plaintiff's ExacTech total hip implant performed as expected.

18. On or about September 30, 2021, not quite eight years after the index implant surgery, Plaintiff George Wilson reported to Paul Edwards, M.D. ("Dr. Edwards") for revision surgery of his left hip prosthesis. Dr. Edwards recommended the revision surgery after Plaintiff George Wilson presented with pain and severe osteolysis.

19. Plaintiff George Wilson's revision surgery was necessary due to a failed polyethylene acetabular liner resulting in severe osteolysis.

20. The revision surgery was performed by Dr. Edwards at the Arkansas Surgical Hospital in North Little Rock, Arkansas.

21. In the revision operative report, Dr. Edwards noted "Cup had severe osteolysis around the superior lateral regions" and "[t]here was severe amount of osteolysis along the posterior wall/superior lateral acetabulum and along the ischium."

22. In the course of the revision surgery performed on September 30, 2021, Dr. Edwards removed Plaintiff's ExacTech hip components, except for the femoral stem.

23. With the exception of the fact that the polyethylene liner of Plaintiff's artificial hip had excessive wear and caused injury to the Plaintiff, at the time of its revision on September 30, 2021, Plaintiff's ExacTech hip was not otherwise in need of hip revision surgery.

EXACTECH CONNEXION GXL

24. ExacTech Novation Crown Cup with GXL Liners were first marketed by ExacTech in 2007.

25. ExacTech marketed some of these components as Novation Crown Cups and Connexion GXL Liners.

26. The Novation Crown Cups and Connexion GXL Liners were indicated for use for adults undergoing primary THA due to osteoarthritis, rheumatoid arthritis, osteonecrosis, post-traumatic degenerative problems of the hip, and for treatment of proximal femoral fractures where prosthetic replacement is determined by the surgeon as the preferred treatment.

27. ExacTech identified its AcuMatch A-Series as the substantially equivalent predicate device.

28. The Novation Crown Cups and Liners were cleared to market as a Class II device via the 510(k) market clearance process of the FDA on March 15, 2007, after a 23-day review process.

29. On or about June 29, 2021, ExacTech initiated a Class II recall of the ExacTech Connexion GXL acetabular polyethylene liners.

30. The basis of the recall was premature prosthesis wear.

31. Since 2007, Defendant, ExacTech, Inc., directly or through its parent corporation, subsidiaries or affiliates, ExacTech U.S., Inc., and others, designed, manufactured, labeled, marketed, promoted, distributed, and sold in the United States the Novation artificial hips with Connexion GXL Liners.

32. After ExacTech Novation with Connexion GXL Liners began to be implanted, ExacTech received reports of excessive polyethylene wear and resulting osteolysis with the Connexion GXL Liners.

33. At some point in time prior to June 29, 2021, ExacTech had notice that higher than normal rates of early failure of the Connexion GXL Liners due to excessive wear have been observed in patients.

34. As the number of reported Novation implants with Connexion GXL Liners continued to increase, case studies appeared in medical journals reporting the failures due to excess polyethylene wear.

35. As the number of reported failures continued to increase, ExacTech began to design and develop a polyethylene liner that was manufactured and/or subjected to a different treatment than the Connexion GXL Liners.

36. In marketing its Connexion GXL Liners, ExacTech represented that the liners had less wear and would last longer than its competitors' polyethylene liners.

37. The design and manufacture of the ExacTech Connexion GXL Liners is such that it in fact promotes the process of wear at the articulation junction of the Novation modular cup.

38. ExacTech's claims that the Connexion GXL liner would have less wear and at a level that would not be problematic for patients, were not supported by unbiased, sound scientific testing.

39. Claims by ExacTech that its Connexion GXL Liners would result in less wear and at a level that would not be problematic for patients were false and misleading.

40. Prior to offering its Novation Acetabular System with Connexion GXL Liner for distribution or sale in the United States, ExacTech did not adequately test its design for polyethylene wear or the biological effect of polyethylene wear particles on the body after implantation in patients.

41. ExacTech rushed the Novation hip system to market without adequately testing them for in vivo performance of its polyethylene liners or test the effects of polyethylene wear particles on human tissue.

42. ExacTech's rush to market was done to preserve market share and its profits from the sale of its Novation hip products.

43. Prior to September 26, 2013, ExacTech had been informed that is Connexion GXL Liners were susceptible to excessive wear in patients to the extent that revision surgeries were necessary to remove the Novation hip system.

44. ExacTech knew or should have known that as of September 26, 2013, the date Plaintiff received his ExacTech Novation hip system:

(a) ExacTech had not adequately tested the Connexion GXL Liners to simulate in vivo performance for resistance to excessive wear;

(b) ExacTech had not adequately tested the Connexion GXL Liners to simulate in vivo performance for edge loading;

(c) ExacTech's Connexion GXL Liners would be subject to excessive wear and early failure;

(d) There was an increased risk of excessive wear and early failure;

(e) There was an increased risk of excessive wear and early failure due to the manufacturing process; and,

(f) There was a substantial risk that patients' bodies would be adversely affected by the exposure to excessive polyethylene wear particles.

45. Product complaint data reported to ExacTech prior to September 26, 2013 indicated an increased risk of adverse events due to excessive polyethylene wear debris associated with the Connexion GXL Liners.

46. Based upon what ExacTech knew or should have known before September 26, 2013, ExacTech should have informed orthopedic surgeons using its Novation hip products that there is an increased risk of excessive polyethylene wear and early failure with the Connexion GXL Liners.

47. Based upon the facts and allegations set forth above, the ExacTech Novation hip systems with the Connexion GXL Liners are defective in design and manufacture in that the risks inherent in this product's use for hip replacement, when weighed against the utility or benefit derived from the product, outweigh the benefit which might have gained by placing this defective product in the body of Plaintiff George Wilson.

48. Additionally, the Novation Hip System with the Connexion GXL Liner implanted in Plaintiff George Wilson is defective in its manufacture, as it was manufactured such that the polyethylene did not comply with ExacTech's design specifications.

49. Furthermore, the Connexion GXL Liner implanted in Plaintiff George Wilson is defective in its manufacture as the treatment, sterilization, and/or processing increases the risk of excessive wear of the polyethylene.

50. Based upon the facts and allegations set forth above, the ExacTech Novation hip system is defective in its labeling in that it does not perform as represented, and the risks that were inherent in this product being used for hip replacement, when weighted against the utility or benefit derived from the product, outweigh any alleged benefit.

51. Based upon the facts and allegations set forth above, the ExacTech Novation with the Connexion GXL Liner is unreasonably dangerous in that the risks that were inherent in this product being used for hip replacement, when weighed against the alleged utility or benefit derived from the product, outweigh the benefit.

52. Defendant was negligent in its design, manufacture, distribution, sale, marketing, promotion, and labeling of the Novation with Connexion GXL Liner hip system.

53. Defendant was negligent in its failure to warn patients and/or surgeons that they had received product complaint data that did indicate an increased risk of adverse events due to excessive polyethylene wear, as compared to other available safe alternative devices.

54. Defendant was negligent in its failure to warn patients or surgeons that they had received product complaint data that did indicate an increased risk of adverse events due to osteolysis as compared to other available safe alternative devices.

PLAINTIFF GEORGE WILSON'S INJURIES AND DAMAGES

55. On or about September 30, 2021, it was discovered the Novation hip system implanted in Plaintiff George Wilson's left hip failed, meaning that due to excessive polyethylene wear at the acetabular articulation it was causing continuing and otherwise irreversible physical injury to the Plaintiff.

56. On or about September 30, 2021, the Novation hip system implanted in Plaintiff George Wilson's left hip was discovered to have failed as a direct and

proximate result of the actions, conduct, negligence, and breach of warranties of the Defendant, as alleged in this Complaint.

57. As a direct and proximate result of the conduct of Defendant as set forth in this Complaint, Plaintiff George Wilson sustained injuries and damages including, but not limited to undergoing surgery to remove and replace his failed Novation hip; past and future pain and anguish, both in mind and in body; permanent diminishment of his ability to participate in and enjoy the affairs of life; medical bills associated with the replacement procedure and recovery therefrom; future medical expenses; loss of enjoyment of life; loss of past and future earnings and earning capacity; disfigurement; physical impairment, and other injuries not fully known at this time.

58. Plaintiff George Wilson's injuries suffered were both factually and proximately caused by the Defendant's defective Novation hip system.

59. Plaintiff George Wilsons' injuries suffered were both factually and proximately caused by the Defendant's unreasonably dangerous Novation hip system.

60. Plaintiff George Wilson is entitled to recover for all economic and special damages incurred, including but not limited to damages for subsequent

surgeries, rehabilitative services, follow up doctor visits and all expenditures incurred as a result of the additional operations and follow up procedures.

61. Plaintiff George Wilson is entitled to compensation for permanent disability as a result of the failure of this Novation hip replacement device which caused substantial injury.

62. Plaintiff George Wilson further shows that he is entitled to recover for all noneconomic and compensatory damages allowed by law, including, but not limited to, pain and suffering for all pain and suffering that he has incurred as a result of the defective product, the follow-up surgery, rehabilitation, and constant pain that occurs as a result of the failure of the product.

63. Plaintiff avers that he is entitled to recover for loss of wages as a result of the Defendant's negligence.

LIABILITY

COUNT 1 – NEGLIGENT DESIGN AND FAILURE TO WARN OR INSTRUCT

64. Plaintiff incorporates by reference as if fully set forth herein the facts alleged in paragraphs 1-63 of this Complaint.

65. Defendant owed a duty of reasonable care to the general public, including Plaintiff George Wilson, when it designed, manufactured, assembled, inspected, tested, marketed, placed into the stream of commerce, and sold the

ExacTech Novation Total Hip System and the Connexion GXL Liner to protect users from an unreasonable risk of harm when using the device for its intended purpose, in a reasonably foreseeable manner.

66. Defendant breached its duty by designing, manufacturing, assembling, inspecting, testing, marketing, distributing and selling the ExacTech Novation Total Hip System in a defective and unreasonably unsafe condition including, but not limited to, its foreseeably appreciated risk of harm from the device's propensity for excessive polyethylene wear and failure. A reasonably careful medical device manufacturer would not have acted in this manner.

67. Likewise, Defendant owed Plaintiff George Wilson a duty of reasonable care to discover the defects and to inform and/or warn him or his implanting surgeon of the defects once they were discovered, and Defendant failed to warn of the dangers inherent in the reasonably foreseeable use of the Novation Total Hip System, further placing Plaintiff at risk for harm and injury.

68. Defendant was negligent in the particulars set forth in this Complaint, and such negligence was a direct and proximate cause of the incident and injuries set forth herein.

COUNT 2 – STRICT PRODUCTS LIABILITY: DEFECTIVE DESIGN

69. Plaintiff incorporates by reference as if fully set forth herein the facts alleged in paragraphs 1-63 of this Complaint.

70. Plaintiff George Wilson was damaged by the defective ExacTech Novation Total Hip System, including, but not limited to, having to undergo revision surgery less than 8 years post-implant.

71. ExacTech was engaged in the business of designing, manufacturing, selling and distributing the Novation Total Hip System.

72. The Novation Total Hip System with Connexion GXL Liner used in Plaintiff Wilson's hip replacement surgery was supplied in a defective condition in its design, such that it would experience excessive polyethylene wear, rendering it unreasonably dangerous.

73. The ExacTech Novation Total Hip System's defective condition proximately caused Plaintiff's damages.

COUNT 3 – STRICT PRODUCTS LIABILITY: MANUFACTURING DEFECT

74. Plaintiff incorporates by reference as if fully set forth herein the facts alleged in paragraphs 1-63 of this Complaint.

75. Plaintiff was damaged by the defective ExacTech Novation Total Hip System with the Connexion GXL Liner, including by having to undergo revision surgery less than 8 years post-implant.

76. ExacTech was engaged in the business of designing, manufacturing, selling and distributing the Novation Total Hip System.

77. The Novation Total Hip System used in Plaintiff George Wilson's hip replacement surgery was supplied in a defective condition in its manufacture, such that it would experience excessive polyethylene wear, rendering it unreasonably dangerous.

78. The Novation Total Hip System's defective condition proximately caused Plaintiff's damages.

COUNT 4 – STRICT PRODUCTS LIABILITY – FAILURE TO WARN

79. Plaintiff incorporates by reference as if fully set forth herein the facts alleged in paragraphs 1-63 of this Complaint.

80. Plaintiff George Wilson was damaged by the defective ExacTech Novation Total Hip System, including by having to undergo revision surgery less than 8 years post-implant.

81. ExacTech was engaged in the business of designing, manufacturing, selling and distributing the Novation Total Hip System with the Connexion GXL Liner.

82. The ExacTech Novation Total Hip System used in Plaintiff's hip replacement surgery was supplied in a defective condition, because the Defendant failed to provide an adequate warning to consumers, implanting surgeons and the public, including Plaintiff and his implanting surgeon Dr. Bowen, regarding the hazards associated with the reasonable and foreseeable use of the Novation Total Hip System with the Connexion GXL Liner, including excessive polyethylene that could lead to early failure of the device. This failure to warn rendered the device unreasonably dangerous.

83. The Novation Total Hip System's defective condition proximately caused Plaintiff's damages.

84. At the time of the incident set forth herein, the ExacTech Novation shell coupled with the ExacTech Connexion GXL Liner as part of the Novation Total Hip System were dangerous to an extent beyond that which would be contemplated by the ordinary health care provider and patient utilizing the product, with the ordinary knowledge common to the medical community as to the product's characteristics.

85. Health care providers and patients, including Plaintiff and orthopedic surgeon Dr. Bowen, did not know and should not have been expected to know of the dangerous characteristics of the ExacTech Novation shell when coupled with the ExacTech Connexion Liner as part of the Novation Total Hip System, which had the potential to cause injury and damage.

86. As a direct and proximate result of the Defendant's failure to warn, Plaintiff George Wilson sustained serious injuries and was damaged.

COUNT 5 – NEGLIGENT MISREPRESENTATION

87. Plaintiff incorporates by reference as if fully set forth herein the facts alleged in paragraphs 1-63 of this Complaint.

88. Defendant had a duty to accurately and truthfully represent to the medical community, Plaintiff, and the public that ExacTech Novation shell coupled with the ExacTech Connexion GXL Liner, had not been adequately tested and found to be safe and effective for the treatment of patients requiring a hip replacement. Instead, the Defendant made representations about the device that they, at a minimum, should have known to be false.

89. Defendant negligently misrepresented to the medical community, implanting orthopedic surgeon Dr. Bowen, Plaintiff, and the public the Novation

shell coupled with the Connexion GXL Liner in the ExacTech Novation Total Hip System presented a low risk of unreasonable and dangerous adverse side effects.

90. Additionally, in various marketing and promotional material published and distributed by ExacTech, and available to ExacTech's sales representatives and distributors, surgeons, patients and the general public, ExacTech made false representations, statements, claims and guarantees about its Connexion GXL Liners.

91. ExacTech advertised a reduced wear rate of 59% for the Connexion GXL Polethylene Liner.

92. ExacTech marketed the Connexion GXL Liner as having "enhanced polyethylene" with a lower wear rate.

93. Post market surveillance conducted by ExacTech proved that excessive polyethylene wear occurred with its Novation Total Hip System with the Connexion GXL Liners.

94. Had Defendant accurately and truthfully represented to the medical community, Dr. Bowen, Plaintiff, and the public the material facts that it knew or should have known regarding the risks of the ExacTech Novation Shell coupled with the ExacTech Connexion GXL Liner as part of the ExacTech Novation Total

Hip System, Plaintiff and/or Plaintiff's healthcare provider(s) would not have utilized Defendant's Novation Total Hip System.

95. As a direct and proximate result of Defendant's negligent misrepresentations, Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages.

COUNT 6 – LOSS OF CONSORTIUM

96. Plaintiff incorporates by reference as if fully set forth herein the facts alleged in paragraphs 1-63 of this Complaint.

97. At all times herein mentioned, Plaintiffs George Wilson and Valerie Wilson were, and are, legally married as husband and wife.

98. As a direct and proximate result of Defendant's defective Novation Total Hip System and tortious conduct, and as a result of the injuries and damages to Plaintiff George Wilson arising therefrom, Plaintiff Valerie Wilson has been deprived of the love, companionship, comfort, affection, society, solace or moral support, protection, loss of enjoyment of sexual relations, and loss of physical

assistance in the operation and maintenance of the home, of her husband, George Wilson, and has thereby sustained and will continue to sustain damages.

99. Plaintiff Valerie Wilson is entitled to recover damages for her loss of consortium in an amount to be proven at trial.

DAMAGES

100. Plaintiff incorporates by reference as if fully set forth herein the facts alleged in paragraphs 1-63 of this Complaint.

101. As a direct and proximate result of the acts and omissions of the Defendant alleged herein, Plaintiffs were injured and damaged. The injuries and damages for which Plaintiffs seek compensation from the Defendant include, but are not limited to:

(a) physical pain and suffering of a past, present and future nature;

(b) emotional pain and suffering of a past, present and future nature;

(c) permanent impairment and scarring;

(d) medical bills and expenses of a past, present and future nature;

(e) loss of enjoyment of life;

(f) loss of income;

(g) pre- and post-judgment interest;

(h) statutory and discretionary costs;

(i) damages for Mrs. Wilson's loss of consortium; and

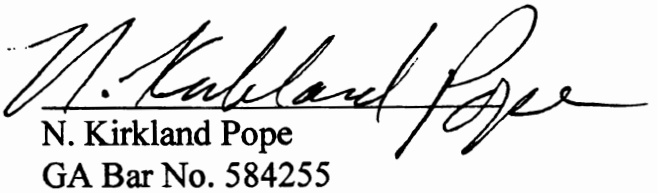
(j) any and all such other and further legal and equitable relief as the Court deems necessary, just and proper.

for all such further relief, both general and specific, to which Plaintiffs may be entitled under the premises.

A TRIAL BY JURY IS RESPECTFULLY DEMANDED.

Dated: February 11, 2022

Respectfully submitted,



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