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U.S. DISTRICT COURT
N.D. OF ALABAMA

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF ALABAMA

BIRMINGHAM DIVISION

MICHAEL WAYNE HOPPER	*	**CIVIL ACTION**
***Plaintiff*,**	*	
	*	**NO.**
VERSUS	*	
	*	**JUDGE**
ZIMMER BIOMET HOLDINGS, INC.	*	
Defendant.	*	**MAGISTRATE JUDGE**

****

COMPLAINT FOR DAMAGES

(JURY TRIAL REQUESTED)

NOW INTO COURT, through undersigned Counsel, comes Michael Hopper who respectfully submits this Complaint for Damages and represents as follows:

I. PARTIES

1. Michael Wayne Hopper ("Plaintiff") is an adult resident citizen of Shelby County, State of Alabama.

2. Zimmer Biomet Holdings, Inc. ("Defendant"), is a Delaware corporation with its principal business office located at 345 E Main St, Warsaw, Indiana. Its Registered Agent for service is Corporation Service Company, 135 North Pennsylvania Street, Suite 1610, Indianapolis, Indiana 46204.

II. FEDERAL SUBJECT MATTER JURISDICTION

3. This Honorable Court has federal subject matter jurisdiction pursuant to 28 U.S.C. § 1332(a)(1) because the amount in controversy exceeds the sum or value of $75,000 exclusive of interest and costs, and is between citizens of different states.

III. PERSONAL JURISDICTION

4. Defendant engages in business and commerce within the Northern District of Alabama and the Birmingham Division, and is subject to the general personal jurisdiction and/or the specific personal jurisdiction of this Honorable Court.

IV. VENUE

5. Venue is correct in this Honorable Court pursuant to 28 U.S.C. § 1391(2)(b) because a substantial part of the events and omissions giving rise to Plaintiff's claims occurred within this judicial district.

V. FACTS

6. At all times relevant to this matter, Defendant conducted substantial business in the State of Alabama and had numerous contacts with the Northern District of Alabama related to the subject matter of this action.

7. Defendant, either directly or through its agents, apparent agents, servants or employees, imported, distributed, and sold the RibFix Blu ® Thoracic Fixation System (more commonly known as "rib plates") and associated fixation hardware within the State of Alabama and within this judicial district.

8. Defendant, which at all times relevant was engaged in the business of distributing or otherwise placing, for any commercial purpose, in the stream of commerce for use or consumption the RibFix Blu ® Thoracic Fixation System and associated fixation hardware, was an "original seller" within the meaning of Ala. Code § 6-5-501(1).

9. On September 13, 2021, at Brookwood Baptist Medical Center in Birmingham, Alabama, cardio-thoracic surgeon William McAlexander, M.D., implanted three RibFix Blu ® Thoracic Fixation Systems ribs 3, 4, and 5 on the right side of Plaintiff's chest.

10. On November 4, 2022, in response to new and increasing right chest area pain and discomfort, a CT scan was performed on Plaintiff.

11. On November 8, 2022, Plaintiff consulted with Dr. McAlexander regarding his chest pain and discomfort, and to discuss the results of a CT-scan taken on November 4, 2022.

12. During a physical examination, Dr. McAlexander detected a clicking/popping sound.

13. The November 4, 2022 CT-scan imagery showed fractures of all three RibFix Blu ® Thoracic Fixation Systems. [1]

14. On December 2, 2022 at Brookwood Baptist Medical Center in Birmingham, Alabama, Dr. McAlexander removed the three fractured RibFix Blu ® Thoracic Fixation Systems and their associated bone screws.

15. Subsequent scanning electron microscope examination revealed that the RibFix Blu ® Thoracic Fixation System's fracture surface showed significant post-fracture damage, appearing "peened-out" (*i.e.*, bent, or flattened, smeared). Undamaged fracture surfaces show signs of fatigue. These undamaged surfaces are in-between the regions of post-fracture damage, and show beach marks and striations caused by fatigue fracture, indicating that the RibFix Blu ® Thoracic Fixation System's material fatigued and then sustained a terminal fracture.

16. More probably than not, the cause of the fatigue and fracture of the three RibFix Blu ® Thoracic Fixation System devices along the common vertical line shown in Exhibit 1 was the expansion and contraction of Plaintiff's rib cage during ordinary breathing over the course of more than one year following implantation.

[1] See Exhibit 1. See also Exhibit 2, a blow-up of the three RibFix Blu ® Thoracic Fixation System devices depicted in Exhibit 1.

17. Defendant, as the original seller of the thoracic plating system is liable to Plaintiff for the damages proximately caused by a characteristic of the product that rendered it unreasonably dangerous, as such danger arose from a reasonable anticipated use of the product by the Plaintiff.

18. Plaintiff has suffered damages as a result of the RibFix Blu ® Thoracic Fixation System's fatigue and fracture, including but not limited to physical injury, disability, medical expenses, pain and suffering, mental anguish and distress, and loss of enjoyment of life.

VI. CLAIMS ASSERTED

19. Plaintiff alleges:

A. That he suffered injury or damages to himself, caused by Defendant, which sold its RibFix Blu ® Thoracic Fixation System product in a defective condition that was unreasonably dangerous to him as the ultimate user or consumer;

B. That Defendant was engaged in the business of selling the RibFix Blu ® Thoracic Fixation System medical device product; and

C. That the RibFix Blu ® Thoracic Fixation System medical device product was expected to, and did, reach the Plaintiff without substantial change in the condition in which it was sold.

COUNT ONE

ALABAMA EXTENDED MANUFACTURER'S LIABILITY DOCTRINE (AEMLD)

20. Plaintiff incorporates the preceding paragraphs as if set out fully herein, and alleging more specifically states:

21. At all times relevant, Defendant was the researcher, designer, manufacturer, tester, advertiser, promoter, marketer, packager, labeler, seller and/or distributor of the RibFix Blu ® Thoracic Fixation System, which is defective and unreasonably dangerous.

22. The RibFix Blu ® Thoracic Fixation System is defective in its design or formulation in that it is not reasonably fit, suitable or safe for its intended purpose and/or its foreseeable risks exceed the benefits associated with its design. The fractured RibFix Blu ® Thoracic Fixation System is defective in design because it poses a greater likelihood of injury, is more dangerous than other available rib plating devices, and the utility of the RibFix Blu ® Thoracic Fixation System does not outweigh its risks.

23. The defective condition of the RibFix Blu ® Thoracic Fixation System rendered it unreasonably dangerous and/or not reasonably safe, and the RibFix Blu ® Thoracic Fixation System was in this defective condition at the time it left the hands of Defendant. The RibFix Blu ® Thoracic Fixation System was expected to and did reach Plaintiff and his physician without substantial change in the condition in which it was designed, manufactured, labeled, sold, distributed, marketed, promoted, supplied, and otherwise released into the stream of commerce.

24. The three RibFix Blu ® Thoracic Fixation Systems were used for their intended purposes and the devices were materially without substantial change in the condition in

which they were designed, manufactured, labeled, sold, distributed, marketed, promoted, supplied, and otherwise released into the stream of commerce.

25. The RibFix Blu ® Thoracic Fixation System is defective in design because the process by which it is constructed and its intended use cause fatigue-related fracture and a failure of the physical integrity of the rib plate.

26. The RibFix Blu ® Thoracic Fixation System is defective in design because it is more prone to suffer fracture-related fracture, perforate internal vasculature, and otherwise malfunction requiring surgery to remove the device.

27. At or before the time the RibFix Blu ® Thoracic Fixation System was released on the market and/or implanted in Plaintiff, Defendant could have designed the RibFix Blu ® Thoracic Fixation System to make it less prone to fatigue-related fracture, and there was a practical, technically feasible safer alternative design that would have prevented the harm Plaintiff suffered without substantially impairing the function of the device.

28. The RibFix Blu ® Thoracic Fixation System is and was being used in Defendant's intended manner at the time it was surgically implanted into Plaintiff and during the time it remained in Plaintiff.

29. Defendant had a duty to create a product that was not unreasonably dangerous for its normal, intended use and breached this duty.

30. Defendant knew or should have known that the RibFix Blu ® Thoracic Fixation System would be implanted in patients and that physicians and patients were relying on them to furnish a suitable product. Further, Defendant knew or should have known that patients in whom the RibFix Blu ® Thoracic Fixation System would be implanted, such as

Plaintiff, could be and would be injured by the defective design and composition of the RibFix Blu ® Thoracic Fixation System.

31. Defendant researched, designed, manufactured, tested, advertised, promoted, marketed, sold and distributed a defective product which, when used in its intended or reasonably foreseeable manner, created an unreasonable risk to the health of consumers, such as Plaintiff, and Defendant is therefore liable for the injuries sustained by Plaintiff.

32. As a direct and proximate result of the RibFix Blu ® Thoracic Fixation System's aforementioned defects, Plaintiff suffered serious physical and mental injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

33. Defendant directly advertised and/or marketed the RibFix Blu ® Thoracic Fixation System to health care professionals and consumers, including Plaintiff and Plaintiff's physicians, and therefore had a duty to warn of the risks associated with the use of the RibFix Blu ® Thoracic Fixation System. Defendant breached this duty.

34. At the time Defendant designed, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold the RibFix Blu ® Thoracic Fixation System into the stream of commerce, the RibFix Blu ® Thoracic Fixation System was defective and presented a substantial danger to users of the device when put to its intended and reasonably anticipated use, namely as a rib fixation device. Defendant failed to adequately warn of the RibFix Blu ® Thoracic Fixation System's known or reasonably scientifically knowable dangerous propensities and further failed to adequately provide instructions on the safe and proper use of the device.

35. Defendant knew or should have known at the time they manufactured, labeled, distributed and sold the RibFix Blu ® Thoracic Fixation System that was implanted into Plaintiff that the RibFix Blu ® Thoracic Fixation System posed a significant and higher risk than other similar devices of device fatigue-related failure and resulting serious injuries.

36. Defendant further knew that RibFix Blu ® Thoracic Fixation System devices were fracturing.

37. Defendant's RibFix Blu ® Thoracic Fixation System:

A. Was defectively designed in that it was not sufficiently robust to withstand the ordinary and expected forces of everyday life (*e.g.*, breathing) which rendered it unreasonably dangerous;

B. A safer alternative design existed at the relevant time (*i.e.*, a more robust version of the RibFix Blu ® Thoracic Fixation System); and

C. The defective design resulted in the fracture of the thoracic plating system which was a producing cause of Plaintiff's injury.

38. Defendant's RibFix Blu ® Thoracic Fixation System was more dangerous than an ordinary consumer would expect when it is used in an intended or reasonably foreseeable manner.

39. A product design other than the one actually used in reasonable probability:

A. Would have prevented or significantly reduced the risk of the Plaintiff's personal injury without substantially impairing the product's utility; and

B. A more robust design was economically and technologically feasible at the time the RibFix Blu ® Thoracic Fixation System left Defendant's control by the application of existing or reasonably achievable scientific knowledge.

40. The RibFix Blu ® Thoracic Fixation System's defective design was a direct and proximate producing cause of the personal injury for which Plaintiff seeks recovery:

A. The RibFix Blu ® Thoracic Fixation System was defectively designed in that it was not sufficiently robust to withstand the ordinary and expected forces of everyday life (*e.g.*, breathing) which rendered it unreasonably dangerous;

B. A safer alternative design existed at the relevant time (*i.e.*, a more robust version of the thoracic plating system); and

C. The defective design resulted in a fatigue induced fracture of the RibFix Blu ® Thoracic Fixation System which was a producing cause of Plaintiff's injury.

41. Defendant's RibFix Blu ® Thoracic Fixation System was more dangerous than an ordinary consumer would expect when it is used in an intended or reasonably foreseeable manner.

42. A product design other than the one actually used in reasonable probability:

A. Would have prevented or significantly reduced the risk of the Plaintiff's personal injury without substantially impairing the product's utility; and

B. A more robust design was economically and technologically feasible at the time the RibFix Blu ® Thoracic Fixation System left Defendant's control by the application of existing or reasonably achievable scientific knowledge.

43. The RibFix Blu ® Thoracic Fixation System's defective design was a direct and proximate producing cause of the personal injury for which Plaintiff seeks recovery

44. Defendant failed to timely and reasonably warn of material facts regarding the safety and efficacy of the RibFix Blu ® Thoracic Fixation Systems. No reasonable health care provider, including Plaintiff's, and no reasonable patient would have used the RibFix Blu ® Thoracic Fixation System in the manner directed, had those facts been made known to the prescribing healthcare providers or patients.

45. The RibFix Blu ® Thoracic Fixation Systems was not accompanied by proper warnings and instructions to physicians and the public regarding potential adverse side effects associated with the RibFix Blu ® Thoracic Fixation System and the comparative severity and duration of such adverse side effects.

46. When Plaintiff was implanted with the three RibFix Blu ® Thoracic Fixation Systems, Defendant failed to provide adequate warnings, instructions, or labels regarding the severity and extent of health risks posed by the device.

47. The health risks associated with the RibFix Blu ® Thoracic Fixation Systems are of such a nature that ordinary patients and consumers would not have readily recognized the potential harm.

48. The RibFix Blu ® Thoracic Fixation System was defective at the time of release into the stream of commerce due to inadequate warnings, labeling and/or instructions accompanying the device.

49. Neither Plaintiff nor his health care providers knew of the substantial danger associated with the intended and foreseeable use of the RibFix Blu ® Thoracic Fixation System as described herein.

50. Plaintiff and his health care providers used the RibFix Blu ® Thoracic Fixation System in a normal, customary, intended, and foreseeable manner, namely as a surgically placed device used for stabilization and rigid fixation of ribs. Moreover, Plaintiff's health care providers did not place or maintain the device incorrectly such that it caused the device to fatigue and fracture, or otherwise malfunction.

51. Upon information and belief, the defective and dangerous condition of the RibFix Blu ® Thoracic Fixation System, including the three implanted into Plaintiff, existed at the time they were manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold by Defendant to distributors and/or healthcare professionals or organizations. Upon information and belief, the RibFix Blu ® Thoracic Fixation System implanted in Plaintiff was in the same condition as when it was manufactured, inspected, marketed, labeled, promoted, distributed and sold by Defendant.

52. Defendant failed to provide proper warning and/or instructions to Dr. McAlexander that its RibFix Blu ® Thoracic Fixation System could and would fracture as a result of commonplace and everyday occurrences (*e.g.*, breathing), which was a producing cause of Plaintiff's injury.

53. Defendant did not warn Dr. McAlexander that everyday light activity, including breathing, can and does cause its RibFix Blu ® Thoracic Fixation System to flex, weaken, and fracture.

54. Defendant deprived Plaintiff's treating surgeon of information necessary to understand the RibFix Blu ® Thoracic Fixation System's limitations, to decide if its implantation was appropriate to Plaintiff's lifestyle and employment circumstances, and to obtain valid informed consent from Plaintiff. As such, Dr. McAlexander was not a "learned intermediary" and Defendant failed to warn the Plaintiff.

55. But for the inadequate warning, Dr. McAlexander would have recommended different treatment, or selected a different device, or would have given Plaintiff advice that would have lead him to withhold consent.

56. Defendant already knew, or should have foreseen, the risk of everyday mundane events like breathing, as a cause of fatigue then fracture of its RibFix Blu ® Thoracic Fixation System at the time the system was marketed.

58. Defendant's failure to warn was a direct and proximate producing cause of the personal injury for which Plaintiff seeks recovery.

59. As a direct and proximate result of Defendant's lack of sufficient warnings and/or instructions, Plaintiff suffered serious physical and mental injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

COUNT TWO - NEGLIGENCE

60. Plaintiff incorporates the preceding paragraphs as if set out fully, and alleging more specifically states:

61. Defendant owed Plaintiff a duty to exercise reasonable care when designing, manufacturing, marketing, advertising, distributing, selling, and conducting post-market

surveillance of the RibFix Blu ® Thoracic Fixation System.

62. Defendant failed to exercise due care under the circumstances and therefore breached this duty by:

A. Failing to properly and thoroughly test the RibFix Blu ® Thoracic Fixation System before releasing the device to market, and/or failing to implement feasible safety improvements;

B. Failing to properly and thoroughly analyze the data resulting from any pre-market testing of the RibFix Blu ® Thoracic Fixation System;

C. Failing to conduct sufficient post-market testing and surveillance of the RibFix Blu ® Thoracic Fixation System;

D. Designing, manufacturing, marketing, advertising, distributing, and selling the RibFix Blu ® Thoracic Fixation System to health care providers and patients/consumers, including Plaintiff, without an adequate warning of the significant and dangerous risks of the RibFix Blu ® Thoracic Fixation System, including but not limited to, its propensity to fatigue and fracture, and without proper instructions to avoid the harm which could foreseeably occur as a result of using the device;

E. Failing to exercise due care when advertising and promoting the RibFix Blu ® Thoracic Fixation System; and

F. Negligently continuing to manufacture, market, advertise, and distribute the RibFix Blu ® Thoracic Fixation System after Defendant knew or should have known of its adverse effects.

63. In performing the foregoing acts, omissions, and misrepresentations, Defendant acted with gross negligence.

64. As a direct, actual, and proximate cause of Defendant's actions, omissions, and misrepresentations, Plaintiff suffered serious physical and mental injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

COUNT III - BREACH OF IMPLIED WARRANTY

65. Plaintiff incorporates preceding paragraphs as if set out fully herein, and alleging more specifically alleges:

66. Defendant was the seller of the RibFix Blu ® Thoracic Fixation System and sold the RibFix Blu ® Thoracic Fixation System to Plaintiff and/or Plaintiff's physician to be implanted in Plaintiff.

67. Defendant impliedly warranted that the RibFix Blu ® Thoracic Fixation System was merchantable and fit for the ordinary purposes for which it was intended.

68. When the RibFix Blu ® Thoracic Fixation System was implanted in the Plaintiff, it was being used for the ordinary purposes for which it was intended.

69. Plaintiff, individually and/or by and through his physician, relied upon Defendant's implied warranties of merchantability in consenting to have the RibFix Blu ® Thoracic Fixation System implanted in her.

70. Privity exists between Plaintiff and Defendant because Plaintiff's physicians acted as Plaintiff's purchasing agents in the subject transaction and/or because Plaintiff was a third-party beneficiary of the subject contract.

71. Defendants breached these implied warranties of merchantability because three RibFix Blu ® Thoracic Fixation Systems implanted in Plaintiff were neither merchantable nor suited for their intended uses as warranted in that the devices varied from their intended specifications.

72. Defendants' breaches of their implied warranties resulted in the implantation of unreasonably dangerous and defective RibFix Blu ® Thoracic Fixation System in the Plaintiff's body, placing Plaintiff's health and safety in jeopardy.

73. As a direct, actual, and proximate cause of Defendant's breach of the aforementioned implied warranty, Plaintiff suffered serious physical and mental injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

COUNT FOUR - BREACH OF EXPRESS WARRANTY

74. Plaintiff incorporates the preceding paragraphs as if set out fully herein, and alleging more specifically states:

75. Defendant, through its officers, directors, agents, representatives, written literature and packaging, and written and media advertisements, expressly warranted to Plaintiff, Plaintiff's healthcare providers and implanting physician, that the RibFix Blu ® Thoracic Fixation System was safe and fit for use by consumers, was of merchantable quality, did not produce dangerous side effects, and was adequately tested and fit for its intended use.

76. The RibFix Blu ® Thoracic Fixation System does not conform to the Defendant's express representations because it is not reasonably safe, has numerous serious side effects, and causes severe and permanent injuries.

77. At all relevant times, the RibFix Blu ® Thoracic Fixation System did not perform as safely as an ordinary consumer would expect, when used as intended or in a reasonably foreseeable manner.

78. Plaintiff, his physicians, and the medical community reasonably relied upon the Defendant's express warranties for the RibFix Blu ® Thoracic Fixation System.

79. At all relevant times, the RibFix Blu ® Thoracic Fixation System was used on Plaintiff by Plaintiff's physicians for the purpose and in the manner intended by Defendant.

80. Plaintiff and Plaintiff's physicians, by the use of reasonable care, could not have discovered the breached warranty and realized its danger.

81. As a direct, actual, and proximate cause of the breach of Defendant's express warranty, Plaintiff suffered serious physical and mental injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

VII. DAMAGES:

82. Plaintiff itemizes his general and special damages as follows:

A. Mental anguish;

B. Physical pain and suffering;

C. Loss of enjoyment of life;

E. Medical expenses; and

F. Loss of income.

VIII. LIABILITY ALLEGATIONS:

83. For reason of the acts of fault, want of care, and/or negligence on the part of Defendant, which were a direct and proximate causes of Plaintiff's injury, the Defendant is liable to Plaintiff in money damages exceeding the sum or value of $75,000.00 exclusive of interest and costs.

IX. JURY TRIAL DEMAND

84. Pursuant to Fed. R. Civ. P. 38, Plaintiff demands trial by jury on all issues of fact and law triable to a jury.

X. PRAYER FOR RELIEF:

85. **WHEREFORE**, Plaintiff demands judgment against Defendant, and prays:

A. That Zimmer Biomet Holdings, Inc., be served with a copy of the Complaint for Damages;

B. That Zimmer Biomet Holdings, Inc., serve its Answer thereto;

C. That after all due proceedings had, there be a final Judgment holding Zimmer Biomet Holdings, Inc., liable to the Plaintiff in money damages reasonable under these premises and exceeding the sum or value of $75,000.00 exclusive of interest and costs;

D. That there be an award of legal interest from the date of judicial demand until all damages awarded are fully paid;

E. That there be an award of all costs allowed by Fed. R. Civ. P. 54(b) and 28 U.S.C. § 1920;

F. That there be trial by jury on all issues of fact and law triable to a jury; and

G. That the Court grant such other relief as the interests of justice may require.

Respectfully submitted this 6th day of September, 2024, by:

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