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IN THE CIRCUIT COURT OF THE EIGHTH JUDICIAL CIRCUIT
IN AND FOR ALACHUA COUNTY, FLORIDA
CIVIL DIVISON

CAROLYN McGRAW, DELORES SHULTZ, and MARY HIGGENBOTHAM, Plaintiffs, v. EXACTECH, INC. and EXACTECH U.S., INC., Defendants.	CASE NO.:

COMPLAINT FOR DAMAGES AND DEMAND FOR JURY TRIAL

COMES NOW, the Plaintiffs, CAROLYN McGRAW, DELORES SHULTZ, and MARY HIGGENBOTHAM, by and through Plaintiffs' undersigned attorneys, and file this Complaint against EXACTECH, INC. and EXACTECH U.S., INC. (hereinafter collectively "Exactech" or "Defendants") and allege as follows:

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I. PARTIES, JURISDICTION, VENUE

1. This is a lawsuit involving unreasonably dangerous hip implant components designed, marketed, manufactured, and sold by Defendants, where such components caused injury to Plaintiffs. The particular components at issue in this lawsuit are the "Connexion GXL Hip Liner" and Novation Crown Liners (hereinafter, these products are referred to as "GXL" or "GXL Liner") which was sold as part of the Novation, Acumatch, and MCS Hip Systems.

2. At all times relevant to this complaint, Plaintiff CAROLYN MCGRAW was a resident of Kokomo, Indiana.

3. At all times relevant to this complaint, Plaintiff DELORES SHULTZ was a resident of Gosport, Indiana.

4. At all times relevant to this complaint, Plaintiff MARY HIGGENBOTHAM was a resident of Peru, Indiana.

5. Defendant, EXACTECH, INC. is a Florida corporation with its principal place of business at 2320 NW 66th Street, Gainesville, Florida 32653.

6. Defendant EXACTECH U.S., INC. is a Florida corporation with its principal place of business at 2320 NW 66th Street, Gainesville, Florida 32653.

7. At all relevant times, Defendants tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold hip implant systems in Alachua County, Florida and throughout the United States.

8. At all times relevant to this action, Defendants received substantial revenue from goods used or consumed, or services rendered, in the State of Florida, including Alachua County.

9. At all relevant times, and from their principal place of business, Defendants were in the business of, and profited from, the design, manufacture, marketing, distribution and/or sale of medical devices, including hip implants which were implanted in Plaintiffs.

10. At all relevant times, and from their principal place of business, Defendants were responsible for placing the medical devices implanted into Plaintiffs into the stream of commerce and advertised, marketed, sold and/or distributed such products either directly or indirectly to members of the general public, including Plaintiffs.

11. Jurisdiction is proper in the courts of the State of Florida because Defendants are all corporations organized under the laws of the State of Florida and have their principal places of business in Florida. This Court has general jurisdiction over Defendants.

12. Venue is proper in the Eighth Judicial Court of Alachua County, Florida because the Defendants reside within the jurisdiction of this Court and because a substantial portion of the tortious conduct alleged in this Complaint took place in Alachua County, Florida at Defendants' principal place of business.

II. FACTUAL ALLEGATIONS

A. Total hip arthroplasty using UHMWPE plastic is common and highly successful.

13. Total Hip Arthroplasty (hereafter "THA") is the term used to describe surgery wherein a patient's natural hip anatomy is replaced with synthetic components. THA is also commonly referred to as "hip replacement surgery." A patient may need a THA for a variety of medical reasons. For example, arthritis may damage the normally smooth cartilage on the femoral head and motion against the damaged cartilage leads to pain.

14. A synthetic hip replacement system implanted during a THA procedure generally has four main components: 1) Acetabular shell; 2) Acetabular liner; 3) Femoral head; and 4) Femoral stem. Figure 1 and Figure 2 below graphically represent these typical components as well as how these components are situated in the body once implanted:

Figure 1

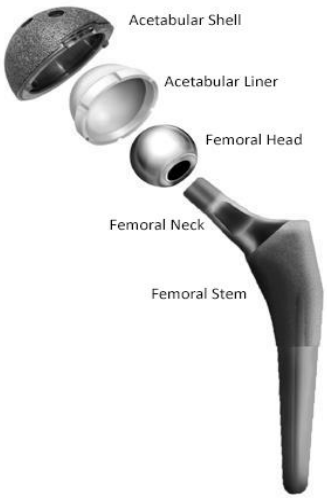

Figure 2

15. The materials used in a hip replacement are very important in determining the outcome of the implant. There are many possible combinations of materials used which can lead to very different clinical success rates.

16. In the 1960s, Sir John Charnley set the standard for today's hip replacement systems by utilizing acetabular liners made of ultra high molecular weight polyethylene ("UHMWPE"). This plastic material family remains the material of choice as the predominant bearing surface in total join replacements today.

17. The original UHMWPE implants utilized by Sir John Charnley in the 1960s had 20-year survivorship rates as high as 90%. [1] [2]

18. Approximately 400,000 hip replacements are performed annually in the United States today and this number is expected to increase to 635,000 by 2030.[3]

19. The great majority of these hip replacements utilize a metal acetabular cup, a plastic acetabular liner, a metal or ceramic femoral head, and a metal femoral stem. Further, almost all of the plastic acetabular liners belong to the UHMWPE lineage of plastics, first introduced by Charnley in the 1960s.

B. Despite unparalleled success, early UHMWPE had challenges due to primitive packaging technology and due to concerns of wear over the long-term.

[1] Neuman L, Freund KG, Sorenson KH, 'Long Term Results of Charnley Total Hip Replacement' J Bone and Joint (British) 76B:245-251(1994)

[2] Wroblewski BM, 'Charnley Low Friction Arthroplasty of the Hip. Long Term Results' Clin Ortho Rel Res 292:191-201(1993)

[3] Sloan M, Premkumar A, SM, Sheth NP, 'Projected Volume of Primary Total Joint Arthroplasty in the US 2014 to 2030' J Bone Joint Surg 100:1455(2019)

20. Despite unparalleled success and low failure rates of hip implants utilizing UHMWPE components, the orthopedic industry recognized room for improvement.

21. In the 1980s, the orthopedic industry recognized that UHMWPE which were sterilized with gamma radiation *and* packaged in air would be subject to oxidation and a degradation of the material properties of the UHMWPE components. This caused delamination, pitting, fracture and breakage of the components, and a host of related negative clinical outcomes in patients.

22. Also in the 1980s, it became evident that UHMWPE liners generated polyethylene particles in clinical use. *Over the long term*, those particles can cause a biological response termed osteolysis. Osteolysis is a process which makes bone weak or even disappear. As a result of osteolysis the patient experiences pain, the implant may loosen, and revision surgery is required. Despite the success of the early generation of UHMWPE devices over early and mid-terms, excessive wear generation ultimately limited the *long-term* success of generation of implants.

C. UHMWPE plastic utilized in hip replacements has improved since the 1980s.

23. In the 1990s, the orthopedic industry pursued improvements in the material properties as well as the packing and sterilization methods utilized for UHMWPE implants.

24. By the late 1990s most manufacturers in the orthopedic industry had addressed the issue of oxidation with changes in the packaging and sterilization process, including but not limited to:

a) Sterilization in vacuum sealed packaging;
b) Sterilization using inert gas instead of oxygen; and
c) Gas Plasma Sterilization.

25. As a result of advancements in the packaging and sterilization methods in the 1990s, the rate of problems associated with oxidation of UHMWPE had been greatly reduced.

26. There were also several attempts of improving the wear rates of UHMWPE which generally involved doses of irradiation and post irradiation treatments.

27. One of the ways in which the wear rate of polyethylene was improved by a process called "cross linking." In this process, the UHMWPE was exposed to certain levels of either gamma or electron beam irradiation.

28. Highly Cross Linked Ultra High Molecular Weight Polyethylene ("XLPE") is stronger, harder, and reduces the amount of plastic wear produced during articulation of components as compared with UHMWPE.

29. If using gamma radiation, crosslinking of UHMWPE requires that UHMWPE be exposed to gamma radiation in the range of 50-100kGy.

30. By the mid 2000s, it became clear that XLPE components had superior clinical performance to UHMWPE as well as the alternative attempts to improve UHMWPE. XLPE implants have less than half the revision rate of UHMWPE

implants. Accordingly, the industry standard shifted to utilization of XLPE for acetabular liners.

31. By 2004, UHMWPE and XLPE components were so successful that they were utilized in 90% of *all* hip replacements. [4]

32. Further, in the mid-2000s, an increasing number of orthopedic manufacturers utilized Vitamin E in their XLPE to further improve the long term wear properties of the implants.[5] The main purpose was to prevent oxidative degradation of the plastic and lower the osteolytic potential of these implants.

33. XLPE and Vitamin E infused XLPE implants, in use since the late 1990s and mid 2000s, have greatly improved the long-term durability, wear resistance, and clinical outcomes with the already successful UHMWPE implants originally introduced in the 1960s.

34. These advancements allow for polyethylene components in hip implants to last 20+ years in a patient.

D. Defendants, like many implant manufacturers, sold UMHWPE implants in the 1990s and 2000s.

35. Defendants have marketed a number of hip implants utilizing liners in the UHMWPE family of plastics.

[4] Kurtz SM. The UHMWPE Handbook: Ultra-High Molecular Weight Polyethylene in Total Joint Replacement. New York, NY: Academic Press; 2004.

[5] Gigante A, Bottegoni C, Ragone V, Banci L. Effectiveness of Vitamin-E-Doped Polyethylene in Joint Replacement: A Literature Review. *J Funct Biomater*. 2015;6(3):889-900. Published 2015 Sep 8. doi:10.3390/jfb6030889.

36. In 1992 and 1999, respectively, Defendants began marketing the MCS[6] and AcuMatch A-Series[7] hip implants, each with a UHMWPE liner.

37. In 2004, Defendants sought clearance from the FDA to sell additional size options for both the MCS and A-Series hip systems.[8] Other than providing these new size options, the Defendants claimed that these new sizes were "substantially equivalent" to the previous sizes "in design, materials of construction, manufacturing, and other characteristics."

38. Each of these AcuMatch and MCS hip systems cleared for sale in 1992, 1999, and 2004 represents a traditional metal on plastic hip system utilizing UHMWPE as the material for the liner component.

E. Defendants began to market "enhanced" UHMWPE in the mid-2000s with the promise of reduced wear and increased longevity.

39. Beginning in 2005, Defendants began to market a new generation of "enhanced" UHMWPE products.

40. This generation of products included the GXL acetabular liners with "enhanced" UHMWPE for use in a variety of hip systems. For example, in 2005 Defendants marketed their AcuMatch A-Series "Connexion GXL Enhanced UHMWPE Acetabular Liner."[9] Further, in 2007, Defendants marketed their

[6] K921114 Summary of Safety and Effectiveness
[7] K993082 Summary of Safety and Effectiveness
[8] K040613 Summary of Safety and Effectiveness
[9] K051556 Summary of Safety and Effectiveness

Novation Crown Cup and Liners, which they claimed also utilized "enhanced" GXL liners.[10]

41. To purportedly "enhance" the standard UHMWPE that Defendants had been using in their previous liners, Defendants exposed the GXL liners to two treatments of gamma radiation at 25kGy for each treatment.

42. Defendants claimed that these purportedly "enhanced" GXL liners were "developed to create a robust arthroplasty respecting the need for lower wear, sufficient fracture toughness, and oxidation behavior to provide a lifelong implant for patients." [11]

43. Defendants explicitly claimed that "Connexion GXL enhanced polyethylene acetabular liners provide a low wear rate." [12]

44. Defendants explicitly claimed that "Connexion GXL liners are a result of development programs that are advancing bearing surface technology *while focusing on increasing the longevity of total hip prostheses.*" (Emphasis added).[13]

45. Defendants explicitly claimed that the GXL "provides a 59% wear reduction" over what it deemed was their "clinically successful" standard polyethylene liners. [14] [15]

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[10] K070479 Summary of Safety and Effectiveness

[11] Peterson, M. J., Yassaman, N., Assessing the Long-Term Clinical Performance of Connexion GXL Polyethylene Acetabular Liners in Total Hip Arthroplasty. 2017 Exactech Brochure.

[12] http://www.exac.com/products/hip/acetabular-systems/connexion-gxl, as of May 11, 2008, as available on the Internet Archive.

[13] Id.

[14] http://www.exac.com/products/hip/emerging-technologies/connexion-gxl-polyethylene, as of May 25, 2008, as available on The Internet Archive.

[15] Peterson, M. J., Yassaman, N., Assessing the Long-Term Clinical Performance of Connexion GXL Polyethylene Acetabular Liners in Total Hip Arthroplasty. 2017 Exactech Brochure.

46. These claims were intended to convince the public, including Plaintiffs and Plaintiffs' doctors, that the GXL was not only a safe and effective product for hip replacement, but that it was advantageous to products already on the market.

F. Defendants rushed the GXL to market without any testing for safety or efficacy.

47. Defendants rushed their "enhanced" UHMWPE products, including the GXL, to market without any testing for safety or efficacy.

48. The rush to market was done in pursuit of market share and profits.

49. Defendants received clearance to sell the GXL after an FDA review process that took less than 30 days.

50. Defendants did not perform any clinical testing for safety or efficacy whatsoever on the GXL prior to marketing.

51. Upon information and belief, Defendants did not conduct any laboratory wear testing on the GXL which replicated clinical use conditions.

52. Defendants relied almost entirely on data for other "predicate" products previously on the market to justify the marketing and sale of the GXL prior to launch. These include Defendants' prior standard UHMWPE liners. [16]

53. Defendants did not have any clinical or clinically-relevant laboratory data supporting their claims that the GXL either produced less wear or had better longevity than standard UHMWPE.

[16] K051556 Summary of Safety and Effectiveness

54. Defendants failed to adequately test the in-vivo performance of their "enhanced" UHMWPE products, including the GXL.

55. Defendants failed to adequately test for the clinical effects of the wear generated by their "enhanced" UHMWPE products, including the GXL.

G. The GXL is defective because it leads to increased wear and early failure.

56. Defendants' claims that the "enhancements" to the UHMWPE in the GXL improve wear resistance and longevity are false.

57. In fact the GXL is defective because the exact opposite is true for the "enhanced" UHMWPE Defendants utilized in the GXL.

58. In clinical use, the GXL exhibits a higher than expected rate of production of plastic wear.

59. In clinical use, the GXL exhibits a higher than expected rate of failure necessitating early revision surgery.

60. The GXL is defective because it leads to excessive wear and early implant failure.

61. The GXL is defective because the gamma radiation process applied to the GXL increases, rather than decreases, the wear produced by the GXL.

62. The GXL is defective because the sterilization process applied to the components increases the risk of fracture and excessive wear with the GXL.

63. The GXL is defective because the GXL is unreasonably likely to undergo oxidation after manufacture and prior to implant. This weakens the implant, greatly increases wear, and leads to early failure.

64. The GXL is defective because it is unreasonably likely to edge load, leading to increased wear and early failure.

65. The excessive wear associated with the GXL leads to adverse clinical effects in patients, including osteolysis, fracture, loosening, and early revisions.

66. The negative clinical outcomes are progressive and correlate with exposure to increased wear. The longer and larger the exposure to wear, the worse the clinical outcome.

67. Early intervention to revise failing implants is critical in order to avoid or minimize injury.

H. Defendants utilized similar "enhanced" UHMWPE in other orthopedic devices which they recalled due to excessive wear and high revision rates.

68. Defendants utilized nearly identical materials and processes for their "enhanced" UHMWPE components utilized in other orthopedic products, including various knee and ankle implants, such as the OPTETRAK, TRULIANT, and VANTAGE.

69. Defendants have recalled these products due to excessive wear and increased revision rates with these products.

70. Upon information and belief, Defendants' entire line of "enhanced" UHMWPE products are defective and unreasonably dangerous for the same or substantially similar reasons.

I. Defendants knew of problems, but failed to inform plaintiff and the public.

71. Quickly after introduction of their "enhanced" UHMWPE products, including the GXL, to the market, Defendants began receiving reports of adverse clinical outcomes due to wear and early revisions.

72. Defendants' competitors' XLPE products, and even Defendants' previous UHMWPE products, performed significantly better clinically than Defendants' "enhanced" UHMWPE products, including the GXL.

73. Surgeons and patients from the United States and around the world notified defendants of adverse clinical outcomes with Defendants "enhanced" UHMWPE products, including the GXL.

74. Defendants failed to properly track and analyze these reports.

75. When surgeons reported concerns due to failures due to wear, Defendants responded to surgeons by claiming that their "enhanced" UHMWPE products, including specifically the GXL, was performing well and that there was no cause for concern, despite Defendants' knowledge to the contrary.

76. The Safe Medical Devices Act of 1990 requires manufacturers to report to the Food and Drug Administration deaths, serious illnesses and injuries associated with medical devices. Revision surgeries are considered a mandatory reportable

concern to The Center for Devices and Radiological Health of the U.S. Food and Drug Administration ("F.D.A.") responsible for issuing Safety Alerts, Public Health Advisories and Notices relative to medical devices.

77. Defendants failed to report deaths, serious illnesses, injuries and revision surgeries involving the GXL to the F.D.A.

78. As the number of failed GXL implants increased, case studies appeared in medical journals reporting the failures due to excess polyethylene wear.

79. Defendants took affirmative efforts to conceal the risk to the public from the excessive wear and early failure of the GXL.

80. Defendants knew, or should have known, of increased wear and early revisions with their "enhanced" UHMWPE and the GXL in enough time to have notified Plaintiff, or Plaintiff's surgeon, and the F.D.A. prior to Plaintiff's implant surgery.

81. Defendants knew, or should have known, of increased wear and early revisions with the GXL in enough time to have notified Plaintiff, or Plaintiff's surgeon, after Plaintiff's implant surgery but before Plaintiff's revision surgery, such that the extent of Plaintiff's injuries due to the wear and erosion of the implant could have been minimized or possibly avoided.

J. Defendants waited to inform the public of any issues with the GXL until they released an XLPE liner as replacement.

82. Despite all of the information Defendants received regarding the failures of their "enhanced" UHMWPE products, including their GXL liners, Defendants have failed to recall the GXL.

83. In 2019, Defendants for the first time began selling their "XLE" liners. This was their first XLPE liner. It is also Vitamin E infused.

84. Defendants' competitors have had XLPE liners available since the late 1990s.

85. Defendants' competitors have had Vitamin E infused XLPE liners available since the mid 2000s.

86. Defendants claim that their XLE is gamma radiated with 100kGy, the maximum acceptable gamma radiation for cross-linking.

87. Defendants claim that the XLE has lower wear propensities than the GXL.

88. Defendants claim that they transitioned GXL liners out of the US market once the XLE was introduced in 2019.

89. Defendants waited until the GXL was transitioned out of the market and its XLE replacement was transitioned in to first inform the public regarding Defendants' observations of premature wear with the GXL.

90. On June 24, 2021, Defendants admitted that they had become aware of "certain conditions that may put certain patients at a higher risk of premature wear of the GXL."

91. Defendants recommended that surgeons consider revising failing GXL liners and replacing them with XLE liners, which are fully compatible replacements.

92. Defendants' delay in informing the public of problems with their GXL until a marketable alternative was available displays a conscious disregard for the safety of the public in favor of profit.

K. Plaintiff Carolyn McGraw.

93. Plaintiff, Carolyn McGraw, was implanted with the GXL in 2015, in Carmel, Indiana at Franciscan Health under the care of Jeffery Pierson, MD.

94. Plaintiff reasonably relied on Plaintiff's surgeon to proceed with THA surgery and have the GXL product implanted.

95. Defendants arranged for the selection and delivery of Plaintiff's specific implant components to the operating room on the day of Plaintiff's surgery.

96. At the time of implant, each of the components implanted into Plaintiff were in substantially the same condition as when they left Defendants' control.

97. Plaintiff used the hip implant system, including the GXL in a normal and reasonably foreseeable manner.

98. Over the ensuing years, Plaintiff began to suffer from symptoms associated with excessive wear of the GXL, including pain and lack of mobility.

99. On or about December 6, 2021, Plaintiff underwent revision surgery by Anthony Feher, MD to replace the failed GXL liner in Carmel, Indiana at Franciscan Health. The revision surgery was necessary due to a failure of Plaintiff's GXL liner.

100. With the exception of the failure of the GXL, Plaintiff would not have needed revision surgery.

101. Plaintiff's ability to bring this suit was delayed due to Defendants' affirmative actions to conceal the defects with the GXL.

L. Plaintiff Delores Shultz.

102. Plaintiff, Delores Shultz, was implanted with the GXL on or about July 6, 2015, in Carmel, Indiana at Franciscan Health under the care of Jeffery Pierson, MD.

103. Plaintiff reasonably relied on Plaintiff's surgeon to proceed with THA surgery and have the GXL product implanted.

104. Defendants arranged for the selection and delivery of Plaintiff's specific implant components to the operating room on the day of Plaintiff's surgery.

105. At the time of implant, each of the components implanted into Plaintiff were in substantially the same condition as when they left Defendants' control.

106. Plaintiff used the hip implant system, including the GXL in a normal and reasonably foreseeable manner.

107. Over the ensuing years, Plaintiff began to suffer from symptoms associated with excessive wear of the GXL, including pain and lack of mobility.

108. On or about December 27, 2021, Plaintiff underwent revision surgery by Anthony Feher, MD, to replace the failed GXL liner in Carmel, Indiana at Franciscan Health. The revision surgery was necessary due to a failure of Plaintiff's GXL liner.

109. With the exception of the failure of the GXL, Plaintiff would not have needed revision surgery.

110. Plaintiff's ability to bring this suit was delayed due to Defendants' affirmative actions to conceal the defects with the GXL.

M. <u>Plaintiff Mary Higgenbotham.</u>

111. Plaintiff, Mary Higgenbotham, was implanted with the GXL on or about February 15, 2012, in Carmel, Indiana at Franciscan Health under the care of Jeffery Pierson, MD.

112. Plaintiff reasonably relied on Plaintiff's surgeon to proceed with THA surgery and have the GXL product implanted.

113. Defendants arranged for the selection and delivery of Plaintiff's specific implant components to the operating room on the day of Plaintiff's surgery.

114. At the time of implant, each of the components implanted into Plaintiff were in substantially the same condition as when they left Defendants' control.

115. Plaintiff used the hip implant system, including the GXL in a normal and reasonably foreseeable manner.

116. Over the ensuing years, Plaintiff began to suffer from symptoms associated with excessive wear of the GXL, including pain and lack of mobility.

117. Plaintiff is currently scheduled to undergo revision surgery in March 2022 by Anthony Feher, MD, to replace the failed GXL liner in Carmel, Indiana at Franciscan Health. The revision surgery is necessary due to a failure of Plaintiff's GXL liner.

118. With the exception of the failure of the GXL, Plaintiff would not have needed revision surgery.

119. Plaintiff's ability to bring this suit was delayed due to Defendants' affirmative actions to conceal the defects with the GXL.

N. Plaintiffs' injuries.

120. As a direct and proximate result of the defective GXL, Plaintiffs were required to undergo surgical removal of the defective device, now have a hip replacement with decreased longevity, and suffered injuries, including but not limited to significant pain, tissue destruction, bone destruction, and loss of mobility.

121. Plaintiffs expect to continue suffering such injuries in the future because of the injuries received from the GXL.

122. As a direct and proximate result of the defective GXL, Plaintiffs incurred medical expenses and expects to incur additional medical expenses in the future.

123. As a direct and proximate result of the defective GXL, Plaintiffs incurred lost earning potential, income, and earnings.

124. As a direct and proximate result of the defective GXL, Plaintiffs experienced pain, suffering, emotional trauma and distress and are likely to experience pain, suffering emotional trauma and distress in the future.

125. As a direct and proximate result of Defendants' defective design, manufacturing, marketing, distribution, sale, servicing, and warnings of the defective GXL implant, Plaintiffs have suffered and continue to suffer injuries and damages, including, but not limited to: past, present and future physical and mental pain and

suffering; physical disability; past, present, and future medical, hospital, rehabilitative, and pharmaceutical expenses; and other related damages.

III. CAUSES OF ACTION

Count One — Strict Liability Failure To Warn — All Defendants

126. Plaintiffs re-allege and incorporates by reference all paragraphs in Sections I-II above as if fully stated herein.

127. At all times relevant to this action, while Defendants engaged in the business of designing, manufacturing, selling, marketing, promoting, and placing into the stream of commerce the GXL, the product contained defects that made it unreasonably dangerous beyond the expectations of the ordinary consumer, such as Plaintiffs, and were unfit for their intended use.

128. The GXL reached Plaintiffs without substantial change in the condition in which it was designed, developed, promoted, manufactured, and sold.

129. At the time and on the occasions in question, the GXL was being properly used for the purpose for which it was intended, and such device was in fact defective, unsafe and unreasonably dangerous.

130. The foreseeable risk of harm from the defects in the GXL could have been reduced or avoided by providing adequate instructions or warnings.

131. At all times relevant to the action, the dangerous propensities of the GXL were known to Defendants or were reasonably and scientifically knowable to them, through appropriate research and testing by known methods, at the time they distributed, supplied, or sold their respective product, and not known to ordinary

consumers.

132. The GXL was defective and unreasonably dangerous in that the labeling was insufficient to warn users of the hazardous conditions posed by said items, including but not limited to its increased propensity to cause osteolysis and other injuries associated with excessive wear of the GXL.

133. The GXL was defective due to inadequate, or the absence of, warnings or instructions, including warning stickers, placards, or proper documentation to alert users regarding the hazards posed by the GXL.

134. Defendants had a duty to warn, including a continuing post-sale duty to warn, regarding the unreasonable risk of harm associated with the GXL, particularly due to the progressive nature of the risk of injury from wear of the GXL.

135. Defendants failed to exercise reasonable care to inform Plaintiffs, Plaintiffs' doctors, and the medical community about dangers regarding the GXL.

136. As a direct and proximate result of the lack of reasonable and adequate instructions or warnings regarding the defects in the GXL, Plaintiffs suffered the injuries described above in Section II(M).

Count Two — Strict Liability Design And Manufacturing Defect — All Defendants

137. Plaintiffs re-allege and incorporate by reference all paragraphs in Sections I-II above as if fully stated herein.

138. At the time that Defendants designed, manufactured, promoted, marketed, sold, supplied, distributed and/or serviced the GXL, it contained defects

that made it unreasonably dangerous beyond the expectations of the ordinary consumer, and were unfit for their intended use.

139. The GXL reached Plaintiffs without substantial change in the condition in which it was sold.

140. At the time and on the occasions in question, the GXL was being properly used for the purpose for which it was intended, and such device was in fact defective, unsafe, and unreasonably dangerous.

141. As a direct and proximate result of the lack of reasonable and adequate instructions or warnings regarding the defects in the GXL, Plaintiffs suffered the injuries described above in Section II(M).

Count Three — Negligent Misrepresentation — All Defendants

142. Plaintiffs re-allege and incorporates by reference all paragraphs in Sections I-II above as if fully stated herein.

143. Defendants made statements concerning material facts which Defendants may have believed to be true but which in fact were false, or otherwise omitted material facts, including but not limited to:

a) Representing to the orthopaedic community, and Plaintiffs' surgeon, prior to implantation into Plaintiffs' bodies, that the GXL performed better than the competitors' Highly Cross Linked Polyethylene;
b) Defendants knew the GXL was failing at a high rate and failed to disclose this information to Plaintiffs and/or Plaintiffs' surgeon prior to installation of the GXL;
c) Defendants knew that other patients experienced problems with the GXL, including but not limited to, osteolysis, loosening of the components, deterioration of the polyethylene, and reports of significant pain, all prior to the installation of the GXL in Plaintiffs, and failed to disclose such information to Plaintiffs and/or Plaintiffs surgeon;

d) Defendants represented to Plaintiffs and/or their orthopedic surgeons, prior to the implantation of the GXL, that the GXL was clinically proven to reduce wear when, in fact, no clinical trials were submitted for approval by the FDA;

e) Defendants misrepresented the success rate of the GXL to Plaintiffs' surgeon; and

f) Defendants failed to disclose to Plaintiffs' surgeon, prior to the installation of the GXL in Plaintiffs' bodies, that they were aware of and/or witnessed revision surgeries in which the GXL failed, including becoming loose, causing osteolysis, and causing excessive wear.

g) Representing the GXL to have lower wear propensities than comparable products.

h) Representing the GXL to have better longevity than comparable products.

i) Failing to disclose adequate information about the safety and efficacy of the GXL either before or after Plaintiffs' purchase.

j) Knowingly producing and publishing deceptive and misleading statements and advertisements regarding the safety and efficacy of the GXL, while knowing of the defects and dangers associated with the GXL.

k) Failing to inform Plaintiffs and the public of the risk of injury after being informed of the increased rate of wear related adverse events with Defendants' other "enhanced" UHMWPE knee and ankle products.

l) Failing to inform Plaintiffs and the public of any potential risks related to Defendants' increased knowledge of problems associated with the GXL until Defendants had already designed and released a marketable replacement for the GXL.

m) Doing all of the above with the sole intent of selling more hip replacements and creating demand for Defendants' systems by using deceptive or untrue statements of fact about the safety and benefits of the GXL system.

144. Defendants were negligent in making such statements because they knew or should have known the statements were false or omitted material information.

145. In making these statements, Defendants intended or expected that another would rely on the statements.

146. Plaintiffs, through their surgeon agents, justifiably relied on the false

statements.

147. As a direct and proximate result of the lack of reasonable and adequate instructions or warnings regarding the defects in the GXL, Plaintiffs suffered the injuries described above in Section II(M).

Count Four — Negligence — All Defendants

148. Plaintiffs re-allege and incorporates by reference all paragraphs in Sections I-II above as if fully stated herein.

149. Defendants designed, tested, distributed, manufactured, promoted, advertised, sold, and marketed the GXL for implantation into consumers such as Plaintiffs by surgeons.

150. Defendants were negligent and careless in the design, testing, distribution, manufacture, promotion, advertising, sale, and marketing of the GXL.

151. Defendants had a duty to perform adequate evaluation on the safety and efficacy of the GXL. This included by reasonably gathering and reporting information regarding complaints and revisions and conducting adequate analysis on the information gathered.

152. Defendants further had a duty to timely share the results of its evaluation so that Plaintiffs, Plaintiffs' orthopedic surgeons, and the orthopedic community could be adequately apprised of the risks of the GXL.

153. Defendants further had a duty to recognize the application to Plaintiffs GXL the clinical risks and data associated with their other, similar "enhanced" UHMWPE products, including those utilized in the OPTETRAK, TRULIANT, and

VANTAGE systems.

154. Defendants failed to adequately evaluate the safety and efficacy of the GXL.

155. Defendants failed to adequately share the results of its evaluations of the GXL with Plaintiff, Plaintiff's orthopedic surgeon, or the orthopedic community.

156. Defendants failed to recognize the application of clinical data from the OPTETRAK, TRULIANT, and VANTAGE systems to patients receiving the GXL, despite the similarities in the products, and in particular, similarities in clinical risks of wear, fracture, and early failure.

157. Instead of acknowledging the uncertainties and dangers of the GXL, Defendants broadcast misrepresentations about the alleged safety and superiority of GXL throughout the orthopedic community knowing such information would be used to guide the surgeons and consumers who would be searching for artificial hip replacement systems.

158. Defendants supplied the false information about the GXL for the guidance of this group of surgeons and consumers, despite awareness of unreasonable risks with the GXL and despite awareness that Defendants' statements regarding the safety and efficacy of the GXL's wear propensities were not adequately supported by data.

159. Plaintiffs and Plaintiffs' surgeons justifiably relied upon the misrepresentations and omissions about the GXL's clinical safety in the determination that the GXL was safe and appropriate for implantation in Plaintiffs'

bodies.

160. Defendants' failure to properly discharge their duties were a direct and proximate cause of Plaintiff's injuries as described above in Section II(M).

Count Five — Information Negligently Supplied For The Guidance Of Others — All Defendants

161. Plaintiffs re-allege and incorporate by reference all paragraphs in Sections I-II above as if fully stated herein.

162. Plaintiffs' purchase of the GXL was a business transaction.

163. Defendants had a pecuniary interest in the promotion, marketing, sale, and servicing of the GXL.

164. Defendants supplied false information for the guidance of others regarding the selection of the GXL as a safe and effective hip replacement option, as alleged above.

165. Defendants failed to exercise reasonable care or competence in obtaining and communicating the information supplied for the guidance of others regarding the GXL.

166. Plaintiffs, and Plaintiffs' orthopedic surgeon agents, were within the limited group of persons for whose benefit and guidance the Defendants intended to supply the information.

167. The Defendants intended for their information to influence either the transaction in which Plaintiffs, through Plaintiffs' orthopedic surgeon agents, purchased the GXL or a substantially similar transaction.

168. Plaintiffs, individually and through Plaintiffs' orthopedic surgeon agents, justifiably relied upon the information provided by Defendants.

169. As a direct and proximate result of the Defendants' false information, Plaintiff suffered pecuniary loss, as described above.

Count Six — Consumer Protection Act — All Defendants [Pursuant To The Florida Unfair Trade Practices Act, F.S. §501.201 *Et. Seq.*]

170. Plaintiffs re-allege and incorporate by reference all paragraphs in Sections I-II above as if fully stated herein.

171. The acts by Defendants in this cause of action include, but are not limited to, the following deceptive and unfair acts:

a) Representing the GXL as safe and effective, while knowing those claims were false and without sufficient medical support.
b) Representing the GXL to be of a higher quality and more desirable product than other available alternatives.
c) Representing the GXL to have lower wear propensities than comparable products.
d) Representing the GXL to have better longevity than comparable products.
e) Failing to disclose adequate information about the safety and efficacy of the GXL either before or after Plaintiffs' purchase.
f) Knowingly providing inadequate warnings about the GXL's dangerous propensities.
g) Knowingly producing and publishing deceptive and misleading statements and advertisements regarding the safety and efficacy of the GXL, while knowing of the defects and dangers associated with the GXL.
h) Failing to inform Plaintiffs and the public of the risk of injury after being informed of the increased rate of wear related adverse events with Defendants other "enhanced" UHMWPE knee and ankle products.
i) Failing to inform Plaintiffs and the public of any potential risks related to Defendants' increased knowledge of problems associated with the GXL until Defendants had already designed and released a marketable replacement for the GXL.
j) Failing to report knowledge of adverse events to the FDA despite a legal requirement to do so.

k) Doing all of the above with the sole intent of selling more hip replacements and creating demand for Defendants' systems by using deceptive or untrue statements of fact about the safety and benefits of the GXL system.

172. The above acts constitute unfair and deceptive trade practices as defined in F.S. § 501.202 because they constitute false, unfair, misleading, and deceptive conduct that not only creates the likelihood of confusion and misunderstanding by Florida consumers but also the inherent capacity, tendency, and effect of deceiving Florida consumers.

173. The above acts constitute unconscionable acts and practices as specified in § 501.202 because they involve deception, fraud, misrepresentation, and knowing concealment, suppression, and omission of material facts related to a product that is intended to alter the health, well-being, and mobility of a human being.

174. Defendants acted with scienter and evil motive.

175. Plaintiffs reasonably and justifiably relied on the false, misleading, unfair, and deceptive oral and written statements and representations of Defendants, and as result of that reliance agreed to implantation of the GXL as directed and intended by Defendants.

176. Such acts occurred in the course of trade or commerce in the State of Florida at Defendants' principal place of business in Gainesville, Florida.

177. Such acts affected, and still affect, the public interest of all the citizens of the State of Florida.

178. Such acts caused injury to Plaintiffs as described above. Had Defendants

not engaged in unfair and deceptive conduct, Plaintiffs would have not paid substantial sums for, or agreed to implantation of, the GXL hip which caused Plaintiffs serious injury as alleged above in Section II(M).

179. Because of Defendants' violations of the Florida Unfair Trade Practices and Consumer Protection Law, Plaintiffs are entitled to any and all damages allowable by statue resulting from the violations, plus all permissible attorney's fees, interest, costs, expenses and such other relief and/or injunctive relief which the Court deems just and proper.

DEMAND FOR JURY TRIAL

180. Plaintiffs respectfully request that a jury be impaneled to hear this cause of action and to award such damages as the jury finds to be fair and reasonable under the circumstances.

WHEREFORE, Plaintiff respectfully demands judgment against Defendants for compensatory damages, attorney's fees, and any other relief the Court deems just and proper.

DATED this 7th day of March 2022.

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