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DENVER DISTRICT COURT
CITY AND COUNTY OF DENVER
1437 Bannock Street
Denver, Colorado 80202

Plaintiff: ALFONSO A. ALARID

v.

Defendants: BIOMET, INC.;
BIOMET ORTHOPEDICS, LLC; and
BIOMET MANUFACTURING, LLC

▲ Court Use Only ▲

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Case No.: 2014CV

Courtroom:

COMPLAINT AND JURY DEMAND

Plaintiff Alfonso A. Alarid, by and through his attorneys, Jennifer Bisset and Gregory A. Hall, for his Complaint states and alleges as follows:

I. PARTIES AND JURISDICTION

1. Plaintiff Alfonso A. Alarid ("Alarid") resides, at 1580 W. Beekman Place, Denver, CO

80221-1517.

2. Defendant Biomet, Inc. is an Indiana corporation registered with the Colorado Secretary of State, transacting business in Colorado.

3. Defendant Biomet Orthopedics, LLC is an Indiana Limited Liability Company and a wholly-owned subsidiary of Biomet, Inc. Biomet Orthopedics, LLC is Biomet's sales and marketing division and is registered with the Colorado Secretary of State conducting business in Colorado.

4. Defendant Biomet Manufacturing LLC, (a/k/a Biomet Manufacturing Corporation) is an Indiana Limited Liability Company conducting business in Colorado. Upon information and belief, Biomet, Inc. is a holding company for Biomet Manufacturing LLC, which includes the Warsaw manufacturing and development activities.

5. Biomet, Inc., Biomet Manufacturing LLC, and Biomet Orthopedics, LLC are collectively referred to herein as "Biomet" or "Defendants."

6. Defendants have authorized as their agent for service of process, Corporate Creations Network, Inc. located within the City and County of Denver.

7. This court has personal and subject matter jurisdiction over this action pursuant to C.R.S. §13-1-124(1)(a), (b) and (c).

8. Venue is proper pursuant to C.R.C.P. 98(c).

II. NATURE OF THE CASE

9. This is a products liability action concerning Biomet's "Comprehensive® Reverse Shoulder" devices.

10. Biomet designed, manufactured, sold, distributed, and delivered the "Comprehensive® Reverse Shoulder": a prosthetic device used in reverse shoulder replacement procedures.

11. Plaintiff's claims are not pre-empted by the Medical Device Amendments of 1976 (MDA), 21 U.S.C.§360(c), *et seq.* because Biomet's Comprehensive® Reverse Shoulder is a Class II Device, approved pursuant to the FDA 510(K) process, instead of the more rigorous FDA "Premarket Approval" process.

12. In 2007 Defendant Biomet, Inc. submitted an application to the Food and Drug Administration (FDA) requesting that the FDA give the Comprehensive® Reverse

Shoulder clearance under the 510(k) process as Class II Device.

13. In 2008 Defendants received clearance through the 510(k) process from the FDA to market the Comprehensive® Reverse Shoulder as a Class II Device.

14. Prior to September 13, 2010, Biomet received multiple adverse reports regarding its defective Comprehensive® Reverse Shoulder.

15. On September 13, 2010 Biomet issued a recall notice regarding the defective Comprehensive® Reverse Shoulder, including the two Comprehensive® Reverse Shoulder devices which were implanted into Plaintiff's left shoulder in 2009 and his right shoulder in 2010.

16. According to Biomet, it issued the recall notice due to complaints it received regarding fracturing of the device at the joint between the trunnion and the baseplate.

17. Biomet designed a special tool specifically designed to remove the trunnion that would snap off because of the defective design and manufacture of the Comprehensive® Reverse Shoulder.

18. Plaintiff was implanted with two of the Biomet Comprehensive® Reverse Shoulder devices. The left shoulder was implanted on September 24, 2009 and the right shoulder was implanted on July 22, 2010. Both devices failed at the joint between the trunnion and the baseplate, causing pain and loss of function, as more specifically set forth below.

19. As a result of the failure of the Biomet products, Plaintiff had to undergo two revision surgeries to remove and replace the defective devices in order to restore function to his shoulders.

III. FACTUAL BACKGROUND – CASE SPECIFIC FACTS

A. Defective Biomet "Comprehensive® Reverse Shoulder"- Left Shoulder

20. Plaintiff repeats and incorporates by reference each and every allegation of paragraphs 1 through 19, as if fully set forth herein.

21. October 21, 2008 Plaintiff was told by Joseph Hsin, M.D. that he would need surgery to repair his left shoulder massive rotator cuff tear.

22. In 2009 orthopedic surgeon David Schneider, M.D. examined Plaintiff and recommended a reverse left total shoulder arthroplasty.

23. Reverse total shoulder arthroplasty ("RTSA") is performed to treat rotator cuff tear arthropathy and other rotator cuff dysfunction.

24. Reverse shoulder replacement, or RTSA, is a surgical procedure that reverses the anatomy of the shoulder. It is designed so that the ball is attached to the shoulder blade (scapula) and the socket is placed on top of the upper-arm bone (humerus). By reversing the normal anatomy, the deltoid muscle, one of the stronger shoulder muscles and the only abducting muscle remaining in the shoulder, is given control to raise the arm.

25. On September 24, 2009 Plaintiff underwent surgery on his left shoulder at Lutheran Medical Center where Dr. Schneider performed a reverse total shoulder arthroplasty and implanted the first Biomet Comprehensive® Reverse Shoulder device.

26. No complications were reported during the surgery.

27. On July 30, 2012 Plaintiff was simply participating in physical therapy when he felt a clicking sensation in his left arm followed by immediate pain.

28. Plaintiff was directed to seek medical attention from Dr. Schneider.

29. On August 1, 2012 Dr. Schneider evaluated Plaintiff's left shoulder and ordered a CT scan.

30. The CT scan on August 6, 2012 showed that the humeral baseplate tray and trunnion of the Biomet Comprehensive® Reverse Shoulder had separated.

31. Dr. Schneider advised Plaintiff that the Comprehensive® Reverse Shoulder implant in his left shoulder had failed and that he would need revision surgery.

32. On October 11, 2012, Dr. Schneider, performed revision surgery at Ortho Colorado Hospital to remove and replace the Biomet Comprehensive® Reverse Shoulder prosthesis that had been implanted into Plaintiff's left shoulder on September 24, 2009.

33. After the Biomet Comprehensive® Reverse Shoulder had been removed from Plaintiff's left shoulder visual inspection confirmed that the device fractured at the joint between the trunnion and the baseplate.

34. As a direct and proximate result of the defective Comprehensive® Reverse Shoulder implanted into Plaintiff's left shoulder, Plaintiff sustained injuries, damages and losses including: emotional distress and mental anguish; past, present, and future pain and suffering; past and future medical and rehabilitation expenses; loss of earnings and

earning capacity; loss of enjoyment of life; permanent disfigurement; and permanent physical impairment.

B. Defective Biomet "Comprehensive® Reverse Shoulder"- Right Shoulder

35. Plaintiff repeats and incorporates by reference each and every allegation of paragraphs 1 through 34, as if fully set forth herein.

36. On May 12, 2010 an MRI of Plaintiff's right shoulder showed severe glenohumeral joint arthritis with labral tearing and irregularity with a large paralabral cyst along the posterior glenoid.

37. Dr. Schneider recommended a reverse right total shoulder arthroplasty.

38. On July 22, 2010, Plaintiff underwent surgery on his right shoulder at Lutheran Medical Center, during which Dr. Schneider performed a reverse right total shoulder arthroplasty and implanted the second Biomet Comprehensive® Reverse Shoulder device.

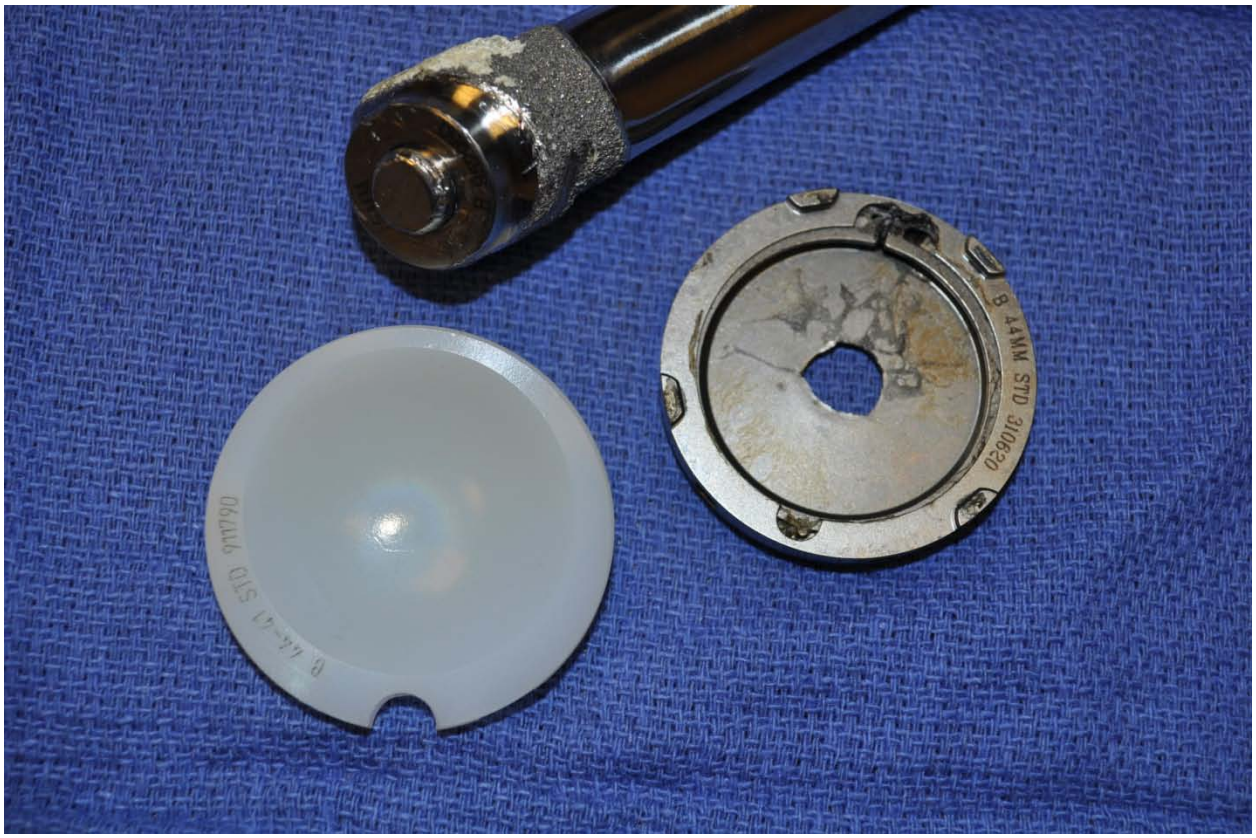
39. No complications were reported during the surgery.

40. On March 22, 2013, Plaintiff was simply getting up off the floor when he experienced right shoulder pain.

41. On April 17, 2013, Dr. Schneider admitted plaintiff to Ortho Colorado Hospital and performed revision surgery on the right shoulder to remove and replace the defective Comprehensive® Reverse Shoulder prosthesis that had been implanted into Plaintiff's right shoulder on July 22, 2010.

42. After the Biomet Comprehensive® Reverse Shoulder had been removed from Plaintiff's right shoulder, visual inspection confirmed the device fractured at the joint between the trunnion and the baseplate, and that the trunnion had snapped off.

43. Below is a picture of the Biomet Comprehensive® Reverse Shoulder prosthesis that Dr. Schneider removed from Plaintiff's right shoulder showing the fractured baseplate and the snapped off trunnion.



44. The Comprehensive® Reverse Shoulder prosthesis was defective when it left Defendants' custody and control.

45. As a direct and proximate result of the defective Comprehensive® Reverse Shoulder implanted into Plaintiff's right shoulder, Plaintiff sustained injuries, damages and losses including: emotional distress and mental anguish; past, present, and future pain and suffering; past and future medical and rehabilitation expenses; loss of earnings and earning capacity; loss of enjoyment of life; permanent disfigurement; and permanent physical impairment.

IV. FIRST CLAIM FOR RELIEF

(Strict Products Liability against All Defendants - Left Shoulder Prosthesis)

46. Plaintiff repeats and incorporates by reference each and every allegation of paragraphs 1 through 45 as if fully set forth herein.

47. Defendants designed, manufactured, prepared, sold, and delivered the Comprehensive® Reverse Shoulder that Dr. Schneider used when he implanted the prosthesis into Plaintiff's left shoulder on September 24, 2009.

48. The Comprehensive® Reverse Shoulder was in a defective condition which was unreasonably dangerous to the Plaintiff at the time Defendants sold the device.

49. The Comprehensive® Reverse Shoulder was expected to reach the Plaintiff without substantial change in the condition in which it was sold.

50. The Comprehensive® Reverse Shoulder was delivered without substantial change in the condition in which it was manufactured and sold by Defendants.

51. The Defendants knew that the device would not be inspected for defects prior to its implantation into patients such as the Plaintiff.

52. The Plaintiff was a person who would reasonably be expected to use the Comprehensive® Reverse Shoulder that Dr. Schneider implanted into his left shoulder on September 24, 2009.

53. The Comprehensive® Reverse Shoulder was being used in a foreseeable manner at the time it failed.

54. The defective and unreasonably dangerous condition of the Comprehensive® Reverse Shoulder implanted into his left shoulder was a proximate cause of Plaintiff's injuries and damages.

V. SECOND CLAIM FOR RELIEF

(Strict Products Liability against All Defendants - Right Shoulder Prosthesis)

55. Plaintiff repeats and incorporates by reference each and every allegation of paragraphs 1 through 54 as if more fully set forth herein.

56. Defendants designed, manufactured, prepared, sold, and delivered the Comprehensive® Reverse Shoulder that Dr. Schneider used when he implanted the prosthesis into Plaintiff's right shoulder on July 22, 2010.

57. The Comprehensive® Reverse Shoulder was in a defective condition which was unreasonably dangerous to the Plaintiff at the time Defendants sold the device.

58. The Comprehensive® Reverse Shoulder was expected to reach the Plaintiff without substantial change in the condition in which it was sold.

59. The Comprehensive® Reverse Shoulder was delivered without substantial change in the condition in which it was manufactured and sold by Defendants.

60. The Defendants knew that the device would not be inspected for defects prior to its implantation into patients such as the Plaintiff.

61. The Plaintiff was a person who would reasonably be expected to use the Comprehensive® Reverse Shoulder that Dr. Schneider implanted into his right shoulder on July 22, 2010.

62. The Comprehensive® Reverse Shoulder was being used in a foreseeable manner at the time it failed.

63. The defective and unreasonably dangerous condition of the Comprehensive® Reverse Shoulder implanted into his right shoulder was a proximate cause of Plaintiff's injuries and damages.

VI. THIRD CLAIM FOR RELIEF

(Breach of Express Warranty against All Defendants - Left Shoulder Prosthesis**)**

64. Plaintiff repeats and incorporates by reference each and every allegation of paragraphs 1 through 63 as if more fully set forth herein.

65. Defendants sold the Comprehensive® Reverse Shoulder that Dr. Schneider used when he implanted the prosthesis into Plaintiff's left shoulder on September 24, 2009.

66. Defendants expressly warranted the Comprehensive® Reverse Shoulder that Dr. Schneider surgically implanted into Plaintiff's left shoulder on September 24, 2009 as a safe and effective orthopedic device that would perform under normal stress placed on the shoulder.

67. The Plaintiff was person who was reasonably expected to use the Comprehensive® Reverse Shoulder prosthesis.

68. The Comprehensive® Reverse Shoulder prosthesis sold by the Defendants was not as warranted because it caused serious injury to the Plaintiff when used as intended.

69. This breach of warranty caused the Plaintiff's injuries and damages.

70. Within a reasonable time after the Plaintiff discovered the Defendants' breach of warranty, the plaintiff notify the Defendants of such breach.

VII. FOURTH CLAIM FOR RELIEF

(Breach of Express Warranty against All Defendants -Right Shoulder Prosthesis)

71. Plaintiff repeats and incorporates by reference each and every allegation of paragraphs 1 through 70 as if more fully set forth herein.

72. Defendants sold the Comprehensive® Reverse Shoulder that Dr. Schneider used when he implanted the prosthesis into Plaintiff's right shoulder on July 22, 2010.

73. Defendants expressly warranted the Comprehensive® Reverse Shoulder that Dr. Schneider surgically implanted into Plaintiff's right shoulder on July 22, 2010 as a safe and effective orthopedic device that would perform under normal stress placed on the shoulder.

74. The Plaintiff was person who was reasonably expected to use the Comprehensive® Reverse Shoulder prosthesis.

75. The Comprehensive® Reverse Shoulder prosthesis sold by the Defendants was not as warranted because it caused serious injury to the Plaintiff when used as intended.

76. This breach of warranty caused the Plaintiff's injuries and damages.

77. Within a reasonable time after the Plaintiff discovered the Defendants' breach of warranty, the plaintiff notify the Defendants of such breach.

VIII. FIFTH CLAIM FOR RELIEF

(Breach of Implied Warranty of Merchantability against All Defendants - Left Shoulder Prosthesis)

78. Plaintiff repeats and incorporates by reference each and every allegation of paragraphs 1 through 77 as if more fully set forth herein.

79. Defendants sold the Comprehensive® Reverse Shoulder that Dr. Schneider used when he implanted the prosthesis into Plaintiff's left shoulder on September 24, 2009.

80. The Plaintiff was person who was reasonably expected to use the Comprehensive® Reverse Shoulder prosthesis.

81. Defendants were a merchant with the respect to the Comprehensive® Reverse Shoulder prosthesis that Dr. Schneider surgically implanted into Plaintiff's left shoulder on

September 24, 2009.

82. The Comprehensive® Reverse Shoulder prosthesis sold by the Defendants was not of merchantable quality at the time of sale.

83. This breach of warranty caused the Plaintiff's injuries and damages.

84. Within a reasonable time after the Plaintiff discovered the Defendants' breach of warranty, the plaintiff notify the Defendants of such breach.

IX. SIXTH CLAIM FOR RELIEF

(Breach of Implied Warranty of Merchantability against All Defendants - Right Shoulder Prosthesis)

85. Plaintiff repeats and incorporates by reference each and every allegation of paragraphs 1 through 84 as if more fully set forth herein.

86. Defendants sold the Comprehensive® Reverse Shoulder that Dr. Schneider used when he implanted the prosthesis into Plaintiff's right shoulder on July 22, 2010.

87. The Plaintiff was person who was reasonably expected to use the Comprehensive® Reverse Shoulder prosthesis.

88. Defendants were a merchant with the respect to the Comprehensive® Reverse Shoulder prosthesis that Dr. Schneider surgically implanted into Plaintiff's right shoulder on July 22, 2010.

89. The Comprehensive® Reverse Shoulder prosthesis sold by the Defendants was not of merchantable quality at the time of sale.

90. This breach of warranty caused the Plaintiff's injuries and damages.

91. Within a reasonable time after the Plaintiff discovered the Defendants' breach of warranty, the plaintiff notify the Defendants of such breach.

WHEREFORE, Plaintiff Alfonso Alarid, demands judgment against Defendants on each of the above referenced claims as follows: Actual and compensatory damages; physical

impairment; disfigurement; Pre and post judgment interest as provided by law; Attorney fees, expert witness fees and costs; such other and further relief as the Court deems just and proper.

A TRIAL BY JURY IS HEREBY DEMANDED AS TO ALL ISSUES SO TRIABLE

Date: July 30, 2014

Respectfully Submitted,

BISSET LAW FIRM
A signed original is maintained in our office

/s/ *Jennifer Bisset*
Jennifer Bisset, No. 13150

LAW OFFICE OF GREGORY A. HALL
A signed original is maintained in our office

/s/Gregory A. Hall
Gregory A. Hall, No. 26078

Plaintiff's address:

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