

UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF TEXAS  
DALLAS DIVISION

	§	
	§	
<b>MARVIN ANDREWS and</b>	§	
<b>ELIZABETH ANDREWS</b>	§	
<b>AND OTHERS</b>	§	
<b>(BUNDLED COMPLAINT).</b>	§	
	§	
<b>Plaintiffs,</b>	§	<b>CIVIL ACTION NO. 3:15-cv-3484</b>
	§	
<b>VS.</b>	§	<b>MDL 2244 (Judge Kinkeade)</b>
	§	
<b>DEPUY ORTHOPAEDICS, INC.,</b>	§	<b>JURY TRIAL DEMANDED</b>
<b>DEPUY PRODUCTS, INC., DEPUY</b>	§	
<b>INTERNATIONAL, LIMITED,</b>	§	
<b>JOHNSON &amp; JOHNSON SERVICES,</b>	§	
<b>INC., JOHNSON &amp; JOHNSON, INC.,</b>	§	
<b>and DOES 1-10, inclusive,</b>	§	
	§	
<b>Defendants.</b>	§	

**PLAINTIFFS’ ORIGINAL COMPLAINT**

COMES NOW Plaintiffs, MARVIN ANDREWS and ELIZABETH ANDREWS, KAREN A. DAVIS and GLENN LEE DAVIS, TANYA WEBSTER-DURHAM, and RAMON ALICEA and CAROLE ALICEA, by and through their undersigned attorneys, and, for their complaint against the Defendants, DEPUY ORTHOPAEDICS, INC., DEPUY PRODUCTS, INC., DEPUY INTERNATIONAL, LIMITED, JOHNSON & JOHNSON SERVICES, INC., JOHNSON & JOHNSON, INC. and DOES 1-10, INCLUSIVE, allege as follows:

**I. PARTIES**

1. Plaintiffs, MARVIN ANDREWS and ELIZABETH ANDREWS, are, citizens of the State of California and reside in Sacramento, Sacramento County, California. Plaintiffs, KAREN A. DAVIS and GLENN LEE DAVIS, are, citizens of the State of North Carolina and

reside in Moyock, Currituck County, North Carolina, but Plaintiff, KAREN A. DAVIS underwent surgery in Norfolk, Norfolk County, Virginia. Plaintiff, TANYA WEBSTER-DURHAM, are, citizens of the State of South Carolina and reside in Sumter, Sumter County, South Carolina, but Plaintiff, TANYA WEBSTER-DURHAM underwent surgery in Charlotte, Mecklenburg County, North Carolina. Plaintiffs, RAMON ALICEA and CAROLE ALICEA, are, citizens of the State of New York and reside in West Islip, Suffolk County, New York. Plaintiffs,

2. Defendant DEPUY ORTHOPAEDICS, INC. is, and at all times relevant to this Complaint was, an Indiana Corporation with its principal place of business at 700 Orthopaedic Drive, Warsaw, Indiana 46581. Defendant DEPUY ORTHOPAEDICS, INC. is and was at all times relevant herein doing business in and/or having directed its activities at Texas, and specifically this judicial district. Defendant DePuy Orthopaedics, Inc.'s registered agent for service is CT Corporation Systems, 251 East Ohio Street, Suite 1100, Indianapolis, IN 46204.

3. At all relevant times to this Complaint, DEPUY ORTHOEPaedICS, INC., designed, manufactured, tested, marketed, distributed and sold the metal-on-metal Pinnacle Device, either directly or indirectly, to customers throughout the United States, including the Plaintiff, MARVIN ANDREWS and ELIZABETH ANDREWS, in the county of Sacramento County, state of California; Plaintiff, KAREN A. DAVIS and GLENN LEE DAVIS, in the county of Currituck County state of North Carolina; Plaintiff, TANYA WEBSTER-DURHAM, in the county of Sumter County, state of South Carolina; Plaintiff, RAMON ALICEA and CAROLE ALICEA, in the county of Suffolk County, state of New York.

4. Defendant DEPUY PRODUCTS, INC. is, and at all times relevant to this Complaint was, an Indiana Corporation with its principal place of business at 700 Orthopaedic Drive, Warsaw, Indiana 46581. Defendant DEPUY PRODUCTS, INC. is and was at all times relevant herein doing business in and/or having directed its activities at Texas, and specifically this

judicial district. Defendant DEPUY PRODUCTS, INC.'s registered agent for service is CT Corporation Systems, 251 East Ohio Street, Suite 1100, Indianapolis, IN 46204.

5. At all relevant times to this Complaint, DEPUY PRODUCTS, INC., designed, manufactured, tested, marketed, distributed and sold the metal-on-metal Pinnacle Device, either directly or indirectly, to customers throughout the United States, including the Plaintiff, MARVIN ANDREWS and ELIZABETH ANDREWS, in the county of Sacramento County, state of California; Plaintiff, KAREN A. DAVIS and GLENN LEE DAVIS, in the county of Currituck County state of North Carolina; Plaintiff, TANYA WEBSTER-DURHAM, in the county of Sumter County, state of South Carolina; Plaintiff, RAMON ALICEA and CAROLE ALICEA, in the county of Suffolk County, state of New York.

6. Defendant DEPUY INTERNATIONAL, LIMITED is, and at all times relevant to this Complaint was, a subsidiary of DEPUY ORTHOPAEDICS, INC., and was a private limited company with its principal place of business at St. Anthony's Road, Beeston, Leeds, West Yorkshire UK LS11 8DT, United Kingdom. Defendant DEPUY INTERNATIONAL, LIMITED is, and was at all times relevant herein doing business in and/or having directed its activities at Texas, and specifically this judicial district. Defendant DEPUY INTERNATIONAL, LIMITED's agent for service is located at St. Anthony's Road, Beeston, Leeds, West Yorkshire UK LS11 8DT.

7. At all relevant times to this Complaint, DEPUY INTERNATIONAL, LIMITED designed, manufactured, tested, marketed, distributed and sold the metal-on-metal Pinnacle Device, either directly or indirectly, to customers throughout the United States, including the Plaintiff, MARVIN ANDREWS and ELIZABETH ANDREWS, in the county of Sacramento County, state of California; Plaintiff, KAREN A. DAVIS and GLENN LEE DAVIS, in the county of Currituck County state of North Carolina; Plaintiff, TANYA WEBSTER-DURHAM, in the county of Sumter County, state of South Carolina; Plaintiff, RAMON ALICEA and CAROLE ALICEA, in the county of Suffolk County, state of New York.

8. Defendant JOHNSON & JOHNSON SERVICES, INC. is, and at all times relevant to this Complaint was, a New Jersey Corporation with its principal place of business at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933, and was the parent company of DEPUY ORTHOPAEDICS, INC. Defendant JOHNSON & JOHNSON SERVICES, INC. is and was at all times relevant herein doing business in and/or having directed its activities at Texas, and specifically this judicial district. Defendant Johnson & Johnson Services, Inc.'s registered agent for service is Johnson & Johnson, One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933.

9. At all relevant times to this Complaint, Defendant JOHNSON & JOHNSON SERVICES, INC., as the parent company of DEPUY ORTHOPAEDICS, INC., designed, manufactured, tested, advertised, marketed, distributed and sold the metal-on-metal Pinnacle Device, either directly or indirectly, to customers throughout the United States including the Plaintiff, MARVIN ANDREWS and ELIZABETH ANDREWS, in the county of Sacramento County, state of California; Plaintiff, KAREN A. DAVIS and GLENN LEE DAVIS, in the county of Currituck County state of North Carolina; Plaintiff, TANYA WEBSTER-DURHAM, in the county of Sumter County, state of South Carolina; Plaintiff, RAMON ALICEA and CAROLE ALICEA, in the county of Suffolk County, state of New York.

10. Defendant JOHNSON & JOHNSON, INC. is, and at all times relevant to this Complaint was, a New Jersey Corporation with its principal place of business at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933, and was the parent company of DEPUY ORTHOPAEDICS, INC. Defendant JOHNSON & JOHNSON, INC. is and was at all times relevant herein doing business in and/or having directed its activities at Texas, and specifically this judicial district. Defendant Johnson & Johnson, Inc.'s registered agent for services is Douglas K. Chin, One Johnson & Johnson Plaza, New Brunswick, NJ 08933.

11. At all relevant times to this Complaint, Defendant JOHNSON & JOHNSON, INC., as the parent company of DEPUY ORTHOPAEDICS, INC., designed, manufactured, tested, advertised, marketed, distributed and sold the metal-on-metal Pinnacle Device, either directly or indirectly, to customers throughout the United States including the Plaintiff, MARVIN ANDREWS and ELIZABETH ANDREWS, in the county of Sacramento County, state of California; Plaintiff, KAREN A. DAVIS and GLENN LEE DAVIS, in the county of Currituck County state of North Carolina; Plaintiff, TANYA WEBSTER-DURHAM, in the county of Sumter County, state of South Carolina; Plaintiff, RAMON ALICEA and CAROLE ALICEA, in the county of Suffolk County, state of New York.

12. Plaintiffs are unaware of the true names and capacities, whether individual, corporate, associate, or otherwise, of defendants DOES 1-10, inclusive, or any of them and therefore sues these Defendants, and each of them, by such fictitious names. Plaintiffs will seek leave of this Court to amend this Complaint when the status and identities of these Defendants are ascertained.

13.

## **II. JURISDICTION AND VENUE**

13. This Court has diversity jurisdiction over the parties pursuant to 28 U.S.C. § 1332(a)(1). The amount in controversy exceeds the sum or value of \$75,000, exclusive of interest and costs, and no Defendant is a citizen of the same state as Plaintiffs.

14. Venue is proper in this Court under 28 U.S.C. § 1391(c) and also under this Court's Case Management Order #1, dated June 29, 2011, permitting direct filing into this Court and for consideration for transfer into MDL No. 3:11-MD-2244-K.

### **III. INTRODUCTION AND SUMMARY OF ACTION**

15. Plaintiffs allege on information and belief against DEPUY ORTHOPAEDICS, INC., Inc., Johnson & Johnson, Inc., and Johnson & Johnson Services, Inc. the following:

16. Defendants manufactured the Pinnacle Hip Implant Device (“Pinnacle Device”). DEPUY launched the Pinnacle Acetabular Cup System in 2001. The Pinnacle Device was designed, developed, and sold for human hip joints damaged or diseased due to, among other things, fracture, osteoarthritis, rheumatoid arthritis, and vascular necrosis. The Pinnacle Device is designed to be fastened to human bone with surgical screws. The Pinnacle Device was designed and sold to provide pain relief and consistent and smooth range of motion. Defendants marketed the Pinnacle devices as having significant advantages over other hip devices and hip replacement systems. Defendants marketed and described the Pinnacle Device as “uniquely designed to meet the demands of active patients like you – and help reduce pain” and advertised it with pictures of a young woman trying on sneakers in an athletic shoe store. Defendants advertised the Pinnacle Device as superior devices featuring TruGlide technology, allowing the body to create a thin film of lubrication between surfaces, which enables “a more fluid range of natural motion.”

17. Defendants also advertised and sold the Pinnacle Device as the best surgical option that “recreates the natural ball-and-socket joint of your hip, increasing stability and range of motion.”

18. On information and belief, Plaintiffs allege that Defendants sold approximately 150,000 Pinnacle Devices. Defendants have stated in Promotional materials that “99.9% of Pinnacle hip components are still in use today.”

19. On information and belief, Plaintiffs allege that over 1,300 adverse reports have been submitted to the U.S. Food and Drug Administration (FDA) regarding failure or complications of the Pinnacle Devices.

20. On information and belief, Plaintiffs allege that Defendants are aware that Pinnacle Devices may result in metallosis, biologic toxicity and high failure rate. Plaintiffs further allege that the Pinnacle Devices result in unsafe release of toxic metal ions into hip implant recipients' tissue and bloodstream. Plaintiffs further allege that Defendants are aware the metal particles from Pinnacle Devices results in metallosis tissue death, bone erosion and development of tumors.

21. On information and belief, Plaintiffs allege that particulate debris from the Pinnacle Devices causes severe inflammation, severe pain, tissue and bone loss, and other related diseases.

22. Plaintiffs further allege that Defendants are aware that Pinnacle Device recipients have elevated cobalt and chromium levels greatly exceeding acceptable safety standards.

23. Plaintiffs were implanted with the Pinnacle Device and have suffered substantial injuries and damage.

#### **IV. FACTUAL ALLEGATIONS**

##### **A. The Pinnacle Device with An "Ultamet" Liner**

24. The Pinnacle Device was developed for the purpose of reconstructing diseased human hip joints from conditions such as osteoarthritis, rheumatoid arthritis, avascular necrosis (AVN), fracture, and other degenerative conditions. The hip joint connects the thigh (femur) bone of a patient's leg to the patient's pelvis. The hip joint is like a ball that fits in a socket. The socket portion of the hip is called acetabulum. The femoral head at the top of the femur bone rotates within the curved surface of the acetabulum.

25. The Pinnacle Device includes four components; the metal femoral stem is inserted inside the femur bone, the metal femoral head (or ball) connects to the top of the stem and then makes contact with a liner that is attached to the interior portion of the metal acetabulum cup (socket). The acetabulum cup is comprised of titanium metal on its outer shell. Either a plastic, ceramic, or cobalt-chromium metal liner is then placed on the inside of the acetabulum cup. The

metal femoral head rotates within the plastic, ceramic, or metal liner, depending on which liner the surgeon selects based on the patient's needs. The cobalt-chromium metal liner is branded by Defendants as the "Ultamet." The Pinnacle Device with an Ultamet liner is a "metal-on-metal" device due to the fact that both articulating surfaces - the femoral head (ball) and acetabulum liner (socket) - are comprised of cobalt-chromium metal.

**B. Defendants Did Not Seek Premarket Approval From the FDA, and Thus the FDA Made No Finding That the Pinnacle Device Is Safe or Effective**

26. The Pinnacle Device is a Class III medical device. Class III devices are those that operate to sustain human life, are of substantial importance in preventing impairment of human health, or pose potentially unreasonable risks to patients.

27. The Medical Device Amendments to the Food, Drug, and Cosmetics Act of 1938 ("MDA"), in theory, require Class III medical devices, including the Pinnacle Device, to undergo premarket approval by the FDA, a process which obligates the manufacturer to design and implement a clinical investigation and to submit the results of that investigation to the FDA.

28. Premarket approval is a rigorous process that requires a manufacturer to submit what is typically a multivolume application that includes, among other things, full reports of all studies and investigations of the device's safety and effectiveness that have been published or should reasonably be known to the applicant; a full statement of the device's components, ingredients, and properties and of the principle or principles of operation; a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and when relevant, packing and installation of, such device; samples or device components required by the FDA; and a specimen of the proposed labeling.

29. The FDA may grant premarket approval only if it finds that there is reasonable assurance that the medical device is safe and effective and must weigh any probable benefit to health from the use of the device against any probable risk of injury or illness from such use.



30. A medical device on the market prior to the effective date of the MDA – a so-called "grandfathered" device -- is not required to undergo premarket approval. In addition, a medical device marketed after the MDA's effective date may bypass the rigorous premarket approval process if the device is "substantially equivalent" to a "grandfathered" pre-MDA device (i.e., a device approved prior to May 28, 1976). This exception to premarket approval is known as the "510(k)" process and only requires the manufacturer to notify the FDA under section 510(k) of the MDA of its intent to market a device at least 90 days prior to the device's introduction on the market, and to explain the device's substantial equivalence to a pre-MDA predicate device. The FDA may then approve the new device for sale in the United States.

31. Rather than being approved for use by the FDA pursuant to the rigorous premarket approval process, the Pinnacle Device metal-on-metal total hip replacement system was certified to be sold on the basis of Defendants' claim that, under section 510(k) of the MDA, it was "substantially equivalent" to another, older metal-on-metal hip implant device that was sold and implanted prior to the enactment of the MDA in 1976.

32. As such, under the 510(k) process, Defendants were able to market the Pinnacle Device with virtually no clinical or non-clinical trials or FDA review of the implant for safety and effectiveness.

**C. Defendants Took No Steps to Test the Pinnacle Device or They Would Have Discovered That It Leads to Metallosis and Other Complications Before Releasing it on the Market**

33. Had Defendants conducted clinical trials of the Pinnacle Device before it was first released on the market in the early 2000s, they would have discovered at that time what they ultimately learned in and around 2007 -- that the Pinnacle Device results in a high percentage of patients developing metallosis, biologic toxicity and an early and high failure rate due to the release of metal particles in the patient's surrounding tissue when the cobalt-chromium metal femoral head rotates within the cobalt-chromium metal acetabular liner.

34. In other words, implantation of the Pinnacle Device results in the nearly immediate systemic release of high levels of toxic cobalt-chromium metal ions into every hip implant patient's tissue and bloodstream. This is because cobalt-chromium metal particles are released by friction from the metal femoral head rotating within the metal liner. The particles then accumulate in the patient's tissue surrounding the implant giving rise to metallosis, pseudotumors or other conditions.

35. The formation of metallosis, pseudotumors, infection and inflammation causes severe pain and discomfort, death of surrounding tissue, bone loss and lack of mobility.

36. The problems with the Pinnacle Device are similar to the issues that gave rise to Defendants' recall of the ASR XL Acetabular System and ASR Hip Resurfacing System. Like the Pinnacle Device, the ASR Device is also prone to early failure, and causes metallosis and cobalt toxicity resulting in serious health problems and the need for revision surgery. As a result, in August 2010, Defendants, in acknowledging the high failure rate of the ASR Device, recalled more than 93,000 ASR hip implants worldwide. It is anticipated that Defendants will at some point recall Pinnacle Devices for the same reasons.

37. On information and belief, Plaintiffs allege that the FDA has received more than 1,300 adverse reports regarding problems associated with or attributed to the Pinnacle Device.

38. On information and belief, Plaintiffs allege that many recipients of the Pinnacle Device are suffering from elevated levels of chromium and cobalt. Plaintiffs further allege on information and belief that Defendants are aware that certain recipients of the Pinnacle Device have significantly elevated levels of chromium and cobalt in amounts many times higher than acceptable or recommended safety levels. Notably, both the ASR XL Acetabular System and the Pinnacle Device were designed by Thomas Schmalzried.

39. A number of governmental regulatory agencies have recognized the problems caused by metal-on-metal implants such as the ASR and Pinnacle Device. For instance, The

Medicines and Healthcare Products Regulatory Agency ("MHRA") in Britain investigated Defendants' metal-on-metal total hip replacement system after receiving widespread reports of soft tissue reactions and tumor growth in thousands of patients who had received these implants. MHRA has required physicians to establish a system to closely monitor patients known to have metal-on-metal hips by monitoring the cobalt and chromium ion levels in their blood and to evaluate them for related soft tissue reactions.

40. Similarly, the Alaska Department of Health recently issued a bulletin warning of the toxicity of Defendants' metal-on-metal total hip replacement systems. The State of Alaska, like the MHRA, identified the need for close medical monitoring, surveillance and treatment of all patients who had received these and similar metal-on-metal implants.

41. Despite the public knowledge to the contrary, Defendants' continue to misrepresent the Pinnacle Device as a high-quality, safe and effective hip replacement product in their marketing and promotional materials. This is despite the fact that Defendants have known for years that the Pinnacle Device poses a danger to patients that have it implanted.

42. Defendants continue to sell the Pinnacle Device to doctors who implant them in countless numbers of patients with an unreasonably high percentage of those patients being forced to endure serious injury from metallosis, pseudotumors and biologic toxicity, among other complications. These patients are reporting severe pain and discomfort and the need for one or more complicated revision surgeries resulting in life-long health problems caused by the defective device.

**D. Plaintiff Specific Allegations**

43. On or about February 9, 2005, Plaintiff MARVIN ANDREWS underwent a total hip arthroplasty procedure performed by Marvin Lo, MD at San Francisco Veterans Administration Hospital in San Francisco, California. A Pinnacle Device with an Ultamet liner was implanted in place of his left hip. After the surgery, friction and wear between the cobalt-

chromium metal head and cobalt-chromium metal liner caused large amounts of toxic cobalt-chromium metal ions and particles to be released into Plaintiff's blood and tissue and bone surrounding the implant. As a result, Plaintiff has been experiencing severe pain and discomfort and inflammation in and around his implant. Due to Plaintiff's chronic pain and discomfort and other symptoms, Plaintiff was required to undergo revision surgery to replace his left hip implant. On or about August 18, 2015, Plaintiff MARVIN ANDREWS underwent a left hip revision procedure performed by Alfred C. Kuo, MD at San Francisco Veterans Administration Hospital in San Francisco, California. Plaintiff only recently became aware of the causal link between the injuries he has suffered and any wrongdoing on the part of Defendants due to the faulty and defective nature of the Pinnacle Device and to the failure of Defendants to properly warn him and his physicians about the Pinnacle Device's defective and faulty nature. Plaintiff was unable to make an earlier discovery of the causal link despite reasonable diligence because of Defendants' failure to properly warn him and his physicians about the Pinnacle Device's defective and faulty nature, and their failure to issue any recall or take any other proactive action to date with respect to the injuries being caused to patients that have been implanted with a Pinnacle Device.

44. Plaintiff, ELIZABETH ANDREWS, was at all times relevant hereto the spouse of Plaintiff, MARVIN A. ANDREWS, and as such lives and cohabitates with him. For the reasons set forth herein, Plaintiffs have necessarily paid and have become liable to pay for medical aid, treatment and for medications, and will necessarily incur further expenses of a similar nature in the future. Plaintiff has been caused, presently and in the future, to suffer the loss of her spouse's companionship, services, society and the ability of the Plaintiff's spouse have in those respects been impaired and depreciated, and the marital association between husband and wife has been altered, and accordingly, the Plaintiff has been caused great mental anguish.

45. On or about March 15, 2006, Plaintiff KAREN A. DAVIS underwent a total hip

arthroplasty procedure performed by James E. Dowd, MD at Sentara Leigh Hospital in Norfolk, Virginia. Also, on or about November 1, 2005, Plaintiff underwent yet another surgical procedure, performed by James E. Dowd, MD at Sentara Leigh Hospital in Norfolk, Virginia, of the right hip in which a second Pinnacle Device was implanted in Plaintiff's body. A Pinnacle Device with an Ultamet liner was implanted in place of her left and right hip. After the surgery, friction and wear between the cobalt-chromium metal head and cobalt-chromium metal liner caused large amounts of toxic cobalt-chromium metal ions and particles to be released into Plaintiff's blood and tissue and bone surrounding the implant. As a result, Plaintiff has been experiencing severe pain and discomfort and inflammation in and around her implant. Due to Plaintiff's chronic pain and discomfort and other symptoms, Plaintiff was required to undergo revision surgery to replace her left and right hip implant. On or about November 10, 2014, Plaintiff KAREN A. DAVIS underwent a bilateral hip revision procedure performed by James E. Dowd, MD at Sentara Leigh Hospital in Norfolk, Virginia. The Plaintiff only recently became aware of the causal link between the injuries she has suffered and any wrongdoing on the part of Defendants due to the faulty and defective nature of the Pinnacle Device and to the failure of Defendants to properly warn her and his physicians about the Pinnacle Device's defective and faulty nature. Plaintiff was unable to make an earlier discovery of the causal link despite reasonable diligence because of Defendants' failure to properly warn her and his physicians about the Pinnacle Device's defective and faulty nature, and their failure to issue any recall or take any other proactive action to date with respect to the injuries being caused to patients that have been implanted with a Pinnacle Device.

46. Plaintiff, GLENN LEE DAVIS, was at all times relevant hereto the spouse of Plaintiff, KAREN A. DAVIS, and as such lives and cohabitates with her. For the reasons set forth herein, Plaintiffs have necessarily paid and have become liable to pay for medical aid, treatment and for medications, and will necessarily incur further expenses of a similar nature in the future.

Plaintiff has been caused, presently and in the future, to suffer the loss of his spouse's companionship, services, society and the ability of the Plaintiff's spouse have in those respects been impaired and depreciated, and the marital association between husband and wife has been altered, and accordingly, the Plaintiff has been caused great mental anguish.

47. On or about November 20, 2009, Plaintiff Tanya A. Webster- Durham underwent a total hip arthroplasty procedure performed by Sami J. Oweida, MD at Carolinas Medical Center-Mercyl in Charlotte, North Carolina. A Pinnacle Device with an Ultamet liner was implanted in place of her right hip. After the surgery, friction and wear between the cobalt-chromium metal head and cobalt-chromium metal liner caused large amounts of toxic cobalt-chromium metal ions and particles to be released into Plaintiff's blood and tissue and bone surrounding the implant. As a result, Plaintiff has been experiencing severe pain and discomfort and inflammation in and around her implant. Plaintiff only recently became aware of the causal link between the injuries she has suffered and any wrongdoing on the part of Defendants due to the faulty and defective nature of the Pinnacle Device and to the failure of Defendants to properly warn her and his physicians about the Pinnacle Device's defective and faulty nature. Plaintiff was unable to make an earlier discovery of the causal link despite reasonable diligence because of Defendants' failure to properly warn her and his physicians about the Pinnacle Device's defective and faulty nature, and their failure to issue any recall or take any other proactive action to date with respect to the injuries being caused to patients that have been implanted with a Pinnacle Device.

48. On or about June 22, 2010, Plaintiff RAMON ALICEA underwent a total hip arthroplasty procedure performed by Jonathan Mallen, MD at South Nassau Communities Hospital in Oceanside, New York. A Pinnacle Device with an Ultamet liner was implanted in place of his left hip. After the surgery, friction and wear between the cobalt-chromium metal head and cobalt-chromium metal liner caused large amounts of toxic cobalt-chromium metal ions and

particles to be released into Plaintiff's blood and tissue and bone surrounding the implant. As a result, Plaintiff has been experiencing severe pain and discomfort and inflammation in and around his implant. Due to Plaintiff's chronic pain and discomfort and other symptoms, Plaintiff was required to undergo revision surgery to replace his left hip implant. On or about October 15, 2015, Plaintiff RAMON ALICEA underwent a left hip revision procedure performed by James Germano, MD at South Nassau Communities Hospital in Oceanside, New York. Plaintiff only recently became aware of the causal link between the injuries he has suffered and any wrongdoing on the part of Defendants due to the faulty and defective nature of the Pinnacle Device and to the failure of Defendants to properly warn him and his physicians about the Pinnacle Device's defective and faulty nature. Plaintiff was unable to make an earlier discovery of the causal link despite reasonable diligence because of Defendants' failure to properly warn him and his physicians about the Pinnacle Device's defective and faulty nature, and their failure to issue any recall or take any other proactive action to date with respect to the injuries being caused to patients that have been implanted with a Pinnacle Device.

49. Plaintiff, CAROLE ALICEA, was at all times relevant hereto the spouse of Plaintiff, RAMON ALICEA, and as such lives and cohabitates with him. For the reasons set forth herein, Plaintiffs have necessarily paid and have become liable to pay for medical aid, treatment and for medications, and will necessarily incur further expenses of a similar nature in the future. Plaintiff has been caused, presently and in the future, to suffer the loss of her spouse's companionship, services, society and the ability of the Plaintiff's spouse have in those respects been impaired and depreciated, and the marital association between husband and wife has been altered, and accordingly, the Plaintiff has been caused great mental anguish.

50. All of the injuries and complications suffered by Plaintiffs were caused by the defective design, lack of adequate warnings, construction and unreasonably dangerous character

of the Pinnacle Devices that were implanted in them. Had Defendants not concealed the known defects, the early failure rate, the known complications and the unreasonable risks associated with the use of the Pinnacle Devices, Plaintiffs would not have consented to the Pinnacle Device being used in her total hip arthroplasties.

51. Consequently, because of Defendants' acts and omissions, Plaintiffs have been harmed as a result of the Defendants' wrongful acts and omissions and files this suit to recover their damages, as described below.

## **V. CAUSES OF ACTION**

### **A. NEGLIGENCE**

52. Plaintiffs adopt by reference and incorporate herein the allegations set forth above.

53. Defendants had a duty to exercise reasonable care in the designing, researching, manufacturing, marketing, supplying, promoting, sale, testing, quality assurance, quality control and distribution of the Pinnacle Device into the stream of commerce, including a duty to assure that the device would not cause those who had it surgically implanted to suffer adverse harmful effects.

54. Defendants failed to exercise reasonable care in the designing, researching, manufacturing, marketing, supplying, promoting, sale, testing, quality assurance, quality control and distribution of the Pinnacle Device into interstate commerce. Defendants knew or should have known that those individuals who had the device surgically implanted were at risk for suffering harmful effects from it, including but not limited to partial or complete loss of mobility, loss of range of motion, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life. Additionally, Defendants knew or should have known about the harmful effects from the need for a revision surgery to replace the device with the attendant risks of



complications and death from such further surgery.

55. The negligence of Defendants, their agents, servants and employees, included but was not limited to the following acts and/or omissions:

- a. Negligently designing the Pinnacle Device in a manner that was dangerous to those individuals who had the device surgically implanted;
- b. Designing, manufacturing, producing, creating and promoting the Pinnacle Device without adequately, sufficiently or thoroughly testing it;
- c. Not conducting a sufficient testing program to determine whether or not the Pinnacle Device was safe for use;
- d. Marketing and selling the Pinnacle Device when Defendants knew or should have known that it was unsafe and unfit for use because of the dangers to its users;
- e. Selling the Pinnacle Device without making proper and sufficient tests to determine the dangers to its users;
- f. Negligently failing to adequately and correctly warn Plaintiffs or their physicians, hospitals and healthcare providers of the dangers of the Pinnacle Device;
- g. Negligently failing to recall their dangerous and defective Pinnacle Device at the earliest date that it became known that the device was, in fact, dangerous and defective;
- h. Failing to provide adequate instructions regarding safety precautions to be observed by surgeons who would reasonably and foreseeably come in contact with, and more particularly, implant the Pinnacle Device into their patients;
- i. Negligently advertising and recommending the use of the Pinnacle Device despite the fact Defendants knew or should have known of its dangerous propensities;
- i. Negligently representing that the Pinnacle Device was safe for use for its intended purpose, when, in fact, it was unsafe;
- j. Negligently representing that the Pinnacle Device offered low wear and high stability, when, in fact, the opposite was true;
- k. Negligently manufacturing the Pinnacle Device in a manner that was dangerous to those individuals who had it implanted;
- l. Negligently producing the Pinnacle Device in a manner that was dangerous to those individuals who had it implanted;
- m. Negligently assembling the Pinnacle Device in a manner, that was dangerous to those individuals who had it implanted;

- n. Negligently under-reporting, underestimating and downplaying the serious dangers of the Pinnacle Device.

56. Defendants were further negligent in the designing, researching, supplying, manufacturing, promoting, packaging, distributing, testing, advertising, warning, marketing and sale of the Pinnacle Device in that they:

- a. Failed to use due care in designing and manufacturing the Pinnacle Device so as to avoid the risks to individuals that had the devices surgically implanted;
- b. Failed to accompany their product with proper warnings;
- c. Failed to accompany their product with proper instructions for use;
- d. Failed to conduct adequate testing, including pre-clinical and clinical testing and post-marketing surveillance to determine the safety of the Pinnacle Device; and
- e. Were otherwise careless and negligent.

57. Despite the fact that Defendants knew or should have known that the Pinnacle Device caused harm to individuals that had the device surgically implanted, Defendants continued to market, manufacture, distribute and sell the Pinnacle Device.

58. Defendants knew or should have known that consumers, such as Plaintiffs, would suffer foreseeable injury and be at increased risk of suffering an injury as a result of Defendants' failure to exercise ordinary care, as set forth above.

59. Defendants' negligence was the proximate cause of Plaintiffs' physical, mental and emotional injuries and harm, and economic loss, which they have suffered and will continue to suffer in the future.

60. By reason of the foregoing, Plaintiffs experienced and will experience severe harmful effects including but not limited to partial or complete loss of mobility, loss of range of motion, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life. Plaintiffs required a

revision surgery to replace the device, which carried the attendant risks of complications and death from such further surgery.

61. In performing the foregoing acts and omissions, Defendants acted grossly negligent, fraudulently and with malice so as to justify an award of punitive and/or exemplary damages.

### **B. STRICT LIABILITY—FAILURE TO WARN**

62. Plaintiffs adopt by reference and incorporate herein the allegations set forth in the paragraphs above.

63. Defendants designed, manufactured, tested, marketed and distributed into the stream of commerce the Pinnacle Devices.

64. The Pinnacle Devices placed into the stream of commerce by Defendants were defective due to inadequate warnings, because Defendants knew or should have known that the Pinnacle Devices could fail early in patients and therefore cause physical injury, pain and suffering, debilitation and the need for a revision surgery to replace the device, with the attendant risks of complications and death from such further surgery, but Defendants failed to give consumers and physicians adequate warning of such risks. Further, the Pinnacle Devices placed into the stream of commerce by Defendants were surgically implanted in a manner reasonably anticipated by Defendants.

65. As a direct and proximate result of Defendants' placement of the defective Pinnacle Devices into the stream of commerce, Plaintiffs experienced and will experience severe harmful effects including but not limited to partial or complete loss of mobility, loss of range of motion, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life.

66. In performing the foregoing acts and omissions, Defendants acted with gross

negligence, fraudulently, and with malice so as to justify an award of punitive and/or exemplary damages.

**C. STRICT LIABILITY-MANUFACTURING DEFECT**

67. Plaintiffs adopt by reference and incorporate herein the allegations set forth in the paragraphs above.

68. Defendants designed, manufactured, tested, marketed and distributed into the stream of commerce the Pinnacle Devices.

69. At all times herein mentioned, the Pinnacle Device designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was in an unsafe, defective and unreasonably dangerous condition at the time it left Defendants' possession.

70. At all times herein mentioned, the Pinnacle Device was expected to and did reach the usual consumers, handlers, and persons coming into contact with said product without substantial change in the condition in which it was designed, produced, manufactured, sold, distributed, and marketed by Defendants.

71. The Pinnacle Devices that were surgically implanted in Plaintiffs were defective in its manufacture when it left the hands of Defendants in that it deviated from product specifications, posing a serious risk that it could fail early in patients thereby giving rise to physical injury, pain and suffering, debilitation and the need for a revision surgery to replace the device with the attendant risks of complications and death from such further surgery.

72. As a direct and proximate result of Defendants' placement of the defective and unreasonably dangerous Pinnacle Devices into the stream of commerce, the Plaintiffs have suffered and will continue to suffer substantial damages.

**D. STRICT LIABILITY-DESIGN DEFECT**

73. Plaintiffs adopt by reference and incorporate herein the allegations set forth in the paragraphs above.

74. At all times herein mentioned, Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed the Pinnacle Devices that were surgically implanted in Plaintiffs.

75. At all times herein mentioned, The Pinnacle Device designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was in an unsafe, defective, and unreasonably dangerous condition, which was dangerous to users such as Plaintiffs who had the devices surgically implanted.

76. At all times herein mentioned, The Pinnacle Device designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was in an unsafe, defective and unreasonably dangerous condition at the time it left Defendants' possession.

77. At all times herein mentioned, The Pinnacle Device was expected to and did reach the usual consumers, handlers, and persons coming into contact with said product without substantial change in the condition in which it was designed, produced, manufactured, sold, distributed, and marketed by Defendants.

78. At all times herein mentioned, The Pinnacle Device's unsafe, defective, and unreasonably dangerous condition was a proximate, producing or other legal cause of injury to Plaintiffs.

79. At all times herein mentioned, The Pinnacle Device failed to perform as safely as an ordinary consumer would expect when used in an intended or reasonably foreseeable manner.

80. Plaintiffs' injuries resulted from use of the Pinnacle Device that was both intended and reasonably foreseeable by Defendants.

81. At all times herein mentioned, The Pinnacle Device posed a risk of danger inherent in its design which outweighed the benefits of that design.

82. At all times herein mentioned, The Pinnacle Device was defective and unsafe, and Defendants knew or had reason to know that it was defective and unsafe, especially when used in the form and manner as provided by Defendants.

83. Defendants knew, or should have known, that the Pinnacle Device was in a defective condition, and was and is unreasonably dangerous and unsafe.

84. At the time of the implantation of the Pinnacle Device into the Plaintiffs, the product was being used for the purposes and in a manner normally intended, namely for use as a hip replacement device.

85. Defendants, with this knowledge, voluntarily designed its Pinnacle Device in a dangerous condition for use by the public and, in particular, the Plaintiffs.

86. Defendants had a duty to create a product that was not unreasonably dangerous for its normal, intended use.

87. Defendants designed, researched, 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 and to Plaintiffs, in particular, and Defendants are therefore strictly liable for the injuries sustained by Plaintiffs.

88. At all times herein mentioned, there was a safer alternative design that was both technologically and economically feasible which would have eliminated or substantially reduced the damage to the Plaintiffs.

89. As a direct and proximate result of Defendants' placement of the defective Pinnacle Devices into the stream of commerce, Plaintiffs experienced and will experience severe harmful effects including but not limited to partial or complete loss of mobility, loss of range of motion, as well as other severe and personal injuries which are permanent and lasting in

nature, physical pain and mental anguish, including diminished enjoyment of life. Plaintiffs required a revision surgery to replace the device, which carried the attendant risks of complications and death from such further surgery.

90. In performing the foregoing acts and omissions, Defendants acted with gross negligence, fraudulently, and with malice so as to justify an award of punitive and exemplary damages.

### **E. NEGLIGENT MISREPRESENTATION**

91. Plaintiffs adopt by reference and incorporate herein the allegations set forth in the paragraphs above.

92. Defendants made misrepresentations and omissions of material facts, including, but not limited to:

- a) That Plaintiffs' implants were fit for its intended use;
- b) That Plaintiffs' implants were of merchantable quality;
- c) That Plaintiffs' implants were safe and efficacious in the treatment of Plaintiffs' medical condition;
- d) That Plaintiffs' implant would function as intended when necessary;
- e) That Plaintiffs' implants were not defective, such that it would fail to function as intended; and
- f) That Plaintiffs' implants were not unreasonably dangerous.

93. These representations and omissions were false and misleading at the time they were made.

94. Defendants negligently and carelessly made the foregoing misrepresentations without a basis.

95. Defendants were aware that they did not possess information on which to accurately base the foregoing representations and concealed from Plaintiffs that there was no reasonable

basis for making these representations.

96. When Defendants made these representations, they knew or should have known them to be false.

97. In reliance upon the misrepresentations by the Defendants, Plaintiffs were induced to and did subject themselves to the use of the Pinnacle Device. If Plaintiffs had known of the true facts, they would not have taken such action and risk. Plaintiffs' reliance on Defendants' misrepresentations and omissions were reasonable because said representations were made by individuals and entities in a position to know the true facts.

98. As a result of the foregoing negligent misrepresentations by Defendants, Plaintiffs have suffered and will continue to suffer injury, expense and economic loss as previously described.

#### **F. BREACH OF EXPRESS WARRANTY**

99. Plaintiffs adopt by reference and incorporate herein the allegations set forth in the paragraphs above.

100. Defendants designed, manufactured, tested, marketed and distributed into the stream of commerce the Pinnacle Devices.

101. Defendants expressly warranted that the Pinnacle Devices were safe and effective hip replacement systems.

102. The Pinnacle Devices placed into the stream of commerce by Defendants did not conform to these express representations because they failed early, as did Plaintiffs', thereby giving rise to unnecessary physical injury, pain and suffering, debilitation, and the possible need for a revision surgery to replace the device with the attendant risks of complications and death from such further surgery.

103. As a direct and proximate result of Defendants' breach of express warranties regarding the safety and effectiveness of the Pinnacle Devices, Plaintiffs have suffered and will



continue to suffer substantial damages.

**G. BREACH OF IMPLIED WARRANTY**

104. Plaintiffs adopt by reference and incorporate herein the allegations set forth in the paragraphs above.

105. Defendants are in the business of designing, manufacturing, supplying and placing into the stream of commerce the Pinnacle Devices for consumers.

106. By placing the Pinnacle Devices into the stream of commerce, Defendants impliedly warranted that they were merchantable and fit and safe for their intended use.

107. The Pinnacle Device placed into the stream of commerce by Defendants and implanted in Plaintiffs were defective and accordingly, were not fit, safe, or merchantable for its intended use.

108. The defects in the Pinnacle Device designed, manufactured, supplied and placed into the stream of commerce by Defendants were present at the time the product left Defendants' control.

109. Defendants breached the implied warranty for the Pinnacle Device because it was defective, unmerchantable, and not fit for its intended purpose.

110. Plaintiffs were foreseeable users of the Pinnacle Device designed, manufactured, supplied and placed into the stream of commerce by Defendants.

111. As a direct and proximate result of Defendants' breach of these implied warranties, Plaintiffs have suffered and will continue to suffer injury, expense and economic loss as previously described, rendering Defendants liable for said damages.

**H. FRAUD (Against All Defendants)**

112. Plaintiffs incorporate by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows:

113. Defendants made representations to Plaintiffs and their physicians that their Pinnacle Device is a high-quality, safe and effective hip replacement system.

114. Before they marketed the Pinnacle Devices that were implanted in Plaintiffs, Defendants knew or should have known of the unreasonable dangers and serious health risks that such a metal-on-metal total hip replacement system posed to patients like Plaintiffs.

115. As specifically described in detail above, Defendants knew that the Pinnacle Device subjected patients to early failure, painful and harmful physical reactions to toxic metallic particles and ions, death of tissue, bone loss and the need for explants and revision surgery.

116. Defendants' representations to Plaintiffs and their physicians that their Pinnacle Devices are high-quality, safe and effective were false.

117. Defendants concealed their knowledge of the unreasonable risks and dangers associated with the use of the Pinnacle Device to induce Plaintiffs and many thousands of others to purchase the system for surgical implantation in their bodies.

118. Neither Plaintiffs nor their physicians knew of the falsity of Defendants' statements regarding the Pinnacle Device.

119. Plaintiffs and their physicians relied upon and accepted as truthful Defendants' representations regarding the Pinnacle Device.

120. Plaintiffs and their physicians had a right to rely on Defendants' representations and in fact did rely upon such representations. Had Plaintiffs known that the Pinnacle Device would fail early and expose themselves to the unreasonable risk of toxic metals, metallosis, and multiple revision surgeries they would not have purchased or allowed the Pinnacle Device to have been surgically implanted in them.

**121.** As a direct and proximate result of Defendants' fraudulent representations, Plaintiffs have suffered significant damages, including but not limited to permanent physical injury, economic loss, pain and suffering and the need for multiple surgeries to repair the physical damage to Plaintiffs caused by the Pinnacle Device.

**VI. JURY DEMAND**

Plaintiffs, MARVIN ANDREWS and ELIZABETH ANDREWS, KAREN A. DAVIS and GLENN LEE DAVIS, TANYA WEBSTER-DURHAM, and RAMON ALICEA and CAROLE ALICEA, hereby demand a trial by jury as to all claims in this action.

**VII. PRAYER FOR RELIEF**

WHEREFORE, Plaintiffs pray as follows:

- a) That process issue according to law;
- b) That Defendants be duly served and cited to appear and answer herein, and that after due proceedings are had, that there be judgment in favor of the Plaintiffs and against Defendants for the damages set forth below, along with court costs, pre-judgment and post-judgment interest at the legal rate;
  1. pain and suffering (past and future);
  2. wage loss (past and future);
  3. loss of earnings and loss of earning capacity;
  4. medical expenses (past and future);
  5. loss of enjoyment of life (past and future);
  6. mental anguish and distress (past and future);
  7. disfigurement (past and future);

8. physical impairment (past and future);
9. attorney's fees;
10. Punitive or exemplary damages in such amounts as may be proven at trial; and
11. For all such other relief as to which Plaintiffs may show themselves justly entitled.

Dated: October 27, 2015

/s/ Richard J. Arsenault  
Richard J. Arsenault - LA Bar Roll # 02563  
**NEBLETT, BEARD & ARSENAULT**  
2220 Bonaventure Court  
P.O. Box 1190  
Alexandria, LA 71309  
Telephone: (318) 487-9874  
[rsenault@nbalawfirm.com](mailto:rsenault@nbalawfirm.com)

Jerrold S. Parker  
**PARKER WAICHMAN LLP**  
6 Harbor Park Drive  
Port Washington, NY 11050  
Telephone: (516)466-6500  
[jerry@yourlawyer.com](mailto:jerry@yourlawyer.com)

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON THE REVERSE OF THE FORM.)

<b>I. (a) PLAINTIFFS</b> MARVIN ANDREWS and ELIZABETH ANDREWS, KAREN A. DAVIS and GLENN LEE DAVIS, TANYA WEBSTER-DURHAM and RAMON ALICEA and CAROLE ALICEA	<b>DEFENDANTS</b> DePuy Orthopaedics, Inc., DePuy Products, Inc., DePuy International, Limited, Johnson & Johnson Services, Inc., and Johnson & Johnson, Inc. and DOES 1-10, inclusive
<b>(b)</b> County of Residence of First Listed Plaintiff <b>Sacramento County</b> (EXCEPT IN U.S. PLAINTIFF CASES)	County of Residence of First Listed Defendant (IN U.S. PLAINTIFF CASES ONLY)
<b>(c)</b> Attorney's (Firm Name, Address, and Telephone Number) Richard J. Arsenault, Neblett, Beard & Arsenault, P.O. Box 1190, Alexandria, LA 71309-1190, (318)487-9874	Attorneys (If Known)

<b>II. BASIS OF JURISDICTION</b> (Place an "X" in One Box Only)	<b>III. CITIZENSHIP OF PRINCIPAL PARTIES</b> (Place an "X" in One Box for Plaintiff and One Box for Defendant)																		
<input type="checkbox"/> 1 U.S. Government Plaintiff <input type="checkbox"/> 2 U.S. Government Defendant <input checked="" type="checkbox"/> 3 Federal Question (U.S. Government Not a Party) <input checked="" type="checkbox"/> 4 Diversity (Indicate Citizenship of Parties in Item III)	(For Diversity Cases Only) <table border="1" style="width:100%; border-collapse: collapse;"> <tr> <td>Citizen of This State</td> <td><input type="checkbox"/> 1</td> <td><input type="checkbox"/> 1</td> <td>Incorporated or Principal Place of Business In This State</td> <td><input type="checkbox"/> 4</td> <td><input type="checkbox"/> 4</td> </tr> <tr> <td>Citizen of Another State</td> <td><input checked="" type="checkbox"/> 2</td> <td><input type="checkbox"/> 2</td> <td>Incorporated and Principal Place of Business In Another State</td> <td><input type="checkbox"/> 5</td> <td><input checked="" type="checkbox"/> 5</td> </tr> <tr> <td>Citizen or Subject of a Foreign Country</td> <td><input type="checkbox"/> 3</td> <td><input type="checkbox"/> 3</td> <td>Foreign Nation</td> <td><input type="checkbox"/> 6</td> <td><input type="checkbox"/> 6</td> </tr> </table>	Citizen of This State	<input type="checkbox"/> 1	<input type="checkbox"/> 1	Incorporated or Principal Place of Business In This State	<input type="checkbox"/> 4	<input type="checkbox"/> 4	Citizen of Another State	<input checked="" type="checkbox"/> 2	<input type="checkbox"/> 2	Incorporated and Principal Place of Business In Another State	<input type="checkbox"/> 5	<input checked="" type="checkbox"/> 5	Citizen or Subject of a Foreign Country	<input type="checkbox"/> 3	<input type="checkbox"/> 3	Foreign Nation	<input type="checkbox"/> 6	<input type="checkbox"/> 6
Citizen of This State	<input type="checkbox"/> 1	<input type="checkbox"/> 1	Incorporated or Principal Place of Business In This State	<input type="checkbox"/> 4	<input type="checkbox"/> 4														
Citizen of Another State	<input checked="" type="checkbox"/> 2	<input type="checkbox"/> 2	Incorporated and Principal Place of Business In Another State	<input type="checkbox"/> 5	<input checked="" type="checkbox"/> 5														
Citizen or Subject of a Foreign Country	<input type="checkbox"/> 3	<input type="checkbox"/> 3	Foreign Nation	<input type="checkbox"/> 6	<input type="checkbox"/> 6														

<b>IV. NATURE OF SUIT</b> (Place an "X" in One Box Only)				
<b>CONTRACT</b>	<b>TORTS</b>	<b>FORFEITURE/PENALTY</b>	<b>BANKRUPTCY</b>	<b>OTHER STATUTES</b>
<input type="checkbox"/> 110 Insurance <input type="checkbox"/> 120 Marine <input type="checkbox"/> 130 Miller Act <input type="checkbox"/> 140 Negotiable Instrument <input type="checkbox"/> 150 Recovery of Overpayment & Enforcement of Judgment <input type="checkbox"/> 151 Medicare Act <input type="checkbox"/> 152 Recovery of Defaulted Student Loans (Excl. Veterans) <input type="checkbox"/> 153 Recovery of Overpayment of Veteran's Benefits <input type="checkbox"/> 160 Stockholders' Suits <input type="checkbox"/> 190 Other Contract <input type="checkbox"/> 195 Contract Product Liability <input type="checkbox"/> 196 Franchise	<input type="checkbox"/> 310 Airplane <input type="checkbox"/> 315 Airplane Product Liability <input type="checkbox"/> 320 Assault, Libel & Slander <input type="checkbox"/> 330 Federal Employers' Liability <input type="checkbox"/> 340 Marine <input type="checkbox"/> 345 Marine Product Liability <input type="checkbox"/> 350 Motor Vehicle <input type="checkbox"/> 355 Motor Vehicle Product Liability <input type="checkbox"/> 360 Other Personal Injury <input type="checkbox"/> 362 Personal Injury - Med. Malpractice <input type="checkbox"/> 370 Other Fraud <input type="checkbox"/> 371 Truth in Lending <input type="checkbox"/> 380 Other Personal <input type="checkbox"/> 385 Property Damage <input type="checkbox"/> 367 Health Care/Pharmaceutical Personal Injury Product Liability <input type="checkbox"/> 368 Asbestos Personal Injury Product Liability <input type="checkbox"/> 370 Other Fraud <input type="checkbox"/> 371 Truth in Lending <input type="checkbox"/> 380 Other Personal <input type="checkbox"/> 385 Property Damage <input type="checkbox"/> 510 Motions to Vacate Sentence <input type="checkbox"/> 535 Death Penalty <input type="checkbox"/> 540 Mandamus & Other <input type="checkbox"/> 550 Civil Rights <input type="checkbox"/> 555 Prison Condition <input type="checkbox"/> 560 Civil Detainee - Conditions of Confinement	<input type="checkbox"/> 625 Drug Related Seizure of Property 21 USC 881 <input type="checkbox"/> 690 Other <input type="checkbox"/> 710 Fair Labor Standards Act <input type="checkbox"/> 720 Labor/Mgmt. Relations <input type="checkbox"/> 740 Railway Labor Act <input type="checkbox"/> 751 Family and Medical Leave Act <input type="checkbox"/> 790 Other Labor Litigation <input type="checkbox"/> 791 Empl. Ret. Inc. Security Act	<input type="checkbox"/> 422 Appeal 28 USC 158 <input type="checkbox"/> 423 Withdrawal 28 USC 157 <input type="checkbox"/> 820 Copyrights <input type="checkbox"/> 830 Patent <input type="checkbox"/> 840 Trademark <input type="checkbox"/> 861 HIA (1395ff) <input type="checkbox"/> 862 Black Lung (923) <input type="checkbox"/> 863 DIWC/DIWW (405(g)) <input type="checkbox"/> 864 SSID Title XVI <input type="checkbox"/> 865 RSI (405(g)) <input type="checkbox"/> 870 Taxes (U.S. Plaintiff or Defendant) <input type="checkbox"/> 871 IRS—Third Party 26 USC 7609	<input type="checkbox"/> 375 False Claims Act <input type="checkbox"/> 400 State Reapportionment <input type="checkbox"/> 410 Antitrust <input type="checkbox"/> 430 Banks and Banking <input type="checkbox"/> 450 Commerce <input type="checkbox"/> 460 Deportation <input type="checkbox"/> 470 Racketeer Influenced and Corrupt Organizations <input type="checkbox"/> 480 Consumer Credit <input type="checkbox"/> 490 Cable/Sat TV <input type="checkbox"/> 850 Securities/Commodities/Exchange <input type="checkbox"/> 890 Other Statutory Actions <input type="checkbox"/> 891 Agricultural Acts <input type="checkbox"/> 893 Environmental Matters <input type="checkbox"/> 895 Freedom of Information Act <input type="checkbox"/> 896 Arbitration <input type="checkbox"/> 899 Administrative Procedure Act/Review or Appeal of Agency Decision <input type="checkbox"/> 950 Constitutionality of State Statutes
<input type="checkbox"/> 210 Land Condemnation <input type="checkbox"/> 220 Foreclosure <input type="checkbox"/> 230 Rent Lease & Ejectment <input type="checkbox"/> 240 Torts to Land <input type="checkbox"/> 245 Tort Product Liability <input type="checkbox"/> 290 All Other Real Property	<input type="checkbox"/> 440 Other Civil Rights <input type="checkbox"/> 441 Voting <input type="checkbox"/> 442 Employment <input type="checkbox"/> 443 Housing/Accommodations <input type="checkbox"/> 445 Amer. w/Disabilities - Employment <input type="checkbox"/> 446 Amer. w/Disabilities - Other <input type="checkbox"/> 448 Education	<input type="checkbox"/> 535 Death Penalty <input type="checkbox"/> 540 Mandamus & Other <input type="checkbox"/> 550 Civil Rights <input type="checkbox"/> 555 Prison Condition <input type="checkbox"/> 560 Civil Detainee - Conditions of Confinement	<input type="checkbox"/> 462 Naturalization Application <input type="checkbox"/> 463 Habeas Corpus - Alien Detainee (Prisoner Petition) <input type="checkbox"/> 465 Other Immigration Actions	<input type="checkbox"/> 870 Taxes (U.S. Plaintiff or Defendant) <input type="checkbox"/> 871 IRS—Third Party 26 USC 7609 <input type="checkbox"/> 870 Taxes (U.S. Plaintiff or Defendant) <input type="checkbox"/> 871 IRS—Third Party 26 USC 7609

<b>V. ORIGIN</b> (Place an "X" in One Box Only)					
<input checked="" type="checkbox"/> 1 Original Proceeding	<input type="checkbox"/> 2 Removed from State Court	<input type="checkbox"/> 3 Remanded from Appellate Court	<input type="checkbox"/> 4 Reinstated or Reopened	<input type="checkbox"/> 5 Transferred from another district (specify)	<input type="checkbox"/> 6 Multidistrict Litigation

<b>VI. CAUSE OF ACTION</b>	Cite the U.S. Civil Statute under which you are filing (Do not cite jurisdictional statutes unless diversity): <b>28 USC 1332</b> Brief description of cause: <b>Injuries and damages caused by metal on metal hip implants</b>
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<b>VII. REQUESTED IN COMPLAINT:</b>	<input type="checkbox"/> CHECK IF THIS IS A CLASS ACTION UNDER F.R.C.P. 23	DEMAND \$	CHECK YES only if demanded in complaint: <b>JURY DEMAND:</b> <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
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<b>VIII. RELATED CASE(S) IF ANY</b>	(See instructions): JUDGE <b>James E. Kinkeade</b>	DOCKET NUMBER <b>3:11-md-02244</b>
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DATE <b>10/27/2015</b>	SIGNATURE OF ATTORNEY OF RECORD <b>/s/ Richard J. Arsenault</b>
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<b>FOR OFFICE USE ONLY</b>					
RECEIPT #	AMOUNT	APPLYING IFP	JUDGE	MAG. JUDGE	

JS 44 Reverse (Rev. 11/04)

**INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44**

**Authority For Civil Cover Sheet**

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

**I. (a) Plaintiffs-Defendants.** Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.

(b) County of Residence. For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)

(c) Attorneys. Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".

**II. Jurisdiction.** The basis of jurisdiction is set forth under Rule 8(a), F.R.C.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.

United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.

United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.

Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.

Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below; federal question actions take precedence over diversity cases.)

**III. Residence (citizenship) of Principal Parties.** This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.

**IV. Nature of Suit.** Place an "X" in the appropriate box. If the nature of suit cannot be determined, be sure the cause of action, in Section VI below, is sufficient to enable the deputy clerk or the statistical clerks in the Administrative Office to determine the nature of suit. If the cause fits more than one nature of suit, select the most definitive.

**V. Origin.** Place an "X" in one of the seven boxes.

Original Proceedings. (1) Cases which originate in the United States district courts.

Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441. When the petition for removal is granted, check this box.

Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.

Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.

Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.

Multidistrict Litigation. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407. When this box is checked, do not check (5) above.

Appeal to District Judge from Magistrate Judgment. (7) Check this box for an appeal from a magistrate judge's decision.

**VI. Cause of Action.** Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity.**

Example: U.S. Civil Statute: 47 USC 553

Brief Description: Unauthorized reception of cable service

**VII. Requested in Complaint.** Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.

Demand. In this space enter the dollar amount (in thousands of dollars) being demanded or indicate other demand such as a preliminary injunction.

Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.

**VIII. Related Cases.** This section of the JS 44 is used to reference related pending cases if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.

**Date and Attorney Signature.** Date and sign the civil cover sheet.