

STATE OF MINNESOTA  
COUNTY OF CARVER

**FILED**  
MAY 17 2011  
CARVER COUNTY COURTS

DISTRICT COURT  
FIRST JUDICIAL DISTRICT  
Case Type: *Product Liability*  
Court File No. *10-CV-11-706*

LINDA ANDERSON, JAMES FESER and  
JUDITH PESKAR,

Plaintiffs,

v.

SIMPSON AND ASSOCIATES, INC.

Defendant.

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COMPLAINT FOR DAMAGES  
AND DEMAND FOR JURY TRIAL

COME NOW Plaintiffs LINDA ANDERSON, JAMES FESER, and JUDITH PESKAR,  
by and through their undersigned counsel, and bring this Complaint against Defendant  
SIMPSON AND ASSOCIATES, INC, and alleges as follows:

1. This is an action for damages resulting from Defendant's promoting, marketing, distributing, supplying, selling, and servicing defective hip replacement components that were subsequently recalled by the United States Food and Drug Administration.
2. Plaintiff Linda Anderson ("Anderson") is a citizen and resident of Hibbing, Minnesota.
3. Plaintiff James Feser ("Feser") is a citizen and resident of Bismarck, North Dakota.
4. Plaintiff Judith Peskar ("Peskar") is a citizen and resident of River Falls, Wisconsin.
5. Defendant is a Minnesota corporation with its principal place of business in Chanhassen, Minnesota, County of Carver and as such is a citizen of the State of Minnesota.

6. At all times relevant to this action, Defendant promoted, marketed, distributed, supplied, sold, and serviced the recalled defective hip replacement components in the states of Minnesota, South Dakota, and North Dakota.

7. Defendant promoted, marketed, distributed, supplied, sold, and serviced the ASR hip replacement components implanted in each of the Plaintiffs to this action.

8. Defendant utilized and employed sales representatives that were responsible for educating Plaintiffs' orthopedic surgeons regarding the supposed advantages of the hip replacement components, answering any questions Plaintiffs' orthopedic surgeons had regarding the hip replacement components, providing the Plaintiffs' orthopedic surgeons with information regarding the proper surgical technique to employ in implanting the hip replacement components, providing the Plaintiffs' orthopedic surgeons with information concerning the hip replacement components appropriate for the patient, providing the Plaintiffs' orthopedic surgeons with the tools to be used to implant the hip replacement components, assisting Plaintiffs' orthopedic surgeons at surgery regarding the hip replacement components, and selling the hip replacement components to Plaintiffs' orthopedic surgeons.

9. Plaintiffs and their surgeons, nurses, and hospital staff relied on information from Defendant in selecting, purchasing, implanting, and servicing the hip replacement components.

10. Venue in this action properly lies in Carver County as Defendant maintains its headquarters in this county.

## HIP REPLACEMENT COMPONENTS

11. In 2005, Defendant began promoting and selling in Minnesota, South Dakota, and North Dakota, hip replacement components with the model identification of “ASR” manufactured by DePuy International, LTD of the United Kingdom.

12. In addition to other means, Defendant used brochures and other printed literature to promote the ASR hip replacement components.

13. Defendant disseminated literature to the orthopedic community in Minnesota, South Dakota, and North Dakota stating that the ASR hip replacement components were “large diameter, high performance metal-on-metal bearings [are] designed and manufactured within fine tolerances to facilitate a state of fluid film lubrication” and “designed to reduce wear and provide high function for all patients.”

14. Defendant also claimed in information provided to the Minnesota, South Dakota, and North Dakota orthopedic communities that the ASR hip replacement components were “based on a strong clinical history” and “reduces wear compared to traditional hip replacement.”

15. Defendant’s efforts were so successful that in 2008 Defendant won a national sales award for selling increasing sales of the ASR hip replacement components in its territory by 362%, generating millions of dollars in additional sales.

16. As a result in large part of aggressive sales of ASR hip replacement components, in 2010 Defendant had sales of more than \$60,000,000.00.

17. As a result of Defendant’s intense promotion of the ASR hip components in Minnesota, South Dakota, and North Dakota, sales of ASR hip replacement components were substantially higher in this region than in comparable regions.

### WARNINGS FROM INDEPENDENT ORTHOPEDIC EXPERTS

18. The same year Defendant began selling the ASR hip replacement components, independent experts from around the world were warning that the design of the ASR hip replacement components was defective.
19. Orthopedic experts warned that some of the ASR hip replacement components were too thin and thus prone to deformation.
20. Orthopedic experts warned that the clearance between the ASR hip replacement component cup and heads was too small and in some patients could lead to jamming of components.
21. Orthopedic experts warned that the treatment of the metal used for the ASR hip replacement components rendered them prone to increased wear.
22. By 2005, ASR hip replacement components were shown to have a 4-fold higher rate of revision than similar components in the Australian Joint Registry.

### DEFENDANT'S RESPONSE TO WARNINGS

23. When questioned by members of the orthopedic community about independent expert warnings that the ASR hip replacement components were defective, Defendant's sales representatives were instructed how to argue that the independent experts were mistaken and to continue to heavily promote the ASR hip replacement components.
24. Defendant, through its employees and agents, was also aware of the problems with the design of the ASR hip replacement components based upon complaints of orthopedic surgeons.

25. Defendant was additionally aware of excessive failures necessitating revision of ASR hip replacement components due to revision surgeries in which Defendant's sales representatives participated, but failed to convey this information to the Plaintiffs' orthopedic surgeons.

#### SUSPENSION AND RECALL

26. From 2005 to 2009, numerous complaints of premature failure of ASR hip replacement components were made by orthopedic surgeons and hospitals to Defendant and the United States Food and Drug Administration.

27. Independent studies showed numerous problems with ASR hip replacement components, including failure of ASR hip replacement cups to achieve proper fixation due to the lack of bony ingrowth into the back of the cup, fracture resulting from loose ASR hip replacement components, significant metal debris in patients with ASR hip replacement components, and the formation of pseudotumors in patients with ASR hip replacement components.

28. On March 24, 2011, the United States Food and Drug Administration issued a recall of all ASR hip replacement components.

29. Unfortunately, the recall came far too late for the Plaintiffs to this action.

#### LINDA ANDERSON

30. Plaintiff Linda Anderson, a homemaker and a mother of three, is a resident of the State of Minnesota.

31. In March of 2007, Linda Anderson's orthopedic surgeon, Brad Edgerton, M.D., advised Ms. Anderson to undergo a total hip replacement surgery for pain in her right hip.

32. Dr. Edgerton explained to Linda Anderson information about the ASR hip replacement components based on the information previously conveyed to him by Defendant's sales representatives.

33. Based upon the information originally provided by Defendant, in March of 2007, Ms. Anderson agreed to undergo a right total hip replacement utilizing ASR hip replacement components performed by Dr. Edgerton at St. Mary's Hospital in Duluth, Minnesota.

34. Following the surgery, Linda Anderson went through a long and painful recovery period.

35. Despite the pain, Ms. Anderson forced herself to undergo extensive physical therapy to regain her strength.

36. Unfortunately, Linda Anderson continued to have pain in her hip and groin, for which she saw Dr. Edgerton monthly.

37. Dr. Edgerton took x-rays at each visit but was unable to determine the cause of the pain.

38. Finally, in late 2007, Dr. Edgerton found fractures on the x-rays in Linda Anderson's pelvis around the ASR hip replacement components.

39. Linda Anderson was required to avoid using her hip which effectively put her on bed rest for several weeks.

40. Following her recovery from the pelvic fractures, Linda Anderson returned to Dr. Edgerton's office with continued severe hip and groin pain.

41. Dr. Edgerton referred her for a second opinion to Robert T. Trousdale, M.D. in Rochester, Minnesota.

42. Dr. Trousdale reviewed x-rays of Linda Anderson's hip and could find nothing visibly wrong.

43. However, Dr. Trousdale recommended that Ms. Anderson undergo a revision surgery to examine the possibility that her pain might stem from a problem with her tendons.

44. On March 5, 2010, Ms. Anderson underwent a revision surgery of her right hip performed by Dr. Trousdale at Rochester Methodist Hospital in Rochester, Minnesota.

45. During that surgery, Dr. Trousdale found Linda Anderson's ASR hip replacement component cup to be grossly loose and replaced both the cup and the femoral head.

46. Since that surgery, Linda Anderson has had a difficult recovery and continues to experience significant pain in her right hip.

JAMES FESER

47. Plaintiff James Feser, the general manager of a grocery wholesaler, is a resident of the State of North Dakota.

48. On March 10, 2008, James Feser saw orthopedic surgeon Timothy Bopp, M.D. to discuss a possible hip resurfacing, at which time they discussed at length the difference between resurfacing and total hip replacement and the many different models of both total hip and resurfacing products.

49. Despite the fact that ASR hip replacement components were not approved for use in resurfacing procedures in the United States, Defendant's employees had aggressively marketed this device for just that use to Dr. Bopp.

50. In promoting the ASR hip replacement components for use in resurfacing procedures, Defendant's employee failed to inform Dr. Bopp that the components were not approved for that use in the United States.

51. On April 3, 2008, James Feser underwent a resurfacing of his right hip performed by orthopedic surgeon Timothy Bopp, MD and utilizing ASR hip replacement components at the St. Alexius Medical Center in Bismarck, North Dakota.
52. Thereafter, James Feser initially recovered well from the procedure and seemed to do well for approximately two years.
53. However, by late 2010, Mr. Feser was experiencing pain in his right hip.
54. At a visit on October 6, 2010, Dr. Bopp ordered laboratory tests to measure James Feser's cobalt and chromium levels and kidney function, and follow up tests to be conducted three months later.
55. The test results showed from the first tests showed that Mr. Feser's cobalt level was 124, 124 times the acceptable range.
56. James Feser underwent additional testing in January of 2011 that showed his cobalt level had increased to 146, 146 times the acceptable range.
57. James Feser returned to Dr. Bopp's office on January 31, 2011 for a consultation regarding his laboratory results, at which time Dr. Bopp explained the results of the metal debris testing.
58. Dr. Bopp immediately prescribed an MRI scan to look for possible fluid collection to be followed by a revision surgery to remove ASR hip replacement components.
59. On March 9, 2011, Plaintiff underwent a revision surgery of his right hip performed by Dr. Bopp at St. Alexius Medical Center in Bismarck, North Dakota.
60. In his operative report on March 9, 2011, Dr. Bopp noted the following:

We then opened up the hip joint, which had a fair amount of fluid in the hip and metallosis was encountered immediately; that is, the fluid was dark metal-stained type fluid that we do see when metallosis present and this was consistent with metallosis. There was no foul smell and no indication of infection... The entire undersurface of the abductors was stained with metal debris and you could see where this actually dissected down along the vastus lateralis, so we incised the vastus lateral is to take out some of that metal debris. Then we completed our exposure by opening up the capsule and thoroughly excising the capsule because it was all stained with metallosis.... At this point, we continued on by placing our acetabular retractors and then we used the Explant Acetabular System to remove the well-fixed acetabulum... We then did a further thorough search for any additional metallosis. Any found was removed. We thoroughly irrigated with copious amounts of bacitracin and saline to try and get all the foreign debris out of the hip as much as possible.

61. Following the surgery to remove the ASR hip replacement components, James Feser has begun a long and painful rehabilitation process.

JUDITH PESKAR

62. Plaintiff Judith Peskar is a retired resident of the State of Wisconsin.

63. On May 21, 2009, Judith Peskar underwent a total hip arthroplasty of her right hip performed by orthopedic surgeon Andrea Saterbak, MD at Lakeview Hospital in Stillwater, Minnesota.

64. During the surgery, Dr. Saterbak implanted ASR hip replacement components into the body of Judith Peskar.

65. Judith Peskar initially seemed to recover well from the procedure and Dr. Saterbak was pleased with her recovery and the position of the device in immediate follow-up visits.

66. Unfortunately, despite the appearance of initial success, the hip rapidly became painful.

67. On February 8, 2010, Judith Peskar returned to Dr. Saterbak's office complaining of pain and a grinding sensation.

68. Dr. Saterbak took x-rays which demonstrated no visible loosening or misalignment and recommended that she wait for the symptoms to resolve.

69. Unfortunately, rather than resolving, Judith Peskar's symptoms worsened, she became concerned that the grinding sensation was causing metal debris, and she saw a second orthopedic surgeon, Robert V. Knowlan, M.D., for an aspiration and injection of her hip.

70. On April 20, 2010, Judith Peskar underwent the hip aspiration, performed by Dr. Knowlan, who found that the fluid in her hip was a grayish color as the result of metallosis.

71. Subsequently, on August 21, 2010, Judith Peskar underwent a revision surgery of her right hip performed by Daniel P. Hoeffel, M.D. at Woodwinds Health Campus in Woodbury, Minnesota.

72. Following the surgery to remove the ASR hip replacement components, Judith Peskar has begun a long and painful rehabilitation process.

#### EFFECT ON PLAINTIFFS

73. Each of the Plaintiffs to this action had ASR hip replacement components that were promoted, marketed, distributed, supplied, sold, and serviced by Defendant.

74. Each of the Plaintiffs to this action had ASR hip replacement components that were defective when implanted in their bodies and were subsequently recalled by the FDA.

75. In the instance of each of the Plaintiffs to this action, the ASR hip replacement cup failed to achieve proper bone ingrowth into the cup and thus failed to achieve proper fixation.

76. In the instance of each of the Plaintiffs to this action, the ASR hip replacement components generated excessive metal debris.

77. In the instance of each of the Plaintiffs to this action, the recognition that ASR hip replacement components had failed was delayed by the failure of Defendant to convey to Plaintiffs' orthopedic surgeons the warnings regarding the product made by independent orthopedic experts and information regarding other failures of ASR hip replacement components throughout the United States and worldwide.

78. As a result of this significant delay in the recognition that the ASR hip replacement components had failed, Plaintiffs needlessly suffered pain and damage to the bones and tissues of their hips.

79. The defective ASR hip replacement components implanted and allowed to remain in the bodies of the Plaintiffs caused extreme pain and suffering to Plaintiffs.

80. Despite Defendant's knowledge of extensive problems with and defects in the ASR hip replacement components, Defendant continued to heavily promote the components.

81. Plaintiffs' orthopedic surgeon relied on the misinformation provided by Defendant and used, continued to use, and failed to suspect the premature failure of the ASR hip replacement components,

#### COUNT ONE - NEGLIGENCE

82. Plaintiffs re-allege and incorporate by reference all paragraphs above as if fully stated herein.

83. Defendant, as the promoter, marketer, seller, distributor, and servicer of the ASR hip replacement components, owed a duty to Plaintiffs to provide accurate information to Plaintiffs, their orthopedic surgeons, and the orthopedic community.

84. Defendant, in breach of the duty described above, negligently and carelessly promoted, marketed, sold, distributed, and serviced the ASR hip replacement components implanted in Plaintiffs.

85. As a direct and proximate result of the conduct of Defendant, Plaintiffs needlessly suffered severe pain and weakness.

86. As a direct and proximate cause of the breaches set forth herein, Plaintiffs have suffered severe physical distress and injury, emotional distress and injury; incurred medical and other expenses; lost wages and income; suffered shame, humiliation and the inability to lead normal lives; and have suffered loss of enjoyment of life. The injuries and losses of Plaintiffs are permanent in nature and Plaintiffs will continue to suffer such losses in the future.

#### COUNT TWO - STRICT LIABILITY

87. Plaintiffs re-allege and incorporate by reference all paragraphs above as if fully stated herein.

88. At the time that Defendant promoted, marketed, distributed, supplied, sold, and serviced the ASR hip replacement components, they contained defects that made them unreasonably dangerous beyond the expectations of the ordinary consumer, and was unfit for its intended use.

89. The ASR hip replacement components reached Plaintiffs without substantial change in the condition in which they were sold.

90. The ASR hip replacement components, for the reasons stated herein, were defective and unreasonably dangerous in design and manufacture.

91. At the time and on the occasions in question, the ASR hip replacement components were being properly used for the purpose for which they were intended, and such components were in fact defective, unsafe and unreasonably dangerous.

92. As a direct and proximate cause of the nature of the ASR hip replacement components, Plaintiffs have suffered severe physical distress and injury, emotional distress and injury; incurred medical and other expenses; lost wages and income; suffered shame, humiliation and the inability to lead normal lives; and have suffered loss of enjoyment of life. The injuries and losses of Plaintiffs are permanent in nature and Plaintiffs will continue to suffer such losses in the future.

### COUNT THREE - BREACH OF IMPLIED WARRANTY

93. Plaintiffs re-allege and incorporate by reference all paragraphs above as if fully stated herein.

94. Defendant promoted, marketed, distributed, supplied, sold, and serviced the ASR hip replacement components at issue in this case.

95. Defendant impliedly warranted that the ASR hip replacement components were reasonably fit for their intended use as hip replacement components.

96. Plaintiffs were foreseeable users of the ASR hip replacement components.

97. Plaintiffs purchased the ASR hip replacement components from Defendant.

98. The ASR hip replacement components failed while being used for their intended purpose, causing serious injury to Plaintiffs.

99. As a direct and proximate cause of this breach, Plaintiffs have suffered severe physical distress and injury, emotional distress and injury; incurred medical and other expenses; lost

wages and income; suffered shame, humiliation and the inability to lead normal lives; and have suffered loss of enjoyment of life. The injuries and losses of Plaintiffs are permanent in nature and Plaintiffs will continue to suffer such losses in the future.

COUNT FOUR - INTENTIONAL MISREPRESENTATION

100. Plaintiffs re-allege and incorporate by reference all paragraphs above as if fully stated herein.

101. As stated above, defendant made false misrepresentations of material facts.

102. Defendant did so knowing that the misrepresentations were false or was ignorant of the truth of the assertion.

103. Defendant did so with the intention of inducing the Plaintiffs and their agents to purchase and continue to purchase the ASR hip replacement components.

104. Plaintiff and their agents were induced to act in reliance on Defendant's misrepresentations.

105. The damages incurred by Plaintiffs were proximately caused by Defendant's misrepresentations.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment against the Defendant for damages and for all other relief as the Court deems necessary, just and proper.

DEMAND FOR JURY TRIAL

Plaintiffs demand a trial by jury.

Dated: April 21, 2011

LOMMEN, ABDO, COLE, KING & STAGEBERG, P.A.

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**ACKNOWLEDGMENT**

If the requirements of good faith pleading set forth in M.S. § 549.211 are breached, the undersigned acknowledges that the Court may award costs, including reasonable attorney's fees to opposing parties.

Sheila A. Bjorklund  
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