

IN THE CIRCUIT COURT OF THE 15TH
JUDICIAL CIRCUIT IN AND FOR PALM
BEACH COUNTY.

CIVIL DIVISION

CASE NO:

DAVID KAUTHEN and VIOLA KAUTHEN,

Plaintiffs,

50 2011 CA 0 04 1 5 8 XXXX MB

vs.

DEPUY ORTHOPAEDICS, INC.; and
MARK DEBIASE, INCORPORATED and/or
MARK DEBIASE, INCORPORATED d/b/a
DEBIASE; and SCOTT ALLEN LEEDY,

Defendants.

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CIRCUIT CIVIL DIVISION

COMPLAINT

PLAINTIFFS, DAVID KAUTHEN ("PLAINTIFF") and VIOLA KAUTHEN sue
DEFENDANTS DEPUY ORTHOPAEDICS, INC. ("DEPUY"); and MARK DEBIASE,
INCORPORATED and/or MARK DEBIASE INCORPORATED d/b/a JOINT VENTURE
("DEBIASE") and SCOTT ALLEN LEEDY ("LEEDY"), (Collectively, "DEFENDANTS") and
allege:

NATURE OF THE CASE

On January 22, 2007 PLAINTIFF underwent total hip replacement surgery during which
a DEPUY ASR™¹ ("ASR") was implanted. The prosthetic implant was designed, manufactured,
marketed, distributed and sold by DEPUY, DEBIASE and LEEDY. The ASR implant fails at an
alarmingly high rate and has been recalled. As a result of the recall, PLAINTIFF had his ASR
implant surgically removed. PLAINTIFF seeks compensatory damages against the manufacturer,
distributor and seller of the ASR device.

¹ ASR is an acronym for Articular Surface Replacement

PARTIES

1. Both DAVID KAUTHEN and VIOLA KAUTHEN are now and have been citizens of the State of Florida. Both reside in Palm Beach County, Florida. PLAINTIFF'S surgery in which the ASR was implanted occurred in Palm Beach County, Florida.

2. DEPUY is an Indiana Corporation with its principal place of business located at 700 Orthopaedic Drive, Warsaw, IN 46582. DEPUY manufactured the ASR and developed, designed, manufactured, promoted, marketed, labeled, distributed, supplied, sold and/or profited from the sale of the defective and recalled ASR device. DEPUY marketed and sold the ASR device implanted in PLAINTIFF'S hip in Palm Beach County, Florida.

3. DEBIASE is a Florida corporation with its principal place of business located in 1525A The Greens Way, Jacksonville Beach, FL 32250. DEBIASE marketed and sold the ASR device implanted in PLAINTIFF'S hip in Palm Beach County, Florida.

4. DEBIASE sold and distributed the ASR within the State of Florida and promoted, distributed, supplied and sold the ASR which reached consumers in the State of Florida, including PLAINTIFF. DEBIASE, directly and by and through its subsidiaries and/or sales representatives engaged in the promotion, sale and distribution of the defective and recalled ASR hip through various means, including but not limited to: and distributing, displaying and advertising information promoting the use and distribution of the defective product to the community; and/or detailing orthopedic physicians including PLAINTIFF'S physician.

5. LEEDY is a resident and citizen of the State of Florida.

6. LEEDY sold, marketed, detailed, demonstrated, delivered and provided detailed instruction and consulting in relation to the sale and provision of the DEPUY ASR hip implant

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system that was implanted in PLAINTIFF'S hip. LEEDY acted individually and as the agent, real or apparent of DEBIASE and DEPUY responsible for selling DEPUY'S ASR hip replacement system to PLAINTIFF'S surgeon and his operating room staff. In this role, LEEDY interacted directly with PLAINTIFF'S surgeon. It is from LEEDY that PLAINTIFF'S surgeon received information regarding the ASR replacement system, its uses, indications, benefits, strengths, risks, durability and fitness for a particular use or application. This "detailing" as it is commonly referred to in industry, went beyond mere salesmanship. The DEPUY ASR system implanted in PLAINTIFF'S hip was ordered directly from LEEDY and LEEDY delivered the device to the operating room. In addition to acting as salesman, LEEDY provided PLAINTIFF'S surgeon with critical and technical information regarding the ASR system's uses, application, installation, benefits and risks that including teaching and demonstration in the operating room before and during surgery.

7. PLAINTIFF, DEBIASE and LEEDY are all citizens of the State of Florida and, therefore, no diversity of citizenship exists.

8. This action is not removable to the United States District Court. There is (a) no diversity of citizenship, (b) no right of removal and (c) no reasonable basis upon which to assert that DEBIASE is fraudulently joined as a DEFENDANT. See *Shallcross v. Bausch & Lomb*, No. 2:06-cv-325-FtM-99SPC, 2007 Westlaw 141280 (M.D. Fla. Jan. 16, 2007) and *Waters v. Bausch & Lomb, et.al.*, Case No. 06-80547-Civ-Dimitouleas (S.D. Fla. July 26, 2006) (remanding improperly removed action; Publix is a proper non-diverse DEFENDANT under Florida law in defective contact lens solution case) and *Wade v. Bausch & Lomb et.al.*, Case No. 06-80546-Civ-Middlebrooks (S.D. Fla. Aug. 16, 2006) (remanding improperly removed action; Eye Express, Inc., the retail distributor, is a proper non-diverse Defendant under Florida law in a

defective contact lens solution case).

JURISDICTION AND VENUE

9. At all relevant times, DEFENDANTS regularly conducted and transacted business in the States of Florida.

10. Venue is proper in Palm Beach County, Florida as the ASR implanted into PLAINTIFF'S hip was marketed and sold in Palm Beach County, Florida.

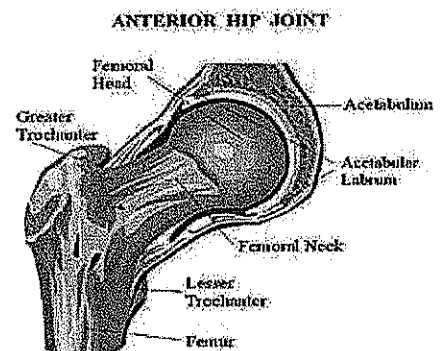
11. This Court has personal jurisdiction over both the PLAINTIFF and the DEFENDANTS.

12. The amount in controversy exceeds this court's jurisdictional minimum.

13. A significant portion of the events or omissions giving rise to the claims asserted herein in whole or in part occurred in this County.

BASIC FACTS

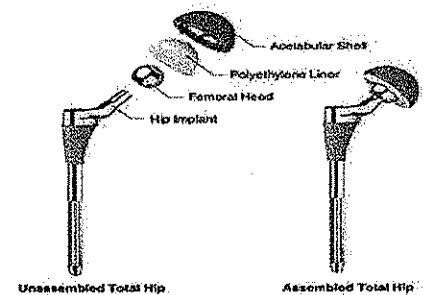
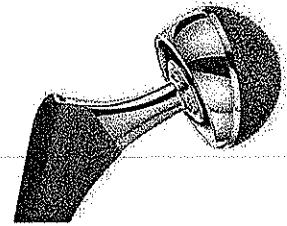
14. The human hip joint is formed by the insertion of the femur or "thigh bone," into a cup shaped socket in the pelvis known as the acetabulum. In a normal, healthy hip joint, both the head of the femur and the acetabulum are covered with smooth articular cartilage allowing the femoral head to glide freely within the socket. The joint space is lubricated with synovial fluid. As humans age, cartilage in the hip joint wears away leaving a rough, irregular surface, a condition commonly known as arthritis. Trauma and disease can both cause or accelerate these changes. In extreme cases, bone can become exposed causing significant pain



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and immobility. Artificial joint replacement offers such patients an extreme but, often life changing alternative.

15. Artificial hip joint surgery involves removing the patient's affected joint anatomy and replacing it with artificial components typically made of metal and plastic. Although there are many different hip replacement systems on the market, a typical system consists of four separate components: (1) a femoral stem (labeled as hip implant in the diagram), (2) a femoral head, (3) a Polyethylene liner and (4) an acetabular shell. The femoral stem is implanted into the femur and the metal ball is affixed. These components take the place of the femoral head. The acetabulum is reamed to specification and the new artificial acetabular shell is implanted in the pelvis. The new hip joint is formed when the ball is placed into the polyethylene sheath that fits within the new acetabular shell.



16. Some of the more modern and innovative hip implant designs have come under intense scrutiny in the regulatory and surgical community. Often the promised “innovation” involves new components, designs or materials that are unproven. The DEPUY ASR was just such a product. The resulting failure of its design and component products resulted in an alarmingly high rate of failure and ultimately the ASR'S recall.

17. The DEPUY ASR hip implant design calls for the metal femoral ball to articulate with a metal acetabular component as opposed to a polyethylene sheath. In the industry, this type of prosthesis is referred to as “metal on metal.” If the prosthesis is poorly designed or manufactured, once implanted, it can produce extensive amounts of metal wear debris. This design also increases the potential for fracture.

18. The ASR and related components were cleared for sale by the Food and Drug Administration (FDA) under an abbreviated regulatory review process known as a 510(k). Unlike the regulatory scrutiny that accompanies a new drug application, a manufacturer seeking 510(k) clearance for a device is required to conduct neither clinical trials or safety studies nor are they required to demonstrate a product's safety and effectiveness prior to marketing a product. A manufacturer seeking 510(k) market clearance is merely required to demonstrate that its proposed device is "substantially equivalent" to a commercially marketed device.

19. On or about December 4, 2003, the first components of the DEPUY ASR system received 510(k) clearance from the FDA.

20. Subsequent ASR components or systems received 510(k) clearance from the FDA on or about August 5, 2005 (K040627), on or about March 6, 2007 (K070359), on or about January 30, 2008 (K073413), and on or about July 2, 2008 (K080991).

21. DEPUY claims, "The device [ASR] is indicated for use in total hip replacement procedures for patients suffering severe pain and disability due to structural damage in the hip joint from rheumatoid arthritis, osteoarthritis, post-traumatic arthritis, collagen disorders, avascular necrosis, and nonunion of femoral fractures. Use of the prosthesis is also indicated for patients with congenital hip dysplasia, protrusio acetabuli, slipped capital femoral epiphysis and disability due to previous fusion, where bone stock is inadequate for other reconstruction techniques."

22. Between 2003 and 2008, DEPUY had both actual and constructive knowledge that the ASR as designed and manufactured was defective. DEPUY knew or should have known that the ASR's defects presented a significant risk of early metal wear and failure. DEPUY was warned by physicians, scientists and its own key opinion leaders that the ASR system was failing

in the field and that patients were being injured.

23. On March 8, 2010, Pamela L. Plouhar, Vice President of Worldwide Clinical Affairs for DEPUY, issued an "URGENT FIELD SAFETY NOTICE" to surgeons citing the high number of explants ASR prosthesis patients were experiencing.

24. On or about July 17, 2010, a Class 2 recall of many of the ASR components was posted on the FDA's website.

25. On or about August 26, 2010, DEPUY issued a press release concerning the recall of the various ASR components citing higher than usual revision rates.

26. PLAINTIFF was implanted with an ASR on January 22, 2007 by his surgeon, Michael Mikolajczak, MD, at Wellington Regional Hospital in Palm Beach County, Florida.

27. PLAINTIFF'S ASR was prematurely removed on November 4, 2010 by Dana Dresser, MD at Wellington Regional Hospital in Palm Beach County, Florida.

28. DEPUY'S forced recall of the ASR was unfortunately too late to protect PLAINTIFF from suffering unnecessarily.

29. PLAINTIFF did suffer injuries and damages and continues to suffer from injuries and damages of a permanent and lasting nature as a result of the ASR failure.

COUNT I

30. PLAINTIFFS incorporate by reference paragraphs 1 through 29 of this Complaint as if fully set forth here and further allege as follows:

31. This is an action for strict liability based upon a design defect against all DEFENDANTS.

32. The ASR system is designed in such a way that it; is difficult if not impossible to

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install properly, fails prematurely, causes or leaves users of the product at unacceptably high risk of device failure, bone loss, heavy metal poisoning and tissue toxicity all of which require surgical removal and replacement. The incidence of ASR device failure was sufficient to require DEPUY to recall the product from the market. The recall, failure rate and the potential for heavy metal poisoning have resulted in some patients having the device removed in the absence of symptoms consistent with, or evidence of, device failure. The necessity of premature removal alone renders the design defective and unreasonably dangerous.

33. The risk of using the product is outweighed by the benefits of using the ASR replacement system.

34. The ASR replacement system is designed in such a way that it leaves users of the ASR replacement system vulnerable to metal poisoning, tissue necrosis, bone loss and premature removal surgery.

35. The ASR replacement system did not perform as safely as an ordinary consumer would expect when used as intended or in a manner reasonably foreseeable to DEPUY and DEBIASE.

36. The ASR replacement system was defective as designed.

37. DEFENDANTS had a duty to place into the stream of commerce, manufacture, distribute, market, promote and sell the ASR so that it was not defective and unreasonably dangerous when put to the use for which it was designed, manufactured, distributed, marketed and sold.

38. PLAINTIFF used the ASR for its intended purpose.

39. PLAINTIFF could not have discovered any defect in the ASR through the exercise of due care.

40. DEFENDANTS as designer, manufacturer, marketer, and distributor of medical devices are held to the level of knowledge of an expert in their field.

41. PLAINTIFF and his implanting physician did not have substantially the same knowledge as the designer, manufacturer or distributor.

42. At all relevant times, DEBIASE and LEEDY were a distributor and, under Florida law, are jointly and severally liable to the PLAINTIFF for injuries sustained from said product. *See Samuel Friedland Family Enterprises v. Amoroso*, 630 So.2d 1067, *1068 (Fla.,1994)(citing *Visnoski v. J.C. Penney Co.*, 477 So.2d 29 (Fla. 2d DCA 1985) (distributors); *Adobe Bldg. Centers, Inc. v. Reynolds*, 403 So.2d 1033 (Fla. 4th DCA) (retailers and wholesalers), review dismissed, 411 So.2d 380 (Fla.1981). *See also Siemens Energy v. Medina*, 719 So.2d 312 (Fla. 3rd DCA 1998). This action is not removable to the United States District Court. There is (a) no diversity of citizenship, (b) no right of removal and (c) no reasonable basis upon which to assert that DEBIASE is fraudulently joined as a DEFENDANT.

43. The design defect in the ASR replacement system caused serious damage to PLAINTIFF including bodily injury, pain and suffering, disability, physical impairment, disfigurement, mental anguish, inconvenience, aggravation of a preexisting condition, loss of the capacity for the enjoyment of life, the cost of medical care and expenses and loss of earnings. These injuries and expenses will continue into the future.

COUNT II

44. PLAINTIFFS incorporate by reference paragraphs 1 through 29 of this Complaint as if fully set forth here and further allege as follows:

45. This is an action for strict liability based on a manufacturing defect against all DEFENDANTS.

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46. DEPUY'S ASR replacement system is designed to rigorous specifications. The product's performance, durability, integrity, safety and longevity depend on it being manufactured such that it meets those very strict design criteria.

47. DEPUY'S ASR replacement system was frequently not manufactured according to design specification and therefor failed at an unacceptable rate causing poor fit, premature wear, mal-alignment, metal failure, metal debris, tissue necrosis, heavy metal poisoning, bone loss and the need for premature explant.

48. DEPUY'S ASR replacement system failed to meet design specification in sufficient quantities that DEPUY issued an emergent recall of the device and notified users that they would incur the expense of having the defective implant removed and replaced.

49. The DEPUY ASR replacement system implanted in PLAINTIFF was not manufactured to specification and as a result it failed. PLAINTIFF suffered metallosis, tissue necrosis, heavy metal poisoning, bone loss and the emergent need for explant and replacement.

50. At all relevant times, DEBIASE and LEEDY were a distributor and, under Florida law, are jointly and severally liable to the PLAINTIFF for injuries sustained from said product. *See Samuel Friedland Family Enterprises v. Amoroso*, 630 So.2d 1067, *1068 (Fla.,1994)(citing *Visnoski v. J.C. Penney Co.*, 477 So.2d 29 (Fla. 2d DCA 1985) (distributors); *Adobe Bldg. Centers, Inc. v. Reynolds*, 403 So.2d 1033 (Fla. 4th DCA) (retailers and wholesalers), review dismissed, 411 So.2d 380 (Fla.1981). *See also: Siemens Energy v. Medina*, 719 So.2d 312 (Fla. 3rd DCA 1998). This action is not removable to the United States District Court. There is (a) no diversity of citizenship, (b) no right of removal and (c) no reasonable basis upon which to assert that DEBIASE is fraudulently joined as a DEFENDANT.

51. The manufacturing defect in the ASR replacement system caused serious damage to PLAINTIFF including bodily injury, pain and suffering, disability, physical impairment, disfigurement, mental anguish, inconvenience, aggravation of a preexisting condition, loss of the capacity for the enjoyment of life, the cost of medical care and expenses and loss of earnings. These injuries and expenses will continue into the future.

COUNT III

52. PLAINTIFFS incorporate by reference paragraphs 1 through 29 of this Complaint as if fully set forth here and further allege as follows:

53. This is an action for strict liability based on a failure to warn against all DEFENDANTS.

54. The DEPUY ASR replacement system sold to and implanted in PLAINTIFF'S hip contained inadequate warnings regarding the following excessive risks; that it could not be implanted in satisfactory alignment, the consequences of mal-alignment, the potential for premature wear, the potential for heavy metal poisoning, tissue necrosis and bone loss, that it could fail prematurely requiring explant, that it could expose the user to excessive metal debris, that it could prematurely loosen and compared to other alternative devices the failure and revision rate associated with the ASR was excessive.

55. The warnings that accompanied DEPUY'S ASR replacement system failed to provide that level of information that an ordinary consumer would expect when using the product in a manner reasonably foreseeable to the DEFENDANTS. Had PLAINTIFF or his physician received a proper or adequate warning as to the risks associated with the use of DEPUY'S ASR replacement system he would not have used DEPUY'S ASR replacement system.

56. At all relevant times, DEBIASE and LEEDY were a distributor and, under Florida law, are jointly and severally liable to the PLAINTIFF for injuries sustained from said product. See *Samuel Friedland Family Enterprises v. Amoroso*, 630 So.2d 1067, *1068 (Fla.,1994)(citing *Visnoski v. J.C. Penney Co.*, 477 So.2d 29 (Fla. 2d DCA 1985) (distributors); *Adobe Bldg. Centers, Inc. v. Reynolds*, 403 So.2d 1033 (Fla. 4th DCA) (retailers and wholesalers), review dismissed, 411 So.2d 380 (Fla.1981). See also *Siemens Energy v. Medina*, 719 So.2d 312 (Fla. 3rd DCA 1998). This action is not removable to the United States District Court. There is (a) no diversity of citizenship, (b) no right of removal and (c) no reasonable basis upon which to assert that DEBIASE is fraudulently joined as a DEFENDANT.

57. The failure to warn of DEPUY'S ASR replacement system's risks caused serious damage to PLAINTIFF including bodily injury, pain and suffering, disability, physical impairment, disfigurement, mental anguish, inconvenience, aggravation of a preexisting condition, loss of the capacity for the enjoyment of life, the costs of medical care and expenses, loss of earnings and loss of the ability to earn money, all of which damage and losses will continue in the future.

COUNT IV

58. PLAINTIFFS incorporate by reference paragraphs 1 through 29 of this Complaint as if fully set forth here and further allege as follows:

59. This is an action for negligent failure to issue a timely post-sale warning against DEPUY only.

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60. DEPUY had a duty to warn the public in a timely fashion when it knew or should have known of the risks associated with DEPUY'S ASR replacement system. DEPUY'S duty to warn with respect to PLAINTIFF extended beyond the date that PLAINTIFF received DEPUY'S ASR replacement system.

61. DEPUY knew or should have known of the risks associated with DEPUY'S ASR replacement system before DEPUY'S ASR replacement system began to cause injury to PLAINTIFF.

62. Had PLAINTIFF received a proper or adequate post-sale warning as to the risks associated with the use of DEPUY'S ASR replacement system he would not have used DEPUY'S ASR replacement system or he would have had DEPUY'S ASR replacement system removed prior to sustaining further damage.

63. At all relevant times, DEBIASE and LEEDY were a distributor and, under Florida law, are jointly and severally liable to the PLAINTIFF for injuries sustained from said product. *See Samuel Friedland Family Enterprises v. Amoroso*, 630 So.2d 1067, *1068 (Fla.,1994)(citing *Visnoski v. J.C. Penney Co.*, 477 So.2d 29 (Fla. 2d DCA 1985) (distributors); *Adobe Bldg. Centers, Inc. v. Reynolds*, 403 So.2d 1033 (Fla. 4th DCA) (retailers and wholesalers), review dismissed, 411 So.2d 380 (Fla.1981). *See also Siemens Energy v. Medina*, 719 So.2d 312 (Fla. 3rd DCA 1998). This action is not removable to the United States District Court. There is (a) no diversity of citizenship, (b) no right of removal and (c) no reasonable basis upon which to assert that DEBIASE is fraudulently joined as a DEFENDANT.

64. The failure to warn of DEPUY'S ASR replacement system risks caused serious damage to PLAINTIFF including bodily injury, pain and suffering, disability, physical impairment, disfigurement, mental anguish, inconvenience, aggravation of a preexisting

condition, loss of the capacity for the enjoyment of life, the costs of medical care and expenses, loss of earnings and loss of ability to earn money, all of which damage and losses will continue in the future.

COUNT V

65. PLAINTIFFS incorporate by reference paragraphs 1 through 29 of this Complaint as if fully set forth here and further allege as follows:

66. This is an action for negligence against all DEFENDANTS.

67. DEPUY had a duty to exercise reasonable care in the design, testing, manufacture, marketing, promotion, sale and post-marketing surveillance of the ASR replacement system to insure that it would be safe for its intended use.

68. DEPUY's negligence in the designing, testing, manufacturing, distributing, marketing, promoting and selling of the ASR includes but is not limited to the following:

- a. The ASR acetabular component was negligently designed creating a coverage angle that is too shallow^{2,3}

²William L. Griffin, Christopher J. Nanson, Bryan D. Springer, Matthew A. Davies and Thomas K. Fehring Components Reduced Articular Surface of One-piece Cups: A cause of Runaway Wear and Early Failure. *Clinical Orthopaedics and Related Research*, Volume 468, Number 9, 2328-2332, May, 2010,

³ C. Lowry Barnes, MD, et. al Differential Hardness Bearings in Hip Arthroplasty. *Journal of Surgical Orthopaedic Advances*, Vol 17, Number 1, Spring 2008, stating (Optimum clearance between the bearing couples is essential to avoid problems with high frictional torque and equatorial seizing. This ensures polar contact between femoral head and acetabular cup. Chan et al. and others confirmed that this is the most influential factor in wear behavior. Too little clearance can result in congruent head-cup surfaces resulting in equatorial contact. Proper clearance is essential for the egress of the wear particles and ingress of lubricant to the articulating surfaces to maintain fluid film lubrication, a phenomenon by which a thick film is formed, thus reducing the wear. Wear and wear rates increase if the clearance between the component is too small or too large)

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- b. the ASR acetabular component was negligently designed creating insufficient coverage of the femoral component;⁴
- c. the ASR acetabular component was negligently designed and manufactured creating increased metal on metal wear between the femoral component and the acetabular component;⁵
- d. the ASR xl hip replacement system was negligently designed and manufactured creating increased metal corrosion particular at the junction of the femoral head component and the neck of the femoral stem⁶
- e. the ASR xl hip replacement system was negligently designed and manufactured creating an unacceptable differential hardness of the cup and femoral head that is caused by among other things the technique and/or manner of the heat treatment of the femoral head and the acetabular cup⁷;
- f. the ASR acetabular component was negligently designed as a monoblock

⁴ Id.

⁵ Langton DJ, Jameson SS, Joyce TJ, Hallab NJ, Natu S, Nargol AV. Early failure of metal-on-metal bearings in hip resurfacing and large-diameter total hip replacement: A consequence of excess wear. *J Bone Joint Surg [Br]*. 2010 Jan;92(1):38-46.

⁶ See generally Meftah, Morteza; Nicolaou, Nicos; Rodriguez, Jose A. Metal allergy response to femoral head-neck corrosion after total hip replacement, *Current Orthopaedic Practice*, September/October 2010 - Volume 21 - Issue 5 - pp 530-533

⁷ http://www.jbjs.org.uk/media/19522/focuson_hipresurfacing.pdf, last visited September 6, 2010, stating (The ASR femoral component is heat treated and the acetabular component has a reduced sector angle.) see also Kinbrum A, Unsworth A. The wear of high-carbon metal-on-metal bearings after different heat treatments. *Proc Inst Mech Eng H* 2008;222:887-95

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construct which among other things leads to errors in surgical placement and in fixation of the cup⁸;

- g. DEPUY created a negligently drafted ASR surgical protocol which, among other things, creates a requisite degree of surgical skill for proper use of the device that is not possessed by a significant number of us surgeons, even after a proper review of all of the ASR surgical technique literature, other DEPUY literature and proper training in United States residency programs⁹;¹⁰
- h. DEPUY committed manufacturing errors including but not limited to component size tolerances out of specification and not within industry acceptable standards.
- i. DEPUY, in advertising, marketing, promoting, packaging, and selling the ASR, negligently misrepresented material facts regarding the ASR's safety, efficacy, and fitness for human use by claiming the ASR was fit for its intended purpose when, in fact, it was not;
- j. DEPUY, in advertising, marketing, promoting, packaging, and selling the ASR,

⁸ Thomas Parker Vail, For hip resurfacing arthroplasty prioritize exposure and cup insertion, Orthopedics Today, June 1, 2010, stating (When using a monoblock cup as part of a hip resurfacing or total hip procedure, it is important to note that a monoblock cup may be more challenging to insert than a modular cup with a dome hole and screw holes.)

⁹ Henrik Malchau, et. al. Quality Improvement of Use of Local Joint Registry: An Example Analysis of Cup Positioning in THA presented at AAOS annual meeting, New Orleans, LA, March 11, 2010. see also Callanan MC, Jarrett B, Bragdon CR, Zurakowski D, Rubash HE, Freiberg AA, Malchau H., Clin Orthop Relat Res. 2010 Aug 18, see also The John Charnley Award: Risk Factors for Cup Malpositioning: Quality Improvement Through a Joint Registry at a Tertiary Hospital. stating (From the 1823 hips, 1144 (63%) acetabular cups were within the abduction range, 1441 (79%) were within the version range, and 917 (50%) were within the range for both.)

¹⁰ Bosker BH, Verheyen CC, Horstmann WG, Tulp NJ. Poor accuracy of freehand cup positioning during total hip arthroplasty, Arch Orthop Trauma Surg. 2007 Jul;127(5):375-9. Epub 2007 Feb 13. stating (Based upon the inaccuracy of estimation, the group's chance on future cup placement within Lewinnek's safe zone (5-25 degrees anteversion and 30-50 degrees abduction) is 82.7 and 85.2% for anteversion and abduction separately. When both parameters are combined, the chance of accurate placement is only 70.5%.)

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negligently misrepresented material facts regarding the ASR's safety, efficacy, and fitness for human use by claiming the ASR had been adequately and reliably tested when, in fact, it was not;

- k. DEPUY, in advertising, marketing, promoting, packaging, and selling the ASR, negligently misrepresented material facts regarding the ASR's safety, efficacy, and fitness for human use by claiming the ASR was safe and effective and was appropriate for use by human beings when, in fact, it was not;
- l. DEPUY, in advertising, marketing, promoting, packaging, and selling the ASR, negligently misrepresented material facts regarding the ASR's safety, efficacy, and fitness for human use by claiming the risk of serious adverse events and/or effects from the ASR was comparable to that of other hip replacement systems when, in fact, it was not;
- m. DEPUY, in advertising, marketing, promoting, packaging, and selling the ASR, negligently misrepresented material facts regarding the ASR's safety, efficacy, and fitness for human use by claiming the ASR had not caused or contributed to serious adverse events and/or effects requiring the premature explants of the device when, in fact, it had.

69. DEPUY knew or had reason to know that PLAINTIFF, as a member of the general public for whose use the ASR was placed into interstate commerce, would be likely to use the ASR in a manner described in this Complaint.

70. DEPUY knew or reasonably should have known of the danger associated with the manner and circumstances of PLAINTIFF'S, foreseeable use of the ASR, which danger would not be obvious to the general public.

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71. DIBIASE and LEEDY also had a duty to exercise reasonable care in the sale, marketing, distribution, detailing, delivery and failure reporting of the ASR system.

72. DIBIASE and LEEDY knew or should have known at some point in its marketing, promotion, sale, delivery, detailing and physician consultation that the ASR system was defective and failing at an alarmingly high rate.

73. Despite this knowledge, DIBIASE and LEEDY continued to market, promote, sell, deliver and detail physicians without conveying material information that would have significantly affected physicians' judgment as to whether to implant the ASR system into their patients.

74. In addition, DIBIASE and LEEDY's failures rendered physicians incapable of transmitting material safety information to their patients frustrating the physicians' ability to obtain full and complete informed consent from their patients.

75. DIBIASE and LEEDY's failure to timely convey accurate safety information obtained in the field to the manufacturer, DEPUY, resulted in the product remaining on the market far beyond the point that it should have been recalled. As a result, thousands of ASR implants were placed in patients like PLAINTIFF.

76. As a direct and proximate result, DEFENDANTS' negligence caused serious damage to PLAINTIFF including bodily injury, pain and suffering, disability, physical impairment, disfigurement, mental anguish, inconvenience, aggravation of a preexisting condition, loss of the capacity for the enjoyment of life, the costs of medical care and expenses, loss of earnings and loss of ability to earn money, all of which damages and losses will continue in the future.

COUNT VI

77. PLAINTIFFS incorporate by reference paragraphs 1 through 76 of this Complaint as if fully set forth here and further allege as follows:

78. At all times relevant, PLAINTIFFS David Kauthen and Viola Kauthen were married.

79. As a result of the injuries and damages sustained by DAVID KAUTHEN, VIOLA KAUTHEN has been deprived the services, comfort, society and attentions of DAVID KAUTHEN in the past , all of which damages and losses will continue in the future.

Wherefore, PLAINTIFFS DAVID KAUTHEN and VIOLA KAUTHEN demand judgment against all DEFENDANTS, together with costs of this action, post-judgment interest and such other relief as the Court deems just.

JURY DEMAND

PLAINTIFFS demand trial by jury.

DATED this 16th day of March, 2011.



C. CALVIN WARRINER, III
Florida Bar No.: 374131
Searcy Denney Scarola Barnhart & Shipley, P.A.
2139 Palm Beach Lakes Boulevard
West Palm Beach, Florida 33409
Phone: (561) 686-6300
Fax: (561) 383-9442
Attorney for Plaintiffs

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Of Counsel:

Douglass A. Kreis
DKreis@awkolaw.com
Justin G. Witkin
JWitkin@awkolaw.com
Aylstock, Witkin, Kreis & Overholtz PLLC
803 North Palafox Street
Pensacola, 32503
(850) 916-7450

Peter J. Flowers (*Pro hac vice application to be filed*)
PJF@Foote-Meyers.com
Craig S. Mielke (*Pro hac vice application to be filed*)
CSM@Foote-Meyers.com
Foote, Meyers, Mielke & Flowers, LLC.
3 North Second Street, Suite 300
St. Charles, Illinois 60174
(630) 232-6333

Herbert Orlandah Phillips IV MD JD (*Pro hac vice application to be filed*)
usamedlaw@gmail.com
hphillips@usa.com
McGuire, Wood & Bisette, P.A.
48 Patton Avenue
Asheville, North Carolina 28801
(828) 254-8800