IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF LOUISIANA

ROCKY THOMPSON Plaintiff, vs. DEPUY SYNTHES SALES, INC. d/b/a/ DEPUY SYNTHES JOINT RECONSTRUCTION; DEPUY ORTHOPAEDICS, INC.; DEPUY INTERNATIONAL LIMITED; JOHNSON & JOHNSON; JOHNSON & JOHNSON SERVICES, INC.; JOHNSON & JOHNSON INTERNATIONAL; MEDICAL DEVICE BUSINESS SERVICES, INC.; DEPUY, INC.; DEPUY SYNTHES PRODUCTS, INC.; DEPUY SYNTHES, INC.; DEPUY IRELAND UNLIMITED COMPANY; DEPUY SYNTHES JOHNSON & JOHNSON IRELAND LTD. Defendants.	Case No_____. **COMPLAINT AND DEMAND FOR JURY TRIAL**

COMPLAINT AND DEMAND FOR JURY TRIAL

COMES NOW Plaintiff, ROCKY THOMPSON, by and through the undersigned counsel, and brings this Complaint against Defendants, Medical Device Business Services, Inc.; DePuy Orthopaedics, Inc.; DePuy, Inc.; DePuy Synthes Products, Inc.; DePuy Synthes, Inc.; Depuy Synthes Sales, Inc. d/b/a DePuy Synthes Joint Reconstruction; DePuy International, Ltd.; DePuy Ireland Unlimited Company; DePuy Synthes Johnson & Johnson Ireland Ltd.; Johnson & Johnson International; Johnson & Johnson; and Johnson & Johnson Services, Inc. (collectively "Defendants") and alleges as follows:

NATURE OF THE ACTION

1. This is an action for damages relating to Defendants' development, designing, testing, assembling, manufacturing, packaging, monitoring, labeling, preparing, distribution, marketing, supplying, and/or selling of the Attune® Knee System (hereinafter "ATTUNE" or "ATTUNE Device(s)").

2. Thousands of patients, like Plaintiff Rocky Thompson, have been, and/or will be, required to undergo extensive revision surgery to remove and replace defective ATTUNE Devices. These revision surgeries have been necessitated, in part, by severe pain, swelling, and instability in the knee and leg caused by loosening of ATTUNE's tibial baseplate component that results from debonding at the baseplate-cement interface. Patients implanted with ATTUNE Devices have also experienced fractures, infection, soft tissue injury and permanent damage to bones and nerves following revision surgery.

3. Recipients of the ATTUNE Devices have been required to undergo revision surgeries well before the estimated life expectancy of the ATTUNE Devices and at a much higher rate than should reasonably be expected for devices of this kind.

4. Despite knowledge that the ATTUNE Devices were defective and resulted in the aforementioned failures and accompanying complications, Defendants continue to aggressively market and sell the defective ATTUNE Devices, all the while maintaining that they are safe and effective for use in total knee replacements.

THE PARTIES

5. Plaintiff Rocky Thompson is a resident of Pitkin, Louisiana. Plaintiff was implanted with a defective ATTUNE Device on January 13, 2015, which failed and resulted in a revision surgery on July 3, 2017 at Baton Rouge General Hospital.

6. Defendant DePuy Synthes Sales, Inc. d/b/a/ DePuy Synthes Joint Reconstruction ("DSS") is and, at all times relevant, was a corporation organized and existing under the laws of the State of Massachusetts, with its principal place of business located at 325 Paramount Drive, Raynham, Massachusetts 02767, and regularly conducted business in the State of Louisiana by selling and distributing its products in Louisiana. Upon information and belief, DSS is a division and/or subsidiary of DePuy Orthopaedics, Inc. ("DOI"). DSS is a wholly-owned subsidiary of Johnson & Johnson, a publicly traded company.

7. DSS designs, makes, imports, distributes, sells and/or offers for sale total knee replacement prostheses, including the ATTUNE Device. DSS was engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, numerous orthopedic products, including the ATTUNE Device, as well as monitoring and reporting adverse events related to the ATTUNE Device.

8. Defendant Medical Device Business Services, Inc. ("Device Business Services") is and, at all times relevant, was a corporation organized and existing under the laws of the State of Indiana, with its headquarters and principal place of business located at 700 Orthopaedic Drive, Warsaw, Indiana 46582, and regularly conducted business in the State of Louisiana by selling and distributing its products in Louisiana, with a registered office and principal place of business in Louisiana. Device Business Services is a wholly-owned subsidiary of Johnson & Johnson, a publicly traded company.

9. Defendant DePuy Orthopaedics, Inc. ("DOI") is and, at all times relevant, was a corporation organized and existing under the laws of the State of Indiana, with its headquarters and principal place of business located at 700 Orthopaedic Drive, Warsaw, Indiana 46582, and

regularly conducted business in the State of Louisiana by selling and distributing its products in Louisiana, with a registered office and principal place of business in Louisiana. DOI is a wholly-owned subsidiary of Johnson & Johnson, a publicly traded company.

10. At all times relevant, DOI and Device Business Services were engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, packaging, labeling and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, numerous orthopedic products, including the ATTUNE Device, as well as monitoring and reporting adverse events associated with ATTUNE. DOI and Device Business Services participated in the decision making process and response of the Defendants, if any, related to ATTUNE adverse events and/or MAUDE reports.

11. Defendant DePuy Synthes Products, Inc. ("DSP") is and, at all times relevant, was a corporation organized and existing under the laws of the State of Delaware with its principal place of business located at 325 Paramount Drive, Raynham, Massachusetts 02767, and regularly conducted business in the State of Louisiana by selling and distributing its products in Louisiana. DSP is division of DOI. DSP is a wholly-owned subsidiary of Johnson & Johnson, a publicly traded company.

12. Defendant DePuy Synthes, Inc. ("DS") is and, at all times relevant, was a corporation organized and existing under the laws of the State of Delaware with its principal place of business located at 700 Orthopaedic Drive, Warsaw, Indiana 46581, and at all relevant times was doing business in the State of Louisiana by selling and distributing its products in Louisiana.

13. DSP and DS design, manufacture, test, package, label, distribute, sell and/or offer for sale certain total knee replacement prostheses, including the ATTUNE Device.

14. Defendant DePuy, Inc. is and, at all times relevant, was a corporation organized and existing under the laws of the State of Delaware, with its headquarters and principal place of business at Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801. At all relevant times, DePuy, Inc. conducted regular and sustained business in Louisiana by selling and distributing its products in Louisiana.

15. As DOI's parent company, DePuy, Inc. was, at all relevant times, involved in the business of designing, licensing, manufacturing, distributing, selling, marketing, and introducing into interstate commerce, either directly or indirectly through third parties or related entities, numerous orthopedic products, including the ATTUNE Device, as well as monitoring and reporting adverse events associated with ATTUNE. Upon information and belief, DePuy, Inc. participated in reviewing, investigating and/or responding to FDA adverse events and/or MAUDE reports related to the ATTUNE Device, and in the decision of whether to submit reports of ATTUNE failures to the FDA.

16. Defendant DePuy International, Ltd. ("DIL") is a public entity or corporation organized and existing under the laws of the United Kingdom, with its principal place of business at St. Anthony's Road, Beeston, Leeds, West Yorkshire, LS11 8DT, United Kingdom, and at all times relevant was doing business within the United States. At all relevant times, DePuy, International, Ltd. conducted regular and sustained business in Louisiana by selling and distributing its products in Louisiana.

17. DIL makes, deigns, imports, distributes, labels, sells and/or offers for sale certain total knee replacement prostheses, including the ATTUNE Device.

18. DePuy Ireland Unlimited Company ("DePuy Ireland") is a company and a citizen of Ireland with its principal place of business located at Loughbeg Industrial Estate, Loughbeg

Ringaskiddy, County Cork, Ireland, and at all relevant times was doing business within the United States. At all relevant times, DePuy Ireland Unlimited Company conducted regular and sustained business in Louisiana by selling and distributing its products in Louisiana.

19. At all times relevant, DePuy Ireland was involved in the business of designing, manufacturing, distributing, selling, marketing, and introducing into interstate commerce, either directly or indirectly, through third parties or related entities, numerous orthopedic products, including the ATTUNE Device, as well as monitoring and reporting adverse events associated with ATTUNE. DePuy Ireland had a role in the decision-making process and response of the Defendants, if any, related to the handling of adverse events and MAUDE reports concerning ATTUNE Device failures.

20. DePuy Synthes Johnson & Johnson Ireland Ltd. ("Synthes Ireland") is an entity doing business and organized in Ireland with its principal place of business located at Unit 2, Block 10, Blanchardstown Corporate Park, Dublin 15, Ireland, and at all relevant times was doing business within the United States. At all relevant times, DePuy Synthes Johnson & Johnson Ireland Ltd. conducted regular and sustained business in Louisiana by selling and distributing its products in Louisiana.

21. At all times relevant, Synthes Ireland was involved in the business of designing, manufacturing, distributing, selling, marketing, and introducing into interstate commerce, either directly or indirectly, through third parties or related entities, numerous orthopedic products, including the ATTUNE Device, as well as monitoring and reporting adverse events associated with ATTUNE. Synthes Ireland had a role in the decision-making process and response of the Defendants, if any, related to the handling of adverse events and/or MAUDE reports concerning ATTUNE Device failures.

22. Defendants DSS, DOI, DIL, DSP, DS, DePuy, Inc., Device Business Services, DePuy Ireland and Synthes Ireland are collectively referred to as "DePuy" and the "DePuy Synthes Companies." The DePuy Synthes Companies are part of the Johnson & Johnson Family of Companies. The DePuy Synthes Companies are a group of functionally-integrated companies with shared management, administrative and general functions, including human resources, legal, quality control, customer service, sales administration, logistics, information technology, compliance, regulatory, finance and accounting and are considered a single business enterprise.

23. Defendant Johnson & Johnson International is and, at all times relevant, was a corporation organized and existing under the laws of the State of New Jersey with its principal place of business at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933, and regularly conducted business in the State of Louisiana by selling and distributing its products in Louisiana.

24. As one of DePuy's parent companies, Johnson & Johnson International is and, at all relevant times, was involved in the business of designing, licensing, manufacturing, distributing, selling, marketing, and introducing into interstate commerce, either directly or indirectly through third parties or related entities, numerous orthopedic products, including the ATTUNE Device, as well as monitoring and reporting adverse events associated with ATTUNE. Johnson & Johnson International participated in the decision-making process and response, if any, related to adverse events and/or MAUDE reports concerning the ATTUNE Device.

25. At all times material hereto, Defendant Johnson & Johnson ("J&J") is and was a public entity or corporation organized and existing under the laws of the State of New Jersey, with a principal place of business at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933, and at all relevant times was doing business in the State of Louisiana by selling and

distributing its products in Louisiana,

26. As DePuy's most senior parent company, Johnson & Johnson is and, at all relevant times, was involved in the business of designing, licensing, manufacturing, distributing, selling, marketing, and introducing into interstate commerce, either directly or indirectly through third parties or related entities, numerous orthopedic products, including the ATTUNE Device, as well as monitoring and reporting adverse events associated with ATTUNE. Johnson & Johnson participated in the decision-making process and response, if any, related to adverse events and/or MAUDE reports related to ATTUNE Device failures.

27. At all times material hereto, Defendant Johnson & Johnson Services ("J&J Services") was a public entity or corporation organized and existing under the laws of the State of New Jersey, with a principal place of business at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933, and at all relevant times was doing business in the State of Louisiana by selling and distributing its products in Louisiana.

28. J&J Services is and, at all relevant times, was involved in the business of designing, licensing, manufacturing, distributing, selling, marketing, and introducing into interstate commerce, either directly or indirectly through third parties or related entities, numerous orthopedic products, including the ATTUNE Device, as well as monitoring and reporting adverse events associated with ATTUNE. J&J Services participated in the decision-making process and response, if any, related to adverse events and/or MAUDE reports related to ATTUNE Device failures.

29. Plaintiff has suffered personal injuries as a direct and proximate result of DePuy Synthes Sales, Inc. d/b/a/ DePuy Synthes Joint Reconstruction; Medical Device Business Services, Inc.; DePuy Orthopaedics, Inc.; DePuy Synthes Products, Inc.; DePuy Synthes, Inc.;

DePuy, Inc.; DePuy International, Ltd.; DePuy Ireland Unlimited Company; DePuy Synthes Johnson & Johnson Ireland Ltd.; Johnson & Johnson International; Johnson & Johnson; and Johnson & Johnson Services Inc. (collectively "Defendants") conduct and misconduct, as described herein, in connection with the design, development, manufacturing, testing, packaging, advertising, marketing, distributing, labeling, warning and sale of the ATTUNE Device.

30. Defendant Johnson & Johnson is the parent company of Defendants DePuy International Limited, DePuy Ireland Unlimited Company and DePuy Synthes Johnson & Johnson Ireland Ltd.

31. Defendant Johnson & Johnson is the alter ego of wholly owned subsidiaries Defendants, DePuy International Limited; DePuy Ireland Unlimited Company and DePuy Synthes Johnson & Johnson Ireland Ltd ("subsidiary Defendants"). Defendant Johnson & Johnson has used these named subsidiary Defendants as its agents; and/or Defendant Johnson & Johnson and the named subsidiary Defendants are one single integrated enterprise.

32. Defendants DePuy Ireland Unlimited Company and DePuy Synthes Johnson & Johnson Ireland Ltd. (hereinafter referred to as the "Ireland Defendants"), in addition to designing and manufacturing the ATTUNE Devices, were identified by the FDA as the manufacturer of failed ATTUNE Devices reported through the FDA's MAUDE system. Upon information and belief, the Ireland Defendants reported, and made decisions about whether or not to report failures of the ATTUNE Devices, which occurred within the United States, to the FDA.

33. Defendants DePuy International Limited; DePuy Ireland Unlimited Company and DePuy Synthes Johnson & Johnson Ireland Ltd. produced and disseminated misleading marketing publications throughout the United States, including Louisiana, touting the safety and

efficacy of the ATTUNE Device to consumers, hospitals and surgeons, including, but not limited to, the following marketing publications:

a. *The Attune Knee System Value Analysis Brief.* http://synthes.vo.llnwd.net/o16/LLNWMB8/US%20Mobile/Synthes%20North%20America/Product%20Support%20Materials/Product%20Information%20Sheets/DSUSJRC05140188(1)%20Attune%20Value%20Brief.pdf;

b. A pamphlet titled "A Knee That Can Help You Get Back Sooner." http://synthes.vo.llnwd.net/o16/LLNWMB8/US%20Mobile/Synthes%20North%20America/Product%20Support%20Materials/Brochures/DSUS-JRC-0614-0294_Attune_Brochure_singles.pdf

c. An article titled *Confidence in the ATTUNE Knee is Driven by Real World Scientific Responses to Inaccuracies and Limitations in Bonutti, et al. Article,* in which Defendants attempt to discredit the Bonutti paper which concluded that high rates of ATTUNE Device failures were occurring due to debonding at the tibial baseplate-cement interface. http://synthes.vo.llnwd.net/o16/LLNWMB8/US%20Mobile/Synthes%20North%20America/Product%20Support%20Materials/Journal%20Articles/CERT%20Attune%20WP%20Response%20to%20Bonutti.pdf;

d. An "Attune Knee System Ordering Information" guide which catalogs component parts of the ATTUNE Device, which was designed for use and was used in the United States.http://synthes.vo.llnwd.net/o16/LLNWMB8/US%20Mobile/Synthes%20North%20America/Product%20Support%20Materials/Brochures/DSUSJRC11140570(2)%20ATTUNE%20Ordering%20Info.pdf.

34. Defendants DePuy International Limited; DePuy Ireland Unlimited Company and DePuy Synthes Johnson & Johnson Ireland Ltd. engaged in substantial business within the

United States related to the ATTUNE Device, availed themselves of the benefits of conducting business in the United States and derived benefits from that business within the United States.

35. At all times relevant, each of the Defendants was the representative, agent, employee, co-conspirator, servant, employee, partner, joint-venturer, franchisee, or alter ego of the other Defendants and was acting within the scope of such authority in such conspiracy, service, agency, employment, partnership, joint venture and/or franchise.

JURISDICTION AND VENUE

36. This Court has jurisdiction over this matter pursuant to 28 U.S.C. § 1332 in that the amount in controversy exceeds $75,000.00, exclusive of interest and costs, and this is an action by an individual Plaintiff against Defendants who are citizens of different states.

37. Venue in the Middle District of Louisiana is proper pursuant to 28 U.S.C. § 1391(a) because a substantial part of the events giving rise to Plaintiff's claims occurred in the Middle District of Louisiana, including the identification of the cause of the failure of the ATTUNE Device implanted in Plaintiff and the revision surgery to remove and replace the failed ATTUNE Device and resulting injury. Upon information and belief, Defendants regularly conducted business in the Middle District of Louisiana. Defendants' commercial activities in the Middle District of Louisiana include, but are not limited to, the advertising, promotion, marketing and sale of ATTUNE Devices.

BACKGROUND AND FACTUAL ALLEGATIONS

38. The knee is the largest joint in the human body, consisting of three individual bones: the shin bone (tibia), the thigh bone (femur), and the knee-cap (patella). The knee joint is lined with cartilage to protect the bones from rubbing against each other. This ensures that the joint surfaces can glide easily over one another. The human knee is a complicated joint which

supports the entire body weight on four small surfaces through a variety of motions essential to everyday life. It is also the joint most susceptible to arthritis.

39. With the increases in lifespan, people have begun to suffer pain and disability from knee joint arthritis at significant rates. Knee replacement technology can provide a solution to the pain and restore basic function to those implanted. The knee replacement implants designed and approved in the 1990s met the goals of reducing pain and restoring function with low failure rates.

40. Total knee arthroplasty ("TKA"), also called total knee replacement ("TKR"), is a commonly performed orthopedic procedure. The surgery is designed to help relieve pain, to improve joint function, and to replace bones, cartilage and/or tissue that have been severely injured and/or worn down generally in people with severe knee degeneration due to arthritis, other disease or trauma. A TKA is ordinarily a successful orthopedic procedure with excellent clinical outcomes and survivorship.

41. In a total knee replacement surgery, sometimes referred to as "arthroplasty," physicians replace the joint surfaces and damaged bone and cartilage with artificial materials. The replacement redistributes weight and removes the tissue and/or bone causing inflammation, and thus reduces pain while improving the joint's function. Replacement requires a mechanical connection between the bones and the implant components.

HISTORY OF DEPUY KNEES AND THE ATTUNE KNEE DEVICE

42. DePuy Orthopaedics, Inc. was founded in 1895 and is purported to be a worldwide leader in the design and manufacture of orthopedic devices and supplies, including hip, knee extremity, cement and other products used in orthopedic procedures.

43. According to DePuy, the ATTUNE Device "builds on the LCS Complete Knee

System and the SIGMA Rotating Platform Knee," both of which are also DePuy products.

44. In 1977, DePuy Orthopaedics, Inc. introduced the LCS Complete Knee System which, at that time, included three options: a bicruciate-retaining option, a posterior cruciate-retaining option, and a cruciate sacrificing option (the rotating-platform design).

45. DePuy introduced the P.F.C. Total Knee System in 1984. According to DePuy, clinical studies have proven the success of the P.F.C. design, with 92.6% survivorship at 15 years.

46. Based on this clinical success, according to DePuy, the company introduced the DePuy Synthes P.F.C. SIGMA System ("SIGMA") in 1996.

47. The SIGMA was one of the most widely used TKAs worldwide, and DePuy quickly became one of the largest manufacturers of knee replacement devices in the United States. According to DePuy, the SIGMA Fixed Bearing Knee System has demonstrated excellent survivorship with 99.6% at 7 years.

48. Notwithstanding DePuy's alleged success with the SIGMA, as reported by DePuy, the company began to tinker with the SIGMA design in an effort to replicate the total flexion of the natural knee and maintain a competitive position in the market. This new project—one that DePuy boasted as their largest research and development project ever, carrying a price tag of approximately $200 million--resulted in the ATTUNE Device.

A. 510(k) approval of the DePuy Attune ™ Knee System and Regulatory History

49. According to DePuy, the new ATTUNE project was an attempt to improve functional outcomes, provide more stability and simplify implantation of the contemporary total knee system.

50. The resulting ATTUNE total knee system purported to feature a gradually reducing

femoral radius, an innovative s-curve design of the posteriorly stabilized cam, a tibial base which can be downsized or upsized two sizes versus the insert, novel patella tracking, lighter innovative instruments, and a new polyethylene formulation, according to DePuy. DePuy sought FDA clearance for the new ATTUNE Device through the "510(k)" process.

51. Section 510(k) of the Food, Drug and Cosmetic Act provides a mechanism for device manufacturers to obtain accelerated FDA clearance for products that are shown to be "substantially equivalent" to a product that has previously received FDA approval. The process requires device manufacturers to notify FDA of their intent to market a medical device at least 90 days in advance of introduction to the market. This is known as Premarket Notification – also called PMN or 510(k). This approval process allows the FDA to determine whether the device is substantially equivalent to a device already approved for marketing.

52. By 2010, DePuy was ready to take the ATTUNE to market. In December 2010, DePuy Orthopaedics, Inc. received FDA clearance of the DePuy Attune™ Knee System under the "510k" notification process. The basis for FDA clearance was substantial similarity to several prior devices, including, but not limited to, the P.F.C. SIGMA Knee System. Consequently, Defendants received FDA approval with only very limited, if any, testing of the new ATTUNE Device.

53. The ATTUNE Device includes the Attune Tibial Base (510K Number K101433) ("ATTUNE tibial baseplate"), also called tibial tray, which, as compared to the SIGMA, included a design change to the keel, the surface texture and/or finish of the tibial baseplate and "combined with new technology to treat the underside of the implant," among other changes.

54. The FDA cleared the following specific medical device components as part of the DePuy Attune™ Knee Total System:

A. The Attune™ Cruciate Retaining (CR) Femoral Component;

B. The Attune™ Fixed Bearing (FB) Tibial Inserts;

C. The Attune™ Tibial Base, which is available in 10 sizes; and

D. The Attune™ Patellae.

55. In August 2011, DePuy Orthopaedics, Inc. received 510K clearance for the DePuy Attune Posterior Stabilized (PS) Femoral Components and PS Fixed Bearing inserts, which were additions to the existing DePuy Attune™ Knee System. These components are compatible with the ATTUNE fixed tibial bases. This product was referred to as the DePuy Attune™ PS Knee System.

56. The claims in this Complaint focus only on the ATTUNE Device as defined herein, which includes the DePuy Attune™ Knee System (including its component parts) and the DePuy Attune™ PS Knee System (including its component parts) (collectively referred to as "ATTUNE" and "ATTUNE Device" herein). The design and composition of the ATTUNE Device, especially the tibial baseplate, is defective and failed resulting in harm to Plaintiff Rocky Thompson.

B. Launch of the DePuy Attune Knee System- ATTUNE Device

57. In March of 2013, DePuy and the J&J defendants introduced its ATTUNE Device, including procedures for implantation, to surgeons and consumers. On March 20, 2013, DePuy issued a press release widely introducing its "latest innovation in total knee replacement—the ATTUNE™ Knee System—at the 2013 American Academy of Orthopedic Surgeons (AAOS) annual meeting in Chicago."

58. According to the press release, the ATTUNE Device was "designed to provide better range of motion and address the unstable feeling some patients experience during

everyday activities, such as stair descent and bending." According to DePuy, its "proprietary technologies include: . . . SOFCAM™ Contact: An S-curve design that provides a smooth engagement for stability through flexion, while reducing stresses placed on the implant."

59. DePuy's launch strategy began with branding multiple "new" technologies and touting the project as one of the largest research and development projects in the history of the DePuy Synthes Companies, costing approximately $200 million. DePuy claimed the following features of the ATTUNE Device:

- "Is the largest clinical program at DePuy,"
- "Improves value of TKA,"
- "Compares favorably in joint registries," and
- "Significantly less symptomatic crepitus, primarily Sigma PS."

60. The most notable improvement Defendants purported to make between the SIGMA and ATTUNE is the patented S-curve design of the femoral component. This feature, according to Defendants, conferred greater mid flexion stability as the implanted knee moves from extension to flexion because of the more gradual change in the femoral component radius of curvature. This design feature was also proposed to offer greater functional benefits and a greater range of movement as compared to other implants.

61. However, in reality, the ATTUNE Device did not deliver on these promises, resulting in significantly higher failure rates than previous DePuy knee counterparts due to the debonding of the tibial baseplate. As a result, thousands of knee replacement patients implanted with ATTUNE Devices have had more expensive, more dangerous and less effective Total Knee Replacement surgeries, and many have required or will require expensive and dangerous knee revision surgery to remove and replace the defective ATTUNE Device.

62. Since the initial launch, Defendants have continued to expand the ATTUNE product line based on claims it would provide patients who were "expecting to maintain an active lifestyle" a more life-like knee. Defendants have aggressively marketed the ATTUNE Device and became the dominant player in the knee market, upon information and belief, selling approximately 400,000 ATTUNE Devices worldwide.

FAILURES OF THE ATTUNE DEVICE

63. The primary reason the ATTUNE Device fails is mechanical loosening. The mechanical loosening is caused by a failure of the bond between the tibial baseplate at the implant-cement interface. Mechanical loosening means that the attachment between the artificial knee and the existing bone has become loose. Such loosening will eventually result in failure of the device. Mechanical loosening has occurred at an unprecedented rate in patients implanted with an ATTUNE Device.

64. In many instances, loosening of an artificial knee can be visualized and diagnosed using radiographic imaging. The loosening can be evident from one or more radiolucent lines around the contours of the artificial knee component where the loosening is occurring.

65. A loose artificial knee generally causes pain and wearing away of the bone. It can severely restrict a patient's daily activities as it can involve a severe physical and emotional burden for the patient.

66. Once the pain becomes unbearable or the individual loses function of the knee, another operation, often times called a "revision surgery," may be required to remove the knee implant and replace it with a new one.

67. Unfortunately, a failed total knee prosthesis often causes severe bone loss.

Therefore, revision surgeries on a failed total knee due to loosening often require reconstruction of the severe bone loss.

68. The success rate of a revision surgery is much lower than that of the initial total knee replacement and the risks and complications are higher, including limitations in range of motion, the ability to walk, and even death.

69. Beginning in 2013 and 2014, Defendants became aware of safety issues with the ATTUNE Device. These concerns were evidenced through failure reports submitted to and kept in the FDA's Manufacturer and User Facility Device Experience (MAUDE), which houses medical device reports submitted to the FDA by reporters such as manufacturers, importers and device user facilities. Most related reports concern failures caused by ATTUNE Device design elements which caused loosening and/or debonding at the tibial baseplate cement/implant interface. These MAUDE reports detail an extremely high incidence of aseptic loosening at the tibial baseplate of the ATTUNE Device resulting in subsequent revision surgeries.

70. Upon information and belief, the FDA MAUDE database, as of June 2017, includes approximately 1,400 reports of failures. Approximately 633 of these reports resulted in revision surgeries. By comparison, for the Persona knee replacement system, manufactured by Zimmer, approximately 384,000 devices have been implanted, and the MAUDE database has a collection of only 183 reports of device failures with 64 of these resulting in revision surgeries.

71. On March 15, 2017, DePuy Synthes, at the American Academy of Orthopaedic Surgeons ("AAOS") Annual Meeting in San Diego, California, announced the launch of the first ATTUNE Knee revision system, which included the ATTUNE Revision Fixed Bearing Tibial Base and a 14 x 50 mm Cemented Stem.

72. Ostensibly, noticing the alarming rate of failure and subsequent revisions related

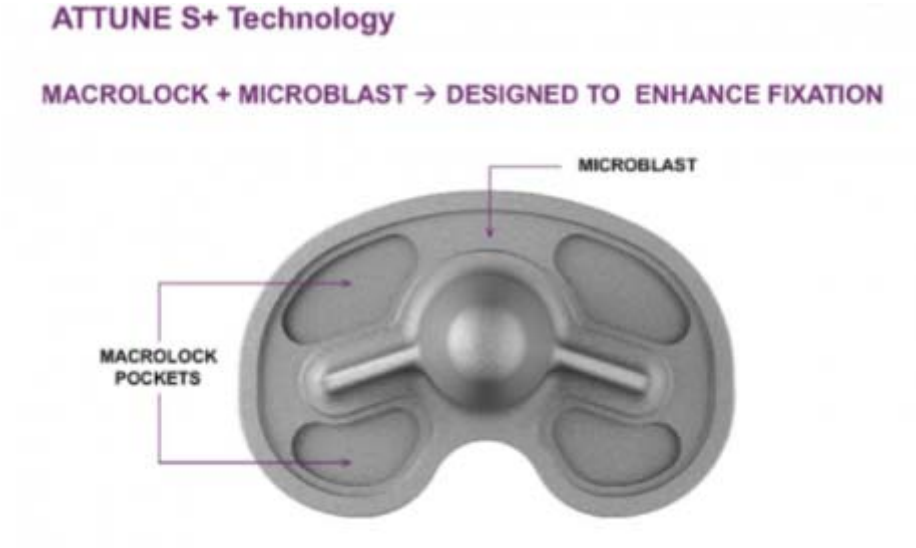
to the ATTUNE Device, on March 10, 2016, DePuy Orthopaedics, Inc. submitted a Section 510(k) premarket notice of intent to market the "ATTUNE® Revision Knee System," which included a new stem, with added length and a keel for additional stability and recessed cement pockets intended to promote cement fixation. The stem of the ATTUNE® Revision Knee System was designed with a cylindrical or tapered body geometry with a blasted and fluted fixation surface.

73. Without notifying consumers, doctors or patients, including Plaintiff and his physicians, Defendants recently attempted to replace the original ATTUNE Fixed Base tibial baseplate with a new tibial baseplate, also called a tibial tray, which received FDA 510(k) clearance on June 15, 2017. This strategic decision to design and launch a newly designed tibial baseplate is an admission, or at the very least strong evidence, that the original ATTUNE Tibial Tray (baseplate) is defective and prone to failure. However, Defendants have not recalled the defective tibial baseplate or informed consumers and surgeons about the dangers of its use.

74. Defendants requested FDA approval of the new tibial baseplate by application dated March 17, 2017 which was "prepared" by Defendants on March 16, 2016. The application requested clearance of a new tibial baseplate component as part of the Attune™ Knee Total System, which, upon information and belief, has been called the "Attune S+ Technology" ("ATTUNE S+") by Defendants. In particular, the application identified the design changes that were implemented with the ATTUNE S+, including a newly designed "keel to provide additional stability," "recessed undercut cement pockets," and a "grit blasted surface for enhanced cement fixation" or microblast finish.

75. The "Summary of Technologies" portion of the 510(k) application for the ATTUNE S+ tibial baseplate includes the following:

> The ATTUNE Cemented Tibial Base, FB provides a macro geometric feature and an optimized micro-blast finish which are both intended to aid in fixation of the tibial implant to the bone cement. The ATTUNE Cemented Tibial Base, FB is designed to enhance fixation by improving resistance (relative to the industry) to intra-operative factors which can result in a reduction in cement to implant bond.



76. Additionally, according to DePuy, the ATTUNE S+ tibial baseplate also features macro geometry and 45 degree undercut pockets designed to provide a macro-lock between the cement-implant interface. According to DePuy, the "ATTUNE S+ Technology finishing process increases the surface roughness compared with other, DePuy Synthes clinically proven, tibial tray designs that were tested." *See* Depuy Synthes Powerpoint, "ATTUNE S+ Technology."

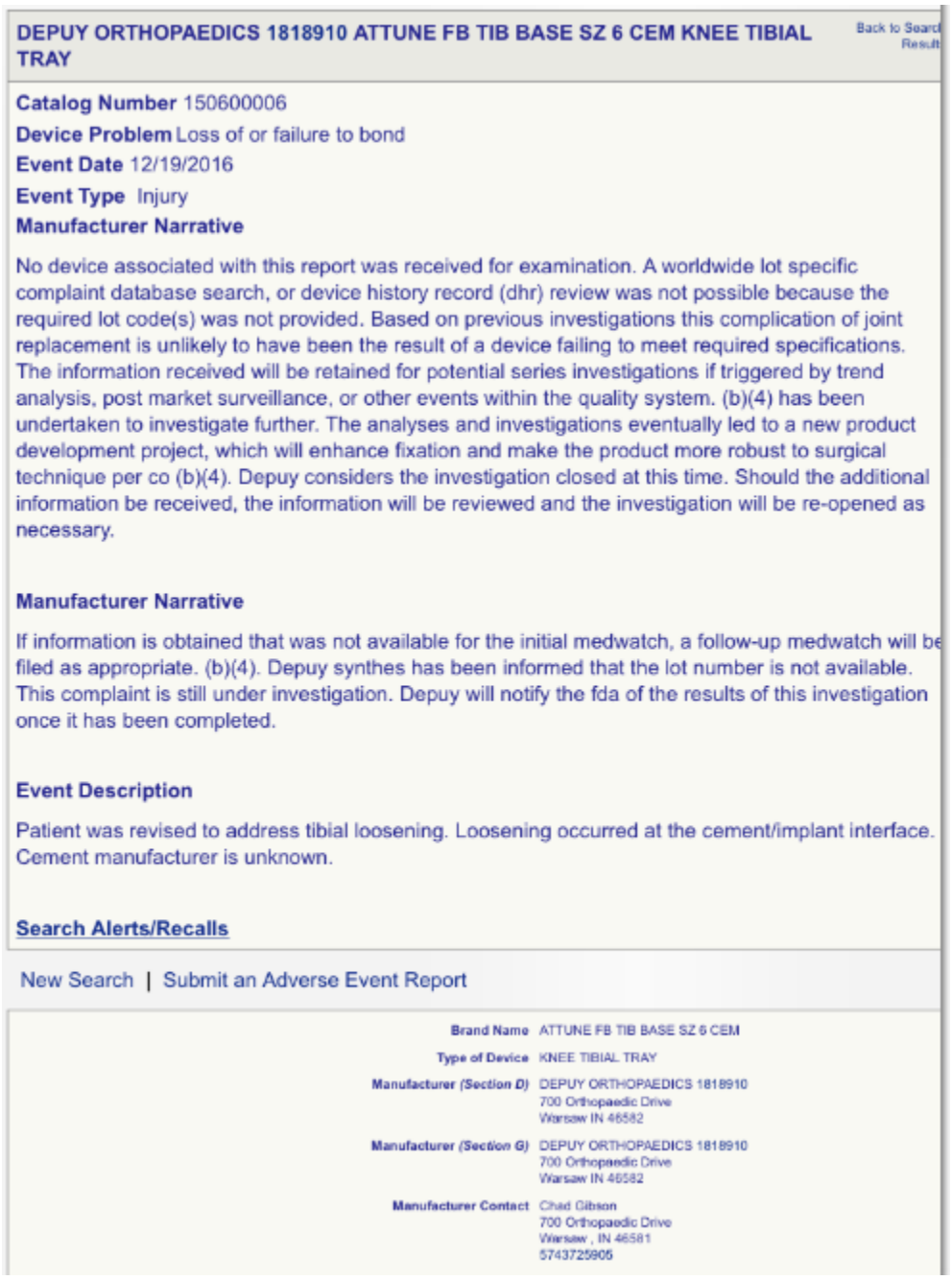
77. Defendants knew about the design defects and resulting failures with the original ATTUNE tibial baseplate long before the newly designed tibial baseplate (ATTUNE S+) was cleared in June of 2017, yet they failed to share this information with orthopedic surgeons using the Attune devices. In fact, the application for approval for the ATTUNE S+ was submitted by DePuy to the FDA on March 16, 2016, and many surgeons are still in the dark about the new and improved Attune design.

78. By March 16, 2016 or before, Defendants had apparently recognized the existence of high failure rates of the original ATTUNE tibial baseplate, identified the defects and/or mechanisms of failure associated with it, researched and designed the new tibial tray/baseplate (Attune S+), conducted testing of this new tibial baseplate, as detailed in the application, and submitted the application to the FDA.

79. Although Defendants obviously knew about the high number of ATTUNE failures resulting in revision surgeries, it failed to warn surgeons, consumers and patients, and allowed the original, defective design to continue to be implanted by unsuspecting surgeons into unsuspecting patients., including Plaintiff and Plaintiff's physicians.

80. In fact, beginning in December 2016, DePuy began openly admitting, in its responses in the MAUDE failure reports, that the ATTUNE Devices were failing. Although DePuy decided to make a change, it did not inform the surgeons, consumers and/or patients. In responding to the MAUDE reports involving failures of ATTUNE tibial baseplates, DePuy frequently provided the following "Manufacturer Narrative":

> The information received will be retained for potential series investigations if triggered by trend analysis, post market surveillance or other events within the quality system. (b)(4) has been undertaken to investigate further. ***The analysis and investigations eventually led to a new product development project, which will enhance fixation and make the product more robust to surgical technique per co (b)(4).*** Depuy considers the investigation closed at this time. Should the additional information be received, the information will be reviewed and the investigation will be re-opened as necessary.



DEPUY ORTHOPAEDICS 1818910 ATTUNE FB TIB BASE SZ 6 CEM KNEE TIBIAL TRAY

Back to Search Result

Catalog Number 150600006
Device Problem Loss of or failure to bond
Event Date 12/19/2016
Event Type Injury
Manufacturer Narrative

No device associated with this report was received for examination. A worldwide lot specific complaint database search, or device history record (dhr) review was not possible because the required lot code(s) was not provided. Based on previous investigations this complication of joint replacement is unlikely to have been the result of a device failing to meet required specifications. The information received will be retained for potential series investigations if triggered by trend analysis, post market surveillance, or other events within the quality system. (b)(4) has been undertaken to investigate further. The analyses and investigations eventually led to a new product development project, which will enhance fixation and make the product more robust to surgical technique per co (b)(4). Depuy considers the investigation closed at this time. Should the additional information be received, the information will be reviewed and the investigation will be re-opened as necessary.

Manufacturer Narrative

If information is obtained that was not available for the initial medwatch, a follow-up medwatch will be filed as appropriate. (b)(4). Depuy synthes has been informed that the lot number is not available. This complaint is still under investigation. Depuy will notify the fda of the results of this investigation once it has been completed.

Event Description

Patient was revised to address tibial loosening. Loosening occurred at the cement/implant interface. Cement manufacturer is unknown.

Search Alerts/Recalls

New Search | Submit an Adverse Event Report

Brand Name	ATTUNE FB TIB BASE SZ 6 CEM
Type of Device	KNEE TIBIAL TRAY
Manufacturer (Section D)	DEPUY ORTHOPAEDICS 1818910 700 Orthopaedic Drive Warsaw IN 46582
Manufacturer (Section G)	DEPUY ORTHOPAEDICS 1818910 700 Orthopaedic Drive Warsaw IN 46582
Manufacturer Contact	Chad Gibson 700 Orthopaedic Drive Warsaw , IN 46581 5743725905

81. In January of 2017, the *Journal of Arthroplasty* published a study, led by Dr. Raymond H. Kim and other surgeons at Colorado Joint Replacement, Department of Orthopedic Surgery, and OrthoCarolina, Department of Orthopaedic Surgery entitled, Tibial Tray Thickness Significantly Increases Medial Tibial Bone Resorption in Cobalt-Chromium Total Knee

Arthroplasty Implants. The study reported that the thicker cobalt-chromium baseplate of the ATTUNE Device was associated with significantly more tibial bone loss.

82. During the AAOS Annual Meeting in March 2017, Dr. Todd Kelley, Assistant Professor of Orthopaedic Surgery at the University of Cincinnati College of Medicine, presented a poster entitled High Incidence of Stress Shielding and Radiolucent Lines with a Novel Total Knee System, which involved a study of the ATTUNE Device.

83. Prior to the study, the evaluators acknowledged that a relationship between stress shielding and bone resorption leading to aseptic loosening and implant failure existed. Consequently, the purpose of the study was to determine the incidence of radiographic stress shielding and radiolucent lines in the tibia and femur during the early postoperative period following the implant of an ATTUNE Device.

84. As part of this study, 164 patients underwent a total knee replacement with the ATTUNE Device between February 2013 and February 2015. The mean length of the postoperative radiographic follow up was eight months. For all evaluators in the study, stress shielding was most frequently identified at the same three zones, with the highest incidence at "tibial AP zone 1," which was the medial baseplate. The incidence rate at this zone was 39.0%-48.5%.

85. The findings also demonstrated that the mean incidence rate of stress shielding at the tibial AP zone 1 among all evaluators was 43.1% and the mean incidence rate of radiolucent lines observed at this zone was 12.0%. These rates far exceed the rate expected in the post-surgery period.

86. In 2017, the alarming rate of failure associated with the ATTUNE Device due to debonding of the tibial baseplate was discussed in a paper written by Dr. Peter M. Bonutti and

colleagues, entitled Unusually High Rate of Early Failure of Tibial Component in ATTUNE Total Knee Arthoplasty System at Implant-Cement Interface. The article presented compelling evidence that the design and/or composition of the ATTUNE Device, and particularly the tibial baseplate component, contribute greatly to debonding at the interface between the cement and the tibial baseplate, resulting in high rates of failure and revision surgery.

87. The authors' intraoperative findings identified freely mobile tibial baseplates with loosening occurring at the implant-cement interface. In all tibial baseplate failures in the study, the tibial component had debonded and was easily separated from the cement mantle, while all the cement was strongly adherent to the tibial bone. On the femoral side, however, the cement was strongly adherent to the implant surface in all cases. The mean time to revision for those ATTUNE Devices involved in the study was 19 months.

88. The authors of the Bonutti study concluded that high rates of ATTUNE failures due to debonding at the tibial-cement interface could be caused by a combination of factors, including the increased constraint of the ATTUNE's tibial polyethylene component; rounded edges and reduced cement pockets necessary for cement interdigitation in the tibia, as compared to the DePuy SIGMA; reduced keel rotational flanges and/or stabilizers on the keel; and insufficient surface roughness of the tibial baseplate component.

89. Despite Defendants' claim that the ATTUNE Device would be easier to implant, after being notified of premature tibial baseplate failures, Defendants began blaming implanting surgeons and their surgical technique for the failures of the ATTUNE tibial baseplates rather than the ATTUNE's defects, which Defendants knew existed long ago.

DEPUY'S MARKETING OF ATTUNE DEVICES

90. According to Defendants, the ATTUNE Device produces better stability of the

knee in deep flexion, reduces the joint forces, and produces better patella tracking, operative flexibility and efficiency, and implant longevity. Defendants aggressively marketed the ATTUNE based on these assertions. Despite these claims, large numbers of revision cases appeared in a short period resulting from the defects in the ATTUNE tibial baseplate.

91. Patients were promised they could recover faster, and engage in more active lifestyles. Contrary to Defendants' representations, however, the ATTUNE Device is prone to failure, causing patients to experience additional pain and injury.

92. Defendants designed, manufactured, tested, labeled, packaged, distributed, supplied, marketed, advertised, and/or otherwise engaged in all activities that are part of the sale and distribution of medical devices, and by these activities, caused ATTUNE Devices to be placed into the stream of commerce throughout the United States and within Louisiana.

93. Defendants actively and aggressively marketed to doctors and the public that the ATTUNE Devices were safe and effective total knee prostheses.

94. From the time that Defendants first began selling ATTUNE Devices, the product labeling and product information for the ATTUNE Device failed to contain adequate information, instructions, and warnings concerning the increased risk that the ATTUNE Device fails at an extremely high rate.

95. Despite Defendants' knowledge of the serious injuries associated with the use of the ATTUNE Device, Defendants continue to engage in marketing and advertising programs which falsely and deceptively create the perception that the ATTUNE Device is safe.

96. Upon information and belief, Defendants downplayed the health risks associated with the ATTUNE Device through promotional literature and communications with orthopedic surgeons. Defendants deceived doctors, including Plaintiff's surgeons, and potential users of the

ATTUNE Device by relaying positive information, while concealing the nature and extent of the known adverse and serious health effects of the ATTUNE.

97. Based on the design changes made to the original ATTUNE tibial baseplate before it was put on the market, and the number of failures reported since it was launched, Defendants, through their premarketing and postmarketing analysis, knew or should have known that the ATTUNE Device was prone to fail. Plaintiff alleges that the ATTUNE Device is defective and unreasonably dangerous.

CASE SPECIFIC FACTUAL ALLEGATIONS

98. On or about January 14, 2015, Plaintiff, Rocky Thompson, underwent a left-sided total knee replacement surgery at Central Louisiana Surgical Hospital in Alexandria, Louisiana. Mr. Thompson was implanted with an ATTUNE Device, including, but not limited to a fixed tibial insert and a fixed tibial baseplate, which was designed, manufactured, marketed, distributed, labeled, marketed and sold throughout the United States by the Defendants. The ATTUNE Device was purchased by Plaintiff.

99. After the ATTUNE Device was implanted, Plaintiff began experiencing severe and persistent pain, discomfort, instability and difficulty ambulating caused by aseptic loosening of the defective tibial baseplate.

100. Radiographs revealed the presence of radiolucent lines underneath the ATTUNE tibial baseplate.

101. On July 3, 2017, Plaintiff underwent revision surgery to replace the defective ATTUNE Device implanted in his left knee with a new prosthesis due to a lack of bond and failure of the implant at the tibial baseplate-cement interface. This surgery was performed by Dr. Niels J. Linschoten at the Baton Rouge General in Baton Rouge, Louisiana.

102. Neither Plaintiff nor his physicians were aware, by warning or otherwise, of the defects in the ATTUNE Device, and would not have used the ATTUNE Device had they been aware of the defective nature of the device.

103. As a direct and proximate result of the Defendants placing the defective ATTUNE Device in the stream of commerce, Plaintiff has suffered and continues to suffer both injuries and damages, including, but not limited to: past, present and future physical and mental pain and suffering; and past, present and future medical, hospital, rehabilitative and pharmaceutical expenses, economic damages and other related damages.

FRAUDULENT CONCEALMENT

104. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows.

105. Any applicable statutes of limitations have been tolled by the knowing and active concealment and denial of the facts as alleged herein by Defendants. Plaintiff has been kept ignorant of vital information essential to the pursuit of these claims, without any fault or lack of diligence on his part.

106. Plaintiff or his physicians could not reasonably have discovered the injury and its cause before the date of the revision surgery.

107. Defendants were under a continuing duty to disclose the true character, quality and nature of the ATTUNE Device and components identified herein, to the Plaintiff as well as his physicians. Because of their concealment of the true character, quality and nature of the ATTUNE Device to Plaintiff, Defendants are estopped from relying on any statute of limitations defense.

108. As a result of Defendants' unlawful and fraudulent concealment of the effects of the ATTUNE Device, the running statute of limitations has been suspended with respect to claims that Plaintiff could bring. Plaintiff had no knowledge of Defendants' unlawful conduct, or any of the facts that might have led to the discovery of Defendants' wrongdoing, until shortly before the Complaint was filed.

LIABILITY UNDER THE LOUISIANA PRODUCTS LIABILITY ACT

109. Plaintiff repeats, reiterates, and re-alleges all paragraphs of this Complaint with the same force and effect as if fully set forth herein.

110. Under the Louisiana Products Liability Act, Plaintiff shows that the serious risk of failure of the ATTUNE Device and other related injuries are the direct and proximate result of breaches of obligations owed by Defendants to Plaintiff, including defects in design, marketing, manufacturing, distribution, instructions and warnings by Defendants, which breaches and defects are listed more particularly, but not exclusively, as follows:

a. Failure to instruct and/or warn of the serious risk of loosening of the tibial baseplate and failure of the ATTUNE Device resulting in injuries;

b. Failure to adequately instruct and/or warn healthcare providers, including those healthcare providers who implanted the ATTUNE Device in Plaintiff, of the serious risk of loosening of the tibial baseplate and failure of the ATTUNE Device resulting in injuries;

c. Manufacturing, producing, promoting, creating, and/or designing the ATTUNE Device without adequately testing it;

d. Failing to provide adequate warning of the dangers associated with the ATTUNE Device;

e. The defects in designing, researching, developing, manufacturing, marketing, promoting and selling a medical device when it knew or reasonably should have known of the high risk of loosening and failure;

f. Defendants' liability under the Louisiana Products Liability Act as a result of its design, development, manufacture, marketing, labeling and sale of a medical device which is defective and unreasonably dangerous;

g. The continued production and sale of the ATTUNE Device given the propensity of the medical device to loosen and fail at high rates resulting in subsequent surgery and injuries;

h. Providing inaccurate labeling and inadequate warnings and instructions with the ATTUNE Device;

i. Other breaches and defects which may be shown through discovery or at trial; and

j. Generally, the failure of Defendants to act with the required degree of care commensurate with the existing situation.

111. At all times relevant, Defendants had a duty to exercise reasonable care in the design, manufacture, sale and/or distribution of the ATTUNE Device into the stream of commerce, including a duty to assure that the ATTUNE Device did not pose a significantly increased risk of bodily harm to its users as well as a duty to comply with federal requirements. Defendants breached this duty.

112. Defendants owed a duty to follow the law in the manufacture, design, testing, assembly, inspection, labeling, packaging, supplying, marketing, selling, advertising, preparing for use, warning of the risks and dangers of the ATTUNE Device, and otherwise distributing the ATTUNE Devices. Defendants breached this duty.

113. Defendants owed a duty of care to provide adequate warnings and instructions to the physicians, providers, suppliers, patients, distributors, or other end users of the ATTUNE Device. Defendants breached this duty.

114. Defendants performed inadequate evaluation and testing on the ATTUNE Device where such evaluation and testing would have revealed the propensity of the ATTUNE tibial baseplate to detach, disconnect and ultimately fail causing pain, swelling, instability and other complications and injuries that Plaintiff has experienced.

115. Prior to and after the date of Plaintiff's initial knee replacement surgery in which the ATTUNE Device was implanted, the Defendants were on notice that the ATTUNE Device caused serious complications, including debonding and detachment at the tibial baseplate – cement interface.

116. Defendants had a duty to perform post-marketing testing of the ATTUNE Device; investigate the root cause of these complications; suspend sales and distribution; and warn physicians and patients of the propensity of ATTUNE'S tibial baseplate to debond, detach and fail. Defendants breached this duty.

117. Plaintiff, as a purchaser of an ATTUNE Device, is within the class of persons that the statutes, regulations and obligations previously described herein are designed to protect, and Plaintiff's injuries are the type of harm these statutes, regulations and obligations are designed to prevent.

118. Defendants knew or should have known that the Plaintiff could foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care as described above.

119. As a direct and proximate result of Defendants' breach of the Louisiana Products Liability Act, Plaintiff suffered serious physical and mental injury, harm, damages, including but

not limited to past, present and future medical expenses and economic loss and will continue to suffer such harm, damages and economic loss in the future.

CAUSES OF ACTION

FIRST CAUSE OF ACTION
STRICT PRODUCTS LIABILITY
(Design Defect under LSA-RS 9:2800.56)

120. Plaintiff adopts and incorporates by reference all the foregoing language of this Complaint as if fully set forth herein and further states as follows.

121. At all times herein mentioned, the ATTUNE Device researched, designed, manufactured, tested, advertised, promoted, marketed, packaged, labeled, sold and/or distributed by Defendants was in an unsafe, defective, and inherently dangerous condition, which was dangerous to users such as Plaintiff.

122. The ATTUNE Device was expected to and did reach the usual consumers, handlers, and persons, including Plaintiff, coming into contact with said product without substantial change in the condition in which it was produced, manufactured, sold, distributed and marketed by Defendants.

123. At all times herein, the ATTUNE Device researched, designed, manufactured, tested, advertised, promoted, marketed, sold and/or distributed by Defendants was in an unsafe, defective, and inherently dangerous condition when it left Defendants' possession and entered the stream of commerce. As designer, manufacturer, and/or seller of such medical devices, Defendants had a duty to design, manufacture, and sell devices that would not cause harm to users, including Plaintiff.

124. The ATTUNE Device's unsafe, defective, and inherently dangerous condition was a cause of the injuries to the Plaintiff.

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

126. The ATTUNE Device is defective in design because of the tibial baseplate's propensity to loosen and cause patients unnecessary pain, failure of the device and repeat surgical procedures, including revision surgery, resulting in additional bone loss and other complications.

127. Defendants were aware of the defects in design of the ATTUNE Device, in particular the ATTUNE tibial baseplate, as Defendants recently redesigned and obtained approval of the ATTUNE S+ tibial baseplate which includes features designed to correct the fixation problems caused by the original ATTUNE tibial baseplate which was implanted into Plaintiff.

128. The ATTUNE Device is defective in design because the increased risk for failure requiring revision surgery is unreasonably greater than other knee implants.

129. Plaintiff is and was a foreseeable user of the ATTUNE Device.

130. Plaintiff was not able to discover, nor could he have discovered through the exercise of reasonable care, the defective nature of the ATTUNE Device. Further, in no way could Plaintiff have known that Defendants had designed, developed and manufactured the ATTUNE Device in a way as to make the risk of harm or injury outweigh any therapeutic benefits.

131. The ATTUNE Device is and was being used in the Defendants' intended manner at the time it was surgically implanted into Plaintiff and during the time it remained in Plaintiff.

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

133. Defendants knew or should have known that the ATTUNE Device would be implanted in patients and that physicians and patients were relying on them to furnish a suitable product.

134. Defendants knew and foresaw or should have known or foreseen that patients in whom the ATTUNE Device would be implanted, such as Plaintiff, could be and should have been affected by the defective design and composition of the ATTUNE Device.

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

136. As a direct and proximate result of Defendants' placement of the defective ATTUNE Device into the stream of commerce and Plaintiff's use of the defective ATTUNE Device as designed, manufactured, sold, supplied, and introduced into the stream of commerce by Defendants, Plaintiff suffered serious physical and mental injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future including all damages available under the Louisiana Products Liability Act.

SECOND CAUSE OF ACTION
STRICT PRODUCTS LIABILITY
(Inadequate Warning Under LSA-RS 9:2800.57)

137. Plaintiff adopts and incorporates by reference all the foregoing language of this Complaint as if fully set forth herein and further states as follows.

138. At all times material hereto, the Defendants researched, tested, developed, designed, licensed, manufactured, packaged, labeled, marketed, sold to patients and/or introduced the ATTUNE Device into the stream of commerce knowing the devices would then

be implanted in patients in need of a knee prosthesis. In the course of the same, Defendants directly advertised and/or marketed the product to health care professionals and consumers, including the Plaintiff and Plaintiff's physicians, and therefore had a duty to warn of the risks associated with the use of the ATTUNE Device. Defendants breached this duty.

139. The ATTUNE Device was expected to, and did, reach the Plaintiff without substantial change or adjustment in its condition as designed, manufactured, and sold by the Defendants.

140. The ATTUNE Device as designed, developed, tested, manufactured, marketed, labeled, sold, and/or placed in the stream of commerce by Defendants was in an unreasonably dangerous and defective condition when it left the hands of the Defendants and posed a threat to any user of the device when put to its intended and reasonably anticipated use.

141. Plaintiff was and is in the class of persons that Defendants actually considered, or should have considered, to be subject to the harm caused by the defective nature of the ATTUNE Device.

142. The ATTUNE Device placed into the stream of commerce by Defendants is defective due to inadequate warning because Defendants knew or should have known that the ATTUNE Device could fail in patients therefore giving rise to physical injury, pain and suffering, debilitation, and the potential need for a revision surgery to replace the defective device with the attendant risks of complications and death from such further surgery, but failed to give consumers adequate warning of such risks.

143. The ATTUNE Device surgically implanted into Plaintiff was implanted in a manner reasonably anticipated by Defendants.

144. Defendants failed to timely and reasonably warn Plaintiff and Plaintiff's physicians of material facts regarding the safety and efficacy of the ATTUNE Device. Had they done so, proper warnings would have been heeded and no healthcare professional, including Plaintiff's physicians, would have used the ATTUNE Device, and no consumer, including Plaintiff, would have purchased and/or used the ATTUNE Device.

145. The ATTUNE Device, which was researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold and otherwise released into the stream of commerce by Defendants, was defective due to inadequate warnings and/or instructions because, after Defendants knew or should have known that there was reasonable evidence of an association between the ATTUNE Device and implant loosening causing serious injury and pain, Defendants failed to provide adequate warnings to healthcare professionals and the consumer public, including Plaintiff and Plaintiff's physician, and continued to aggressively promote the ATTUNE Device.

146. Defendants' acts and omissions constitute an adulteration, misbranding, or both, as defined by the Federal Food, Drug and Cosmetic Act, 21 U.S.C §§ 331 and 333, and constitute a breach of duty, subjecting Defendants to civil liability for all damages arising therefrom.

147. Defendants failed to provide adequate and timely warnings regarding the ATTUNE Device and its known defects, including but not limiting to the propensity for mechanical loosening caused by a failure of the bond of the tibial baseplate.

148. In addition, Defendants acquired knowledge of a characteristic of the ATTUNE Device, including loosening of the tibial baseplate, that may cause damage and the danger of such characteristic, or the Defendants would have acquired such knowledge had the Defendants

acted as a reasonably prudent manufacturer. Accordingly, Defendants are liable for the damages caused by their subsequent failure to use reasonable care to provide an adequate warning regarding such characteristics and their dangers to users and handlers of the ATTUNE Device.

149. Furthermore, Defendants failed to comply with the FDA's Medical Device Reporting regulations requiring a manufacturer of a device to report incidents in which the device may have caused or contributed to death or serious injury, or malfunctioned in such a way that would likely cause or contribute to death or serious injury if the malfunction recurred. 21 U.S.C. §360i(a)(1); 21 C.F.R. § 803.50(a).

150. As a direct and proximate result of Defendants' placement of the defective ATTUNE Device into the stream of commerce and Plaintiff's use of the defective ATTUNE Device as designed, manufactured, labeled, sold, supplied, and introduced into the stream of commerce by Defendants and/or the Defendants' failure to comply with federal requirements, Plaintiff suffered serious physical and mental injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

THIRD CAUSE OF ACTION
STRICT PRODUCTS LIABILITY
(Construction/Composition Defect under LSA-RS 9:2800.55)

151. Plaintiff adopts and incorporates by reference all the foregoing language of this Complaint as if fully set forth herein and further states as follows.

152. At all times material hereto, Defendants were the manufacturers, designers, researchers, distributors, sellers, and/or suppliers of the ATTUNE Device and placed a product on the market with a condition which rendered it unreasonably dangerous due to its propensity to result in failure of the device. The subject product was unreasonably dangerous in construction or composition.

153. The ATTUNE Device surgically implanted in Plaintiff was defective in its construction and/or composition when it left the hands of Defendants in that it deviated from product specifications, posing a serious risk that it could fail in patients therefore giving rise to physical injury, pain and suffering, debilitation, and the potential need for a revision surgery to replace the device with the attendant risks of complications and death from such further surgery.

154. Defendants knew or should have known that the ATTUNE Devices could fail in patients therefore giving rise to injury. Defendants' research, design, marketing and placement of the ATTUNE S+ with new design features on the market aimed at increasing fixation is an admission that the original ATTUNE tibial baseplate was defective in its composition and/or construction.

155. As a direct and proximate result of the defective manufacture or construction of the Defendants' ATTUNE Device and Plaintiff's use of the defective ATTUNE Device as designed, manufactured, sold, supplied, and introduced into the stream of commerce by Defendants and/or the Defendants' failure to comply with federal requirements, Plaintiff suffered serious physical and mental injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

FOURTH CAUSE OF ACTION
STRICT PRODUCTS LIABILITY
(Breach of Express Warranty Under LSA-RS 9:2800.58)

156. Plaintiff adopts and incorporates by reference all the foregoing language of this Complaint as if fully set forth herein and further states as follows.

157. Defendants made and continue to make representations to consumers, including Plaintiff and/or his physicians, regarding the character or quality of the ATTUNE Device,

including, but not limited to, statements that the ATTUNE Devices are a safe and effective knee replacement system.

158. The ATTUNE Device was defective in that when it left the Defendants' hands, it did not conform to Defendants' representations.

159. Plaintiff and/or Plaintiff's physicians justifiably relied on Defendants' representations regarding the safety of the ATTUNE Device.

160. As a direct and proximate result of Defendants' placement of the defective ATTUNE Device into the stream of commerce and Plaintiff's use of the defective ATTUNE Device as designed, manufactured, sold, supplied, and introduced into the stream of commerce by Defendants and/or the Defendants' failure to comply with federal requirements, Plaintiff suffered serious physical and mental injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

FIFTH CAUSE OF ACTION
(Breach of Warranty in Redhibition)

161. Plaintiff adopts and incorporates by reference all the foregoing language of this Complaint as if fully set forth herein and further states as follows.

162. The ATTUNE Device contains a vice or defect which renders it useless or its use so inconvenient that consumers, including Plaintiff, would not have purchased it had they known about the vice or defect.

163. Pursuant to Louisiana Civil Code Article 2520, a seller warrants the buyer against redhibitory defects, or vices, in the thing sold. The ATTUNE Device, which was sold and promoted by Defendants, possess a redhibitory defect because it is unreasonably dangerous, as described above, which renders the ATTUNE Device useless or so inconvenient that it must be

presumed that Plaintiff would not have bought the ATTUNE Device had he known of the defects.

164. Defendants were aware of the substantial risk of failure of the ATTUNE Device but failed to fully disclose those risks to Plaintiff.

165. In accordance with Louisiana Civil Code article 2545, Defendants, as the manufacturers, distributors and sellers of the ATTUNE Device, are deemed to be aware of its redhibitory defects.

166. Had Plaintiff been made aware of the defects contained in the ATTUNE Device, he would not have purchased the device. The loosening of the tibial baseplate of the ATTUNE Device is a characteristic that renders it unfit for its intended purpose.

167. Defendants are liable to Plaintiff under the theory of redhibition as a consequence of the sale to Plaintiff a product unfit for its intended use.

168. Plaintiff is entitled to the return of purchase price paid for the ATTUNE Device, including, but not limited to, insurance co-payments, interest on these amounts from the date of purchase, attorneys' fees and costs, pecuniary and non-pecuniary damages, as well as any other legal and equitable relief to which Plaintiffs may be entitled.

169. As a result of the aforementioned breach of obligation by Defendants, Plaintiff suffered and continues to suffer from the following items of damage, all past, present, and future, for which he is entitled to be compensated by Defendants, *in solido*, in an amount which is just and reasonable:

a. Medical and related expenses;

b. Physical injury and disability;

c. Physical pain and suffering;

d. Mental anguish and distress;

e. Loss of earnings;

f. Impairment of earning capacity;

g. Loss of enjoyment of life; and

h. Other items of damage which may be shown through discovery or at trial.

170. By reason of the foregoing, Plaintiff demands judgment against each Defendant, individually, jointly and severally for compensatory damages in a sum in excess of $75,000.00, together with interest, costs of suit, and all such other and further relief as the Court deems proper.

JURY DEMAND

Plaintiff demands a trial by jury on all issues so triable with the maximum number of jurors permitted by law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment against the Defendants, individually and collectively, jointly and severally, as follows:

1. Trial by jury;

2. For an award of compensatory damages in excess of Seventy-Five Thousand Dollars ($75,000.00), in an amount to fully compensate Plaintiff for all of his injuries and damages, both past and present;

3. Compensation for non-economic damages, both past and present, including but not limited to, past and future medical expenses, costs for past and future rehabilitation and/or home health care, lost income, permanent disability, including permanent instability and loss of balance, and pain and suffering;

4. Restitution and disgorgement of all revenue that Defendants have obtained through the manufacture, marketing, sale and administration of the ATTUNE Device;

5. For reasonable attorneys' fees and costs;

6. For pre-judgment interest; and

7. For such further and other relief this Court deems just and equitable.

Dated: September 26, 2017

Respectfully submitted,

/s/ Nicholas R. Rockforte_____
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JS 44 (Rev. 06/17)

CIVIL COVER SHEET

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 NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS
Rocky Thompson

DEFENDANTS
DePuy Synthes Sales, Inc., et al.

(b) County of Residence of First Listed Plaintiff Vernon Parish
(EXCEPT IN U.S. PLAINTIFF CASES)

County of Residence of First Listed Defendant Bristol
(IN U.S. PLAINTIFF CASES ONLY)
NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Nicholas R. Rockforte, Pendley, Baudin & Coffin, LLP 1515 Poydras St., Suite 1400 New Orleans, LA 70112, (504) 355-0086

Attorneys *(If Known)*

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ❒ 1 U.S. Government Plaintiff
- ❒ 3 Federal Question *(U.S. Government Not a Party)*
- ❒ 2 U.S. Government Defendant
- ☒ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☒ 1	❒ 1	Incorporated *or* Principal Place of Business In This State	❒ 4	❒ 4
Citizen of Another State	❒ 2	❒ 2	Incorporated *and* Principal Place of Business In Another State	☒ 5	❒ 5
Citizen or Subject of a Foreign Country	❒ 3	❒ 3	Foreign Nation	❒ 6	❒ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

Click here for: Nature of Suit Code Descriptions.

CONTRACT	TORTS		FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES
❒ 110 Insurance	PERSONAL INJURY	PERSONAL INJURY	❒ 625 Drug Related Seizure of Property 21 USC 881	❒ 422 Appeal 28 USC 158	❒ 375 False Claims Act
❒ 120 Marine	❒ 310 Airplane	❒ 365 Personal Injury - Product Liability	❒ 690 Other	❒ 423 Withdrawal 28 USC 157	❒ 376 Qui Tam (31 USC 3729(a))
❒ 130 Miller Act	❒ 315 Airplane Product Liability	☒ 367 Health Care/ Pharmaceutical Personal Injury Product Liability		PROPERTY RIGHTS	❒ 400 State Reapportionment
❒ 140 Negotiable Instrument	❒ 320 Assault, Libel & Slander	❒ 368 Asbestos Personal Injury Product Liability		❒ 820 Copyrights	❒ 410 Antitrust
❒ 150 Recovery of Overpayment & Enforcement of Judgment	❒ 330 Federal Employers' Liability	PERSONAL PROPERTY	LABOR	❒ 830 Patent	❒ 430 Banks and Banking
❒ 151 Medicare Act	❒ 340 Marine	❒ 370 Other Fraud	❒ 710 Fair Labor Standards Act	❒ 835 Patent - Abbreviated New Drug Application	❒ 450 Commerce
❒ 152 Recovery of Defaulted Student Loans (Excludes Veterans)	❒ 345 Marine Product Liability	❒ 371 Truth in Lending	❒ 720 Labor/Management Relations	❒ 840 Trademark	❒ 460 Deportation
❒ 153 Recovery of Overpayment of Veteran's Benefits	❒ 350 Motor Vehicle	❒ 380 Other Personal Property Damage	❒ 740 Railway Labor Act	SOCIAL SECURITY	❒ 470 Racketeer Influenced and Corrupt Organizations
❒ 160 Stockholders' Suits	❒ 355 Motor Vehicle Product Liability	❒ 385 Property Damage Product Liability	❒ 751 Family and Medical Leave Act	❒ 861 HIA (1395ff)	❒ 480 Consumer Credit
❒ 190 Other Contract	❒ 360 Other Personal Injury		❒ 790 Other Labor Litigation	❒ 862 Black Lung (923)	❒ 490 Cable/Sat TV
❒ 195 Contract Product Liability	❒ 362 Personal Injury - Medical Malpractice		❒ 791 Employee Retirement Income Security Act	❒ 863 DIWC/DIWW (405(g))	❒ 850 Securities/Commodities/ Exchange
❒ 196 Franchise				❒ 864 SSID Title XVI	❒ 890 Other Statutory Actions
				❒ 865 RSI (405(g))	❒ 891 Agricultural Acts
					❒ 893 Environmental Matters
					❒ 895 Freedom of Information Act
REAL PROPERTY	CIVIL RIGHTS	PRISONER PETITIONS	IMMIGRATION	FEDERAL TAX SUITS	❒ 896 Arbitration
❒ 210 Land Condemnation	❒ 440 Other Civil Rights	Habeas Corpus:	❒ 462 Naturalization Application	❒ 870 Taxes (U.S. Plaintiff or Defendant)	❒ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
❒ 220 Foreclosure	❒ 441 Voting	❒ 463 Alien Detainee	❒ 465 Other Immigration Actions	❒ 871 IRS—Third Party 26 USC 7609	❒ 950 Constitutionality of State Statutes
❒ 230 Rent Lease & Ejectment	❒ 442 Employment	❒ 510 Motions to Vacate Sentence			
❒ 240 Torts to Land	❒ 443 Housing/ Accommodations	❒ 530 General			
❒ 245 Tort Product Liability	❒ 445 Amer. w/Disabilities - Employment	❒ 535 Death Penalty			
❒ 290 All Other Real Property	❒ 446 Amer. w/Disabilities - Other	Other:			
	❒ 448 Education	❒ 540 Mandamus & Other			
		❒ 550 Civil Rights			
		❒ 555 Prison Condition			
		❒ 560 Civil Detainee - Conditions of Confinement			

V. ORIGIN *(Place an "X" in One Box Only)*

☒ 1 Original Proceeding ❒ 2 Removed from State Court ❒ 3 Remanded from Appellate Court ❒ 4 Reinstated or Reopened ❒ 5 Transferred from Another District *(specify)* ❒ 6 Multidistrict Litigation - Transfer ❒ 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing ***(Do not cite jurisdictional statutes unless diversity)***:
28 U.S.C. § 1332

Brief description of cause:
Personal Injury caused by Defendants' defective medical device

VII. REQUESTED IN COMPLAINT:

❒ CHECK IF THIS IS A **CLASS ACTION** UNDER RULE 23, F.R.Cv.P.

DEMAND $

CHECK YES only if demanded in complaint:
JURY DEMAND: ☒ Yes ❒ No

VIII. RELATED CASE(S) IF ANY

(See instructions):
JUDGE _____ DOCKET NUMBER _____

DATE
09/26/2017

SIGNATURE OF ATTORNEY OF RECORD
/s/Nicholas R. Rockforte

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

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.Cv.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**; NOTE: 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 there are multiple nature of suit codes associated with the case, pick the nature of suit code that is most applicable. Click here for: Nature of Suit Code Descriptions.

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 – Transfer. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407.
Multidistrict Litigation – Direct File. (8) Check this box when a multidistrict case is filed in the same district as the Master MDL docket.
PLEASE NOTE THAT THERE IS NOT AN ORIGIN CODE 7. Origin Code 7 was used for historical records and is no longer relevant due to changes in statue.

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 actual dollar amount 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.