# IN THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF MISSOURI

DAVID LOVE and	
MARCIA LOVE,	
Plaintiffs,	) )
vs.	Case. No.: 4:18-cv-695
DEPUY SYNTHES SALES, INC. d/b/a DEPUY SYNTHES JOINT RECONSTRUCTION; DEPUY ORTHOPAEDICS, INC; DEPUY INTERNATIONAL LIMITED; 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. JOHNSON & JOHNSON; and DEPUY MITEK, INC.,	Claims: Negligence, Strict Liability, Warranty, Consumer Protection, Fraud,

Defendants. )

## JURY TRIAL DEMANDED

# **COMPLAINT AND DEMAND FOR JURY TRIAL**

COMES NOW, Plaintiffs David Love and Marcia Love, by and through the undersigned

counsel, and allege of Defendants 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 David Love, 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, sliding or migration 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 certain defective ATTUNE Devices, all the while maintaining that they are safe and effective for use in total knee replacements and conceal the true safety information related to these devices.

### **THE PARTIES**

5. Plaintiff David Love is a citizen of Missouri and resides in Jackson County, Missouri. Plaintiff David Love was implanted with a defective Attune Device on December 16, 2015 at Research Medical Center in Kansas City, Missouri, which failed and resulted in a revision surgery on December 18, 2017 at Menorah Medical Center in Overland Park, Kansas.

6. Plaintiff Marcia Love is a citizen of Missouri and resides in Jackson County, Missouri. At all times relevant, Plaintiff Marcia Love was and is the lawful wife of Plaintiff David Love. 7. 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 Missouri by selling and distributing its products in Missouri. 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.

8. 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.

9. 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 Missouri by selling and distributing its products in Missouri, with a registered office in Missouri. Device Business Services is a wholly-owned subsidiary of Johnson & Johnson, a publicly traded company.

10. 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 Missouri by selling and distributing its products in

Missouri, with a registered office in Missouri. DOI is a wholly owned subsidiary of Johnson & Johnson, a publicly traded company.

11. 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.

12. 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 Missouri by selling and distributing its products in Missouri.

13. DSP is division of DOI. DSP is a wholly-owned subsidiary of Johnson & Johnson, a publicly traded company.

14. 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 Missouri by selling and distributing its products in Missouri.

15. Defendant DePuy Mitek, LLC ("DM") is and, at all times relevant, was a limited liability company 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 Missouri by selling and distributing its products in

Missouri, with a registered office in Missouri. DM operates as a subsidiary of DS, which is a wholly owned subsidiary of Johnson & Johnson, a publicly traded company.

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

17. 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 Missouri by selling and distributing its products in Missouri.

18. As DOI's parent company, DePuy, Inc. 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. 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.

19. 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 Missouri by selling and distributing its products in Missouri.

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

21. 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 Missouri by selling and distributing its products in Missouri.

22. 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.

23. 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 Missouri by selling and distributing its products in Missouri.

24. 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.

25. Defendants DSS, DOI, DIL, DSP, DS, DM, 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.

26. 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 Missouri by selling and distributing its products in Missouri.

27. 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.

28. 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 Missouri by selling and distributing its products in Missouri.

29. 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.

30. 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 Missouri by selling and distributing its products in Missouri.

31. 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.

32. Plaintiffs have 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 Mitek, 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.

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

34. 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.

35. 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.

36. 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 Missouri, over-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;<sup>1</sup>
- b. A pamphlet titled "A Knee That Can Help You Get Back Sooner;"<sup>2</sup>
- 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;<sup>3</sup>
- 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.<sup>4</sup>

<sup>&</sup>lt;sup>1</sup> Available at,

http://synthes.vo.llnwd.net/o16/LLNWMB8/US%20Mobile/Synthes%20North%20America/Product%20Support%2 0Materials/Product%20Information%20Sheets/DSUSJRC05140188(1)%20Attune%20Value%20Brief.pdf. <sup>2</sup> Available at,

http://synthes.vo.llnwd.net/o16/LLNWMB8/US%20Mobile/Synthes%20North%20America/Product%20Support%2 0Materials/Brochures/DSUS-JRC-0614-294\_Attune\_Brochure\_singles.pdf.

<sup>&</sup>lt;sup>3</sup> Available at, http://synthes.vo.llnwd.net/o16/LLNWMB8/US%20Mobile/Synthes%20North%20America/Prod uct%20Support%20Materials/Journal%20Articles/CERT%20Attune%20WP%20Response%20t o%20Bonutti.pdf

<sup>&</sup>lt;sup>4</sup> Available at, http://synthes.vo.llnwd.net/o16/LLNWMB8/US%20Mobile/Synthes%20North%20Americ a/Product%20Support%20Materials/Brochures/DSUSJRC11140570(2)%20ATTUNE%20Orderi ng%20Info.pdf.

37. 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.

38. At all times relevant, each of the Defendants was the representative, agent, employee, co-conspirator, servant, employee, partner, joint-venture, 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

39. 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 Plaintiffs against Defendants who are citizens of different states.

40. Venue in the Western District of Missouri is proper pursuant to 28 U.S.C. §1391(a) because a substantial part of the events giving rise to Plaintiffs' claims occurred in the Western District of Missouri, including the implantation of the defective and unreasonably dangerous ATTUNE Device. Upon information and belief, Defendants regularly conducted business in the Western District of Missouri. Defendants' commercial activities in the Western District of Missouri include, but are not limited to, the advertising, promotion, marketing and sale of ATTUNE Devices.

## **BACKGROUND AND FACTUAL ALLEGATIONS**

41. 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.

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

43. 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.

44. In a total knee replacement surgery, sometimes referred to as "arthroplasty," physicians replace the joint surfaces and damaged bone and cartilage with artificial materials, such as the ATTUNE Device. 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

45. 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.

46. 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).

47. 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.

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

49. 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.

50. 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.

# A. 510(k) clearance of the DePuy Attune <sup>™</sup> Knee System and Regulatory History

51. 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.

52. 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.

13

4815-5964-1967, v. 1

53. 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 clearance process allows the FDA to determine whether the device is substantially equivalent to a device already approved for marketing.

54. By 2010, DePuy was ready to take the ATTUNE to market. In December 2010, DePuy Orthopaedics, Inc. received FDA clearance of the DePuy Attune<sup>™</sup> Knee System under the "510(k)" 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 clearance with only very limited, if any, testing of the new ATTUNE Device.

55. The ATTUNE Device includes the Attune Tibial Base (510(k) 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.

56. The FDA cleared the following specific medical device components as part of the DePuy Attune<sup>™</sup> Knee Total System:

a. The Attune<sup>TM</sup> Cruciate Retaining (CR) Femoral Component;

b. The Attune<sup>™</sup> Fixed Bearing (FB) Tibial Inserts;

c. The Attune<sup>™</sup> Tibial Base, which is available in 10 sizes; and

d. The Attune<sup>TM</sup> Patellae.

4815-5964-1967, v. 1

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

58. The claims in this Complaint focus only on the ATTUNE Device as defined herein, which includes the DePuy Attune<sup>™</sup> Knee System (including its component parts) and the DePuy Attune<sup>™</sup> 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 David

Love.

# B. Launch of the DePuy Attune Knee System

59. 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<sup>TM</sup> Knee System—at the 2013 American Academy of Orthopedic Surgeons (AAOS) annual meeting in Chicago."

60. 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<sup>TM</sup> Contact: An S-curve design that provides a smooth engagement for stability through flexion, while reducing stresses placed on the implant."

61. 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:

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

62. 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.

63. 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, among other things, the debonding, the lack of long-term fixation. loosening and migration of the tibial baseplate and other components of the device. 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.

64. 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

65. The primary reason the ATTUNE Device fails is mechanical loosening, sliding, migration or a lack of long-term fixation. The mechanical loosening, sliding or migration is caused by a failure of the bond between the tibial baseplate at the implant-cement interface, or a mechanical mismatch of poorly designed device component marketed as replicating the human anatomy. Mechanical loosening, sliding, migration or the mechanical mismatch means that the attachment between the artificial knee and the existing bone has become loose, migrated or lacks long-term fixation. Such loosening will eventually result in failure of the device and other complications including severe pain. Mechanical loosening, lack of long-term fixation and migration has occurred at an unprecedented and unacceptable rate in patients implanted with an ATTUNE Device.

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

67. The loosening, migration and/or lack of long-term fixation can be visualized by the surgeon revising the defective and failed ATTUNE Device and is often noted in the operative reported accompanying a failed and defective ATTUNE Device.

68. A loose artificial knee and/or loose tibial components generally cause severe, wearing away of the bone and surrounding tissue, early failures and painful revision surgeries. It

can severely restrict a patient's daily activities as it can involve a severe physical and emotional burden for the patient.

69. 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.

70. Unfortunately, a failed total knee prosthesis often causes severe bone loss, excessive scarification and damage to the surrounding tissue. Therefore, revision surgeries on a failed total knee due to loosening, migration and lack of long-term fixation often require reconstruction of the severe bone loss and increase the risk of additional failures in the future, chronic pain and immobility.

71. 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, but not limited to, limitations in range of motion, the ability to walk, and even death.

72. 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, lack of long-term fixation, migration and/or debonding at the tibial baseplate cement/implant interface or related components. These MAUDE reports detail an extremely high incidence of aseptic loosening at the tibial baseplate of the ATTUNE Device resulting in subsequent revision surgeries.

73. 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.

74. 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.

75. 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 - attempting to alleviate the defective mechanical mismatch design of the ATTUNE device and rectify the unacceptable failures and revisions due to the loosening, lack of long-term fixation and migration of the components of the device, specifically the tibial components. The stem of the ATTUNE® Revision Knee System was designed with a cylindrical or tapered body geometry with a blasted and fluted fixation surface.

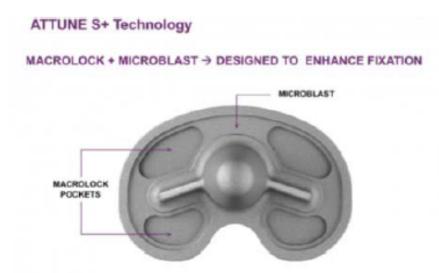
76. Without notifying consumers, doctors or patients, including Plaintiff and his physicians, Defendants recently attempted to replace the original ATTUNE Fixed Base tibial baseplate with a new tibial baseplate, which received FDA 510(k) clearance on June 15, 2017. This strategic decision to design and launch a newly designed tibial baseplate is an acknowledgment of the defective and unsafe nature of the ATTUNE, 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 ATTUNE, nor the defective tibial baseplate components, or informed consumers and surgeons about the dangers of its use.

77. 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<sup>TM</sup> 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.

78. 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.



79. 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."

80. Defendants knew about the design defects and resulting failures with the original ATTUNE, and the ATTUNE tibial baseplate components, 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 Defendants abandoning the original ATTUNE design and the replacement Attune design.

81. By March 16, 2016 or before, Defendants had apparently recognized the existence of high failure rates of the original ATTUNE and 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.

82. Upon information and belief, Defendants were also communicating, conspiring and concealing the safety issues and unacceptable safety defects with the original ATTUNE as early as 2013 or before.

83. 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.

84. 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	Back to Searc
TRAY	Flower

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 ida 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 CEN Type of Device KIEE TIBIAL TRAY Nenefacturer (Section 8) DEPUY ORTHCPAEDICS 1818910 TOD Orthopaedic Drive Verson IN 46862 Nenefacturer Center Menufacturer Center Chal Gibson TOD Orthopaedic Drive Werson IN 46502

85. 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, <u>Tibial Tray Thickness</u> <u>Significantly Increases Medial Tibial Bone Resorption in Cobalt-Chromium Total Knee</u> <u>Arthroplasty Implants.</u> The study reported that the thicker cobalt-chromium baseplate of the ATTUNE Device was associated with significantly more tibial bone loss.

86. 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 <u>High Incidence of Stress Shielding and Radiolucent Lines with a Novel Total Knee System</u>, which involved a study of the ATTUNE Device.

87. Surgeons were now reporting what Defendants had known and concealed from the public for years.

88. 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.

89. 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%.

90. 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.

91. In 2017, the alarming rate of failure associated with the ATTUNE Device due to debonding, loosening, and migration of the tibial baseplate was discussed in a paper written by Dr. Peter M. Bonutti and colleagues, entitled <u>Unusually High Rate of Early Failure of Tibial</u> <u>Component in ATTUNE Total Knee Arthroplasty System at Implant-Cement Interface</u>. 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 or lack of long-term fixation at the interface between the cement and the tibial baseplate, resulting in high rates of failure and revision surgery.

92. 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 deboned 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.

93. 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.

94. The Defendants began a campaign immediately, communicating, first, internally, on how to attack the data now being made public about the lack of safety with the ATTUNE device and how to smear those who would alert the public as to the lack of safety with the ATTUNE device, and, subsequently, spreading innuendo and press releases to smear, attack and undermine the data being made public for the first time regarding the serious defective nature of the ATTUNE device device and the mechanical mismatch component design of the device.

95. 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, and using consultants of the company to attack and undermine safety reports and falsely reassure any fears or concerns the public had. Defendants paid millions of dollars to these consultants and spent millions on marketing the device.

## **DEPUY'S MARKETING OF ATTUNE DEVICES**

96. 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.

97. 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.

98. 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 Missouri.

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

100. 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.

101. 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.

102. 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.

103. 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 post marketing analysis, knew or should have known that the ATTUNE Device was prone to fail. Plaintiffs allege that the ATTUNE Device is defective and unreasonably dangerous.

4815-5964-1967, v. 1

104. Defendants represented to consumers the Attune Knee System; had undergone extensive research and testing to improve outcomes for patients, would relieve pain and restore function and mobility for arthritis pain sufferers, over 90% of patients had successful outcomes at 15 years, saved patients and society money due to reduced disability costs and improved productivity after receiving the Attune, was designed to deliver a "high level of stability" and "minimized unnatural sliding," was uniquely designed to deliver "optimal wear resistance" and long-term stability, was designed to address stability, prevent loosening or sliding and closely match motion and stability found in the native knee anatomy, reduced the risk of soft tissue irritation and tracking complications, was similar to the native knee functions, and, was specifically designed to address one of the most common complaints after knee replacement surgery, pain.

105. These claims were unfounded, lacked reliable scientific support, downplayed and concealed the design deficiencies of the device, and Defendants were on notice these claims were false and misleading.

## **CASE SPECIFIC FACTUAL ALLEGATIONS**

106. On or about December 16, 2015, Plaintiff David Love underwent a right-sided total knee replacement surgery at Research Medical Center in Kansas City, Missouri. Mr. Love 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 and sold throughout the United States by Defendants.

107. After the ATTUNE Device was implanted, Plaintiff began experiencing severe and persistent pain, discomfort, instability, popping and clicking of his device, and difficulty

ambulating caused by, among other things, the loosening, the lack of long-term fixation, debonding and migration of the defective tibial baseplate and ATTUNE device components.

108. On December 18, 2017, Plaintiff underwent revision surgery to replace the defective ATTUNE Device implanted in his right knee with a new prosthesis due, among other things, to a lack of bond and/or long-term fixation, loosening and failure of the implant. This surgery was performed by Dr. Robert P. Bruce at Menorah Medical Center in Overland Park, Kansas.

109. Dr. Bruce diagnosed Mr. Love with a "Failed tibial component" and described in the revision surgery operative note tibial component(s) being "grossly loose."

110. Neither Plaintiff nor his physicians were aware, by warning or otherwise, of the defects in the ATTUNE Device or excessive risks due to the unique design of the ATTUNE, and would not have used the ATTUNE Device had they been aware of the defective nature of the device, or at the very least would not relayed the additional material safety information Defendants withheld from the public to Plaintiff, and Plaintiff would not have consented to said device.

111. As a direct and proximate result of the Defendants placing the defective ATTUNE Device in the stream of commerce, Plaintiffs Mr. and Mrs. Love suffered and continue to suffer both injuries and damages, including, but not limited to: past, present and future physical pain and mental pain and suffering; and past, present and future medical, hospital, rehabilitative and pharmaceutical expenses, economic damages, loss of consortium and other related damages.

## **COUNT I -- NEGLIGENCE**

## (Plaintiffs Against All Defendants)

112. Plaintiffs incorporate by reference every allegation set forth in the preceding paragraphs and alleges:

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

114. Defendants failed to exercise reasonable care in the designing, researching, manufacturing, marketing, supplying, promoting, sale, testing, quality assurance, quality control, and/or distribution of the ATTUNE Device into the stream of commerce in that Defendants knew or should have known 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 and other severe and personal injuries which are permanent and lasting, physical pain and mental anguish, including diminished enjoyment of life and the need for a revision surgery to replace the ATTUNE Device with the attendant risks of complications and death from such further surgery.

115. The negligence of Defendants, their agents, servants, and/or employees includes, but is not limited to, the following acts and/or omissions:

- Designing the ATTUNE Device in a manner dangerous to those individuals who had the device surgically implanted;
- b. Designing, manufacturing, producing, creating, and/or promoting the ATTUNE Device without adequately, sufficiently, or thoroughly testing it;
- c. Designing, researching, developing, manufacturing, marketing, promoting and selling a medical device when it knew or should have known of the

unacceptable risk of loosening, sliding, migration, lack of long-term fixation and early failure;

- d. Not conducting sufficient testing to determine whether the ATTUNE
   Device was safe for use;
- e. Selling the ATTUNE Device without making proper and sufficient tests to determine the dangers to its users;
- f. Failing to adequately and correctly warn Plaintiff or his physicians, hospitals and/or healthcare providers of the dangers of the ATTUNE Device;
- g. Failing to instruct and/or warn of the serious risks specific to the defective design and mechanical mismatch of the ATTUNE components, including of loosening, sliding, migration, and lack of long-term fixation of the tibial baseplate and related components, and early failure of the ATTUNE Device resulting in injuries;
- h. Failing to provide adequate warning of the dangers associated with the ATTUNE Device;
- Failing to provide adequate instructions regarding safety precautions to be observed by surgeons who would reasonably and foreseeably come into contact with, and more particularly, implant the ATTUNE Device into their patients;
- j. 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, sliding or migration of the tibial baseplate and failure of the ATTUNE Device resulting in injuries;

- k. Providing inaccurate labeling and inadequate warnings and instructions with the ATTUNE Device;
- Advertising and recommending using the ATTUNE Device although Defendants knew or should have known of its dangerous nature and propensities;
- m. Representing the ATTUNE Device offered for sale was safe for use for its intended purpose when it was unsafe;
- n. Manufacturing, producing and/or assembling the ATTUNE Device in a manner that was dangerous to those individuals into which it was implanted;
- Under-reporting, underestimating and downplaying the serious danger of the ATTUNE Device to the public and to healthcare professionals to which it marketed and sold the ATTUNE Device;
- p. Continuing to produce and sell the ATTUNE Device given the propensity of the medical device to loosen, slide or migrate and fail at high rates resulting in subsequent surgery and injuries;
- q. Failing to recall their dangerous and defective ATTUNE Device at the earliest date it became known or should have become known to Defendants that the ATTUNE Device was dangerous and defective; and
- r. Other breaches and defects which may be shown through discovery or at trial.

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

- Failed to use due care in designing and manufacturing the ATTUNE Device to avoid the aforementioned risks to individuals that had the devices surgically implanted;
- b. Failed to accompany the ATTUNE Device with proper warnings;
- c. Failed to accompany the ATTUNE Device with proper instructions for use;
- Failed to conduct adequate testing, including pre-clinical and clinical testing and post-market surveillance to determine the safety of the ATTUNE Device; and
- e. Were otherwise careless and/or negligent.

117. Although Defendants knew or should have known that the ATTUNE Device caused harm to individuals that had the device surgically implanted, Defendants continue to manufacture, market, distribute and/or sell the ATTUNE Device.

118. Defendants knew or should have known that consumers such as Plaintiffs would suffer foreseeable injury, and/or be at an increased risk of suffering injury because of Defendants' failure to exercise ordinary care.

119. 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.

120. By the foregoing, Plaintiffs suffered and will suffer significant damages, including, but not limited to, partial or complete loss of mobility, loss of range of motion, and other severe

and personal injuries which are permanent and lasting, physical pain and mental anguish, including diminished enjoyment of life and the need for revision surgery to replace the device with the attendant risks of complications and death from such further surgeries. Because of the foregoing, Plaintiffs suffered wage loss and will in the future suffer wage loss and a diminished capacity to earn wages.

121. The conduct of Defendants as described showed complete indifference to and conscious disregard for the health and safety of others, including David Love, entitling Plaintiffs to punitive damages to punish and to deter Defendants and others from like conduct.

WHEREFORE, Plaintiffs pray for judgment against Defendants for compensatory damages in an amount fair and reasonable, for punitive damages for his costs incurred and expended, and for such other relief as is just and proper.

# **COUNT II -- STRICT PRODUCTS LIABILITY (MANUFACTURING DEFECT)**

## (Plaintiffs Against All Defendants)

122. Plaintiffs incorporate by reference every allegation set forth in the preceding paragraphs and alleges:

123. Defendant designed, manufactured, marketed and transferred the ATTUNE Device in the course of its business into the stream of commerce.

124. The ATTUNE Device surgically implanted in Plaintiff was in a defective condition unreasonably dangerous in its manufacture when it left the hands of Defendants in that it deviated from product specifications, posing a serious risk it could fail early in patients, could cause debonding, fractures, infection, soft tissue injury and permanent damage to bones and nerves surrounding the knee joint and, therefore, give rise to physical injury, pain and suffering, debilitation, and the need for revision surgery to replace the device with the attendant risks of complication and death from such further surgery.

125. As a direct and proximate result of Defendants' transfer of the defective ATTUNE Device into the stream of commerce, Plaintiffs suffered and will suffer significant damages, including, but not limited to, partial or complete loss of mobility, loss of range of motion and other severe and personal injuries which are permanent and lasting, physical pain and mental anguish, including diminished enjoyment of life and the need for revision surgery to replace the device with the attendant risks of complications and death from such further surgeries. Further, as a direct and proximate result of the foregoing, Plaintiffs suffered wage loss and will in the future suffer wage loss and a diminished capacity to earn wages.

126. When Defendants sold the ATTUNE Device for implantation in David Love, Defendants knew of the defective condition and danger and showed complete indifference to and a conscious disregard for the health and safety of others, including David Love, entitling Plaintiffs to punitive damages to punish Defendants and to deter Defendants and others from like conduct.

WHEREFORE, Plaintiffs pray for judgment against Defendants for compensatory damages in an amount fair and reasonable, for punitive damages for his costs incurred and expended, and for such other relief as is just and proper.

# **COUNT III -- STRICT PRODUCTS LIABILITY (DESIGN DEFECT)**

## (Plaintiffs Against All Defendants)

127. Plaintiffs incorporate by reference every allegation set forth in the preceding paragraphs and alleges:

128. Defendants designed, researched, manufactured, advertised, promoted, marketed, sold and/or distributed the ATTUNE Device as hereinabove described that was surgically implanted in David Love's right leg.

129. The ATTUNE Device designed, researched, manufactured, advertised, promoted, marketed, sold and/or distributed by Defendants was in an unsafe, defective, and inherently dangerous condition dangerous to users such as David Love in that the ATTUNE Device could fail early in patients and could cause debonding, fractures, infection, soft tissue injury and permanent damage to bones and nerves surrounding the knee joint and, therefore, give rise to physical injury, pain and suffering, debilitation, and the need for revision surgery to replace the device with the attendant risks of complication and death from such further surgery.

130. The ATTUNE Device designed, researched, manufactured, advertised, promoted, marketed, sold and/or distributed by Defendants was in an unsafe, defective and inherently dangerous condition when it left Defendants' possession.

131. The ATTUNE Device was expected to and reached the usual consumers, handlers and persons coming into contact with said product without substantial change in which it was designed, produced, manufactured, sold, distributed and marketed by Defendants.

132. The unsafe, defective and inherently dangerous condition of the ATTUNE Device was a cause of injury to Plaintiffs.

133. The ATTUNE Device failed to perform as safely as an ordinary consumer would expect when used as intended and in a reasonably foreseeable manner.

134. Plaintiffs' injuries directly and proximately resulted from the ATTUNE Device that was both intended and reasonably foreseeable by Defendants.

135. The ATTUNE Device posed a risk of danger inherent in the design which outweighed the benefits of that design.

136. The ATTUNE Device was defective and unsafe, and Defendants knew or had reason to know said device was defective and unsafe, especially when used in the form and manner as provided by Defendants.

137. Defendants knew or should have known the ATTUNE Device was in a defective condition and was and is inherently dangerous and unsafe.

138. When the ATTUNE Device was implanted into David Love, the ATTUNE Device was being used for the purposes and in a manner normally intended - namely, for use as a knee replacement device.

139. Defendants, with this knowledge, voluntarily designed their ATTUNE Device in a dangerous condition for use by the public and, more particularly, David Love.

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

141. Defendants designed, researched, manufactured, advertised, promoted, marketed, sold and/or 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 David Love; therefore, Defendants are strictly liable for the injuries sustained by Plaintiffs.

142. As a direct and proximate result of Defendants' placement of the defective ATTUNE Device into the stream of commerce, Plaintiffs suffered and will suffer significant damages, including, but not limited to, partial or complete loss of mobility, loss of range of motion and other severe and personal injuries which are permanent and lasting, physical pain and mental anguish, including diminished enjoyment of life and the need for revision surgery to replace the

device with the attendant risks of complications and death from such further surgeries. Further, as a direct and proximate result of the foregoing, Plaintiffs suffered wage loss and will in the future suffer wage loss and a diminished capacity to earn wages.

143. When Defendants sold the ATTUNE Device for implantation in David Love, Defendants knew of the defective condition and danger and showed complete indifference to and a conscious disregard for the health and safety of others, including David Love, entitling Plaintiffs to punitive damages to punish Defendants and to deter Defendants and others from like conduct.

WHEREFORE, Plaintiffs pray for judgment against Defendants for compensatory damages in an amount fair and reasonable, for punitive damages for his costs incurred and expended, and for such other relief as is just and proper.

## **COUNT IV -- STRICT PRODUCTS LIABILITY (INADEQUATE WARNING)**

#### (Plaintiffs Against All Defendants)

144. Plaintiffs incorporate by reference every allegation set forth in the preceding paragraphs and alleges:

145. Defendants designed, researched, manufactured, advertised, promoted, marketed, sold and/or distributed the ATTUNE Device as hereinabove described that was surgically implanted in David Love's knee.

146. The ATTUNE Device placed into the stream of commerce by Defendants was defective due to inadequate warning, because Defendants knew or should have known that the ATTUNE Device could fail early in patients and could cause debonding, fractures, infection, soft tissue injury and permanent damage to bones and nerves surrounding the knee joint and, therefore, give rise to physical injury, pain and suffering, debilitation, and the need for revision surgery to replace the device with the attendant risks of complication and death from such further surgery.

147. Further, the ATTUNE Device placed into the stream of commerce by Defendants was surgically implanted in David Love's knee in a manner intended and/or reasonably anticipated by Defendants.

148. As a direct and proximate result of Defendants' placement of the defective ATTUNE Device into the stream of commerce, Plaintiffs suffered and will suffer significant damages, including, but not limited to, partial or complete loss of mobility, loss of range of motion and other severe and personal injuries which are permanent and lasting, physical pain and mental anguish, including diminished enjoyment of life, and the need for revision surgery to replace the device with the attendant risks of complications and death from such further surgeries. Further, as a direct and proximate result of the foregoing, Plaintiffs suffered wage loss and will in the future suffer wage loss and a diminished capacity to earn wages.

149. When Defendants placed the ATTUNE Device into the stream of commerce for implantation in David Love, Defendants knew of the defective condition and danger but failed to warn of that defective condition and danger and thereby showed complete indifference to and a conscious disregard for the health and safety of others, including David Love, entitling Plaintiffs to punitive damages to punish Defendants and to deter Defendants and others from like conduct.

WHEREFORE, Plaintiffs pray for judgment against Defendants for compensatory damages in an amount fair and reasonable, for punitive damages, for his costs incurred and expended, and for such other relief as is just and proper.

#### **COUNT V – BREACH OF EXPRESS WARRANTY**

#### (Plaintiffs Against All Defendants)

150. Plaintiffs incorporate by reference every allegation set forth in the preceding paragraphs and alleges:

39

151. Defendants designed, manufactured and distributed into the stream of commerce the ATTUNE Device.

152. Defendants expressly warranted the ATTUNE Device was a safe and effective knee replacement system, along with aforementioned claims and warranties, and these express warranties and representations were material factors inducing Plaintiffs to purchase the ATTUNE Device for implantation in David Love's right knee.

153. The ATTUNE Device placed into the stream of commerce by Defendants did not conform to these express warranties and representations because the ATTUNE Device failed early in patients and caused debonding, loosening, sliding, fractures, infection, soft tissue injury and permanent damage to bones and nerves surrounding the knee joint and, therefore, give rise to physical injury, pain and suffering, debilitation, and the need for revision surgery to replace the device with the attendant risks of complication and death from such further surgery.

154. As a direct and proximate result of Defendants' nonconformity with their express warranties regarding the safe and effective nature of the ATTUNE Device, Plaintiffs suffered and will suffer significant damages, including, but not limited to, partial or complete loss of mobility, loss of range of motion and other severe and personal injuries which are permanent and lasting, physical pain and mental anguish, including diminished enjoyment of life and the need for revision surgery to replace the device with the attendant risks of complications and death from such further surgeries. Further, as a direct and proximate result of the foregoing, Plaintiffs suffered wage loss and will in the future suffer wage loss and a diminished capacity to earn wages.

155. When Defendants placed the ATTUNE Device into the stream of commerce for implantation in David Love, Defendants knew of the defective condition and danger and thereby showed complete indifference to and a conscious disregard for the health and safety of others,

including David Love, entitling Plaintiffs to punitive damages to punish Defendants and to deter Defendants and others from like conduct.

WHEREFORE, Plaintiffs pray for judgment against Defendants for compensatory damages in an amount fair and reasonable, for punitive damages, for his costs incurred and expended, and for such other relief as is just and proper.

# COUNT VI – BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY (Plaintiffs Against All Defendants)

156. Plaintiffs incorporate by reference every allegation set forth in the preceding paragraphs and alleges:

157. Defendants designed, manufactured, marketed and distributed into the stream of commerce the ATTUNE Device.

158. When Defendants designed, manufactured, marketed and distributed into the stream of commerce the ATTUNE Device, Defendants, knowing the use for which the ATTUNE Device was intended, impliedly warranted the ATTUNE Device to be of merchantable quality and safe for such use.

159. Plaintiffs reasonably relied upon the skill and judgment of Defendants whether the ATTUNE Device was of merchantable quality and safe for its intended use.

160. Contrary to Defendants' implied warranties, the ATTUNE Device was not of merchantable quality or safe for its intended use because the ATTUNE Device was unreasonably dangerous and in a condition dangerous to users such as David Love in that the ATTUNE Device could fail early in patients and could cause debonding, fractures, infection, soft tissue injury and permanent damage to bones and nerves surrounding the knee joint and, therefore, give rise to

physical injury, pain and suffering, debilitation, and the need for revision surgery to replace the device with the attendant risks of complication and death from such further surgery.

161. As a direct and proximate result of Defendants' breach of implied warranties regarding the safe and effective nature of the ATTUNE Device, Plaintiffs suffered and will suffer significant damages, including, but not limited to, partial or complete loss of mobility, loss of range of motion and other severe and personal injuries which are permanent and lasting, physical pain and mental anguish, including diminished enjoyment of life and the need for revision surgery to replace the device with the attendant risks of complications and death from such further surgeries. Further, as a direct and proximate result of the foregoing, Plaintiffs suffered wage loss and will in the future suffer wage loss and a diminished capacity to earn wages.

162. When Defendants placed the ATTUNE Device into the stream of commerce for implantation in David Love, Defendants knew of the defective condition and danger and thereby showed complete indifference to and a conscious disregard for the health and safety of others, including David Love, entitling Plaintiffs to punitive damages to punish Defendants and to deter Defendants and others from like conduct.

WHEREFORE, Plaintiffs pray for judgment against Defendants for compensatory damages in an amount fair and reasonable, for punitive damages, for his costs incurred and expended, and for such other relief as is just and proper.

#### **COUNT VII – NEGLIGENT MISREPRESENTATION**

#### (Plaintiffs Against All Defendants)

163. Plaintiffs incorporate by reference every allegation set forth in the preceding paragraphs and alleges:

164. Defendants supplied false information to the public, to Plaintiffs, and to the physicians that implanted the ATTUNE Device regarding the high quality, safety and effectiveness of the ATTUNE Device. Defendants provided this false information to induce the public, Plaintiffs and Plaintiff David Love's physicians to purchase and implant ATTUNE Devices.

165. Defendants knew or should have known that the information they supplied regarding the high quality, safety and effectiveness of the ATTUNE Device to induce Plaintiffs and Plaintiff's physicians to purchase and use the ATTUNE Device was false.

166. Defendants were negligent in obtaining or communicating false information regarding the high quality, safety and effectiveness of the ATTUNE Device.

167. Plaintiffs and Plaintiff's physicians relied on the false information supplied by the Defendants to Plaintiffs' detriment by causing the ATTUNE Device to be purchased and implanted in David Love's right knee.

168. Plaintiffs and Plaintiff's physicians were justified in their reliance on the false information supplied by Defendants regarding the high quality, safety and effectiveness of the ATTUNE Device.

169. As a direct and proximate result of Defendants' negligent misrepresentations, Plaintiffs suffered and will suffer significant damages, including, but not limited to, partial or complete loss of mobility, loss of range of motion and other severe and personal injuries which are permanent and lasting, physical pain and mental anguish, including diminished enjoyment of life and the need for revision surgery to replace the device with the attendant risks of complications and death from such further surgeries. Further, as a direct and proximate result of the foregoing, Plaintiffs suffered wage loss and will in the future suffer wage loss and a diminished capacity to earn wages. 170. The conduct of Defendants as described showed complete indifference to and conscious disregard for the health and safety of others, including David Love, entitling Plaintiffs to punitive damages to punish Defendants and to deter Defendants and others from like conduct.

WHEREFORE, Plaintiffs pray for judgment against Defendants for compensatory damages in an amount fair and reasonable, for punitive damages, for his costs incurred and expended, and for such other relief as is just and proper.

#### **COUNT VIII – FRAUD**

#### (Plaintiffs Against All Defendants)

171. Plaintiffs incorporate by reference every allegation set forth in the preceding paragraphs and alleges:

172. Defendants made representations to Plaintiffs and Plaintiff's physicians that the ATTUNE Device was a high quality, safe and effective knee replacement system.

173. Before they marketed the ATTUNE Device implanted in David Love, Defendants knew or should have known of the unreasonable dangers and serious health risks that ATTUNE Device posed to patients like David Love.

174. Defendants knew that the ATTUNE Device subjected patients to early failure, painful and harmful physical reactions secondary to loosening, sliding or migration of ATTUNE's tibial baseplate component that results from debonding at the baseplate-cement interface, which leads to death of tissue, bone loss and the need for explanation and revision surgery.

175. Defendants' representations to Plaintiffs and Plaintiff's physicians that the ATTUNE Device was high quality, safe and effective were false.

44

176. Defendants concealed their knowledge of the unreasonable risks and dangers associated with the ATTUNE Device to induce Plaintiffs and many thousands of other patients to purchase the system for surgical implantation in their bodies.

177. Neither Plaintiffs' nor Plaintiff's physicians knew of the falsity of Defendants' statements regarding the ATTUNE Device.

178. Plaintiffs' and Plaintiff's physicians relied upon and accepted as truthful Defendants' representations regarding the ATTUNE Device.

179. Plaintiffs and Plaintiff's physicians had a right to rely upon Defendants' representations and relied upon such representations.

180. Had Plaintiffs known that the ATTUNE Device would fail early and expose Plaintiff David Love to the unreasonable risk of device failure and need for revision surgery, Plaintiffs would not have purchased or allowed the ATTUNE Device to be surgically implanted in him.

181. As a direct and proximate result of Defendants' fraudulent representations, Plaintiffs suffered and will suffer significant damages, including, but not limited to, partial or complete loss of mobility, loss of range of motion and other severe and personal injuries which are permanent and lasting, physical pain and mental anguish, including diminished enjoyment of life and the need for revision surgery to replace the devices with the attendant risks of complications and death from such further surgeries. Further, as a direct and proximate result of the foregoing, Plaintiffs suffered wage loss and will in the future suffer wage loss and a diminished capacity to earn wages.

182. When Defendants marketed and sold the ATTUNE Device, Defendants knew or had information from which Defendants, in exercising ordinary care, should have known that such

conduct created a high degree of probability of injury, and Defendants thereby showed complete indifference to and conscious disregard for the health and safety of others, including David Love, entitling Plaintiffs to punitive damages to punish Defendants and to deter Defendants and others from like conduct.

WHEREFORE, Plaintiffs pray for judgment against Defendants for compensatory damages in an amount fair and reasonable, for punitive damages, for his costs incurred and expended, and for such other relief as is just and proper.

### **COUNT IX - VIOLATIONS OF THE MISSOURI MERCHANDISING PRACTICES ACT**

(Plaintiffs Against All Defendants)

183. Plaintiffs incorporate by reference every allegation set forth in the preceding paragraphs and alleges:

184. Defendants sold merchandise - namely, the ATTUNE Device - within the meaning of the Missouri Merchandising Practice Act in the state of Missouri. R.S.Mo. § 407.010.

185. Defendants are therefore subject to the requirements and provisions of the Missouri Merchandising Practices Act, R.S.Mo. § 407.020.

186. Defendants made representations to Plaintiffs and Plaintiff's physicians that the Attune device was a high quality, safe and effective knee replacement system.

187. Before they marketed the ATTUNE Device implanted in David Love, Defendants knew or should have known of the unreasonable dangers and serious health risks that ATTUNE Device posed to patients like David Love.

188. Defendants knew that the ATTUNE Device subjected patients to early failure, painful and harmful physical reactions secondary to loosening, sliding or migration of ATTUNE's tibial baseplate component that results from debonding at the baseplate-cement interface, which leads to death of tissue, bone loss and the need for explantation and revision surgery.

189. Defendants' representations to Plaintiffs and Plaintiff's physicians that the ATTUNE Device was high quality, safe and effective were false.

190. Defendants concealed their knowledge of the unreasonable risks and dangers associated with the ATTUNE Device to induce Plaintiffs and many thousands of other patients to purchase the system for surgical implantation in their bodies.

191. Neither Plaintiffs nor Plaintiff's physicians knew of the falsity of Defendants' statements regarding the ATTUNE Device.

192. Defendants' acts, use and employment of deception, false pretenses, false promises, misrepresentations, unfair practices and concealment, suppressions, and omission of material facts in selling the ATTUNE Device in the state of Missouri to Plaintiffs is and was and unlawful practice.

193. Defendants' conduct as described herein constitutes violations of R.S.Mo. § 407.020.

194. Under R.S.Mo. § 407.020, plaintiffs are entitled to recover actual damages; punitive damages; attorney's fees and expenses for Defendants' violations of R.S.Mo. § 407.020; and to equitable relief.

195. As a direct result of Defendants' unlawful acts and practices, Plaintiffs incurred actual damages, including, but not limited to, partial or complete loss of mobility, loss of range of motion and other severe and personal injuries which are permanent and lasting, physical pain and mental anguish, including diminished enjoyment of life and the need for revision surgery to replace the devices with the attendant risks of complications and death from such further surgeries.

Further, as a direct and proximate result of the foregoing, Plaintiffs suffered wage loss and will in the future suffer wage loss and a diminished capacity to earn wages.

196. When Defendants marketed and sold the ATTUNE Device, Defendants knew or had information from which Defendants, in exercising ordinary care, should have known that such conduct created a high degree of probability of injury, and Defendants concealed and/or misrepresented this information from Plaintiffs, and thereby showed complete indifference to and conscious disregard for the health and safety of others, including David Love, entitling Plaintiffs to punitive damages to punish Defendants and to deter Defendants and others from like conduct.

WHEREFORE, Plaintiffs pray for judgment against Defendants for compensatory damages in an amount fair and reasonable, for punitive damages, for his costs incurred and expended, and for such other relief as is just and proper.

#### **COUNT IX -- LOSS OF CONSORTIUM**

#### (Plaintiffs Against All Defendants)

197. Plaintiffs incorporate by reference every allegation set forth in the preceding paragraphs and alleges:

198. Marcia Love was and is the lawful wife of David Love.

199. As a direct and proximate result of Defendants' conduct as set out in the aforesaid Counts, Marcia Love has experienced and will continue to experience in the future losing David Love's services, companionship and consortium.

200. The conduct of Defendants as described above showed conscious disregard for and complete indifference to the Plaintiffs, entitling Plaintiffs to punitive damages to punish Defendants and deter Defendants and others from like conduct.

WHEREFORE, Plaintiffs pray for judgment against Defendants for compensatory damages in an amount fair and reasonable, for punitive damages, for her costs incurred and expended, and for such other relief as is just and proper.

## JURY DEMAND

Plaintiffs demand a trial by jury.

Respectfully submitted,

/s/ Jeffrey Kuntz					
Thomas Cartmell	MO # 45366				
Jeffrey Kuntz	MO # 52371				
Diane Watkins	MO # 57238				
Nate Jones	MO # 61474				
WAGSTAFF & CARTMELL LLP					
4740 Grand Blvd., Suite 300					
Kansas City, Missouri 64112					
816-701-1100					
FAX 816-531-2372					
tcartmell@wcllp.com					
jkuntz@wcllp.com					
dwatkins@wcllp.com					
njones@wcllp.com					
_					

# **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				DEFENDANTS			
				DePuy Synthes Sales, Inc., d/b/a DePuy Synthes Joint			
David Love and Marcia Love				Reconstruction, et al. (See additional Defendants on			
(b) County of Residence of	of First Listed Plaintiff <u>J</u>	ackson		Attached Sheet) County of Residence of First Listed Defendant			
(E.	XCEPT IN U.S. PLAINTIFF CA	ISES)		(IN U.S. PLAINTIFF CASES ONLY)			
				NOTE: IN LAND CO	NDEMNATION CASES, USE T OF LAND INVOLVED.	HE LOCATION OF	
				THE TRACT	OF LAND INVOLVED.		
(c) Attorneys (Firm Name, )	Address, and Telephone Numbe	r)		Attorneys (If Known)			
Jeffrey Kuntz		- /					
Wagstaff & Cartmell, LLF							
4740 Grand Avenue, Sui	te 300 Kansas City, M	IO 64112					
II. BASIS OF JURISD				TIZENSIIID OF D	DINCIDAL DADTIES	(Place an "X" in One Box for Plaintif	
II. BASIS OF JURISDI	ICTION (Place an "X" in C	ne Box Only)		(For Diversity Cases Only)	NINCIFAL FARTIES	(Place an "X" in One Box for Plaintifj and One Box for Defendant)	
□ 1 U.S. Government □ 3 Federal Question			PTF DEF PTF DEF				
Plaintiff	(U.S. Government)	Not a Party)	Citize	en of This State	1		
					of Business In T	This State	
□ 2 U.S. Government	🛛 4 Diversity		Citize	Citizen of Another State 🛛 2 🗔 2 Incorporated and Principal Place 🗔 5 👳 5			
Defendant	(Indicate Citizensh	ip of Parties in Item III)		of Business In Another State			
			Citize	en or Subject of a	3 🗖 3 Foreign Nation		
				reign Country			
IV. NATURE OF SUIT	(Place an "X" in One Box Or	ıly)			Click here for: Nature	of Suit Code Descriptions.	
CONTRACT		ORTS	FC	DRFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES	
□ 110 Insurance	PERSONAL INJURY	PERSONAL INJUR	Y 🛛 62	5 Drug Related Seizure	422 Appeal 28 USC 158	375 False Claims Act	
□ 120 Marine	□ 310 Airplane	365 Personal Injury -		of Property 21 USC 881	□ 423 Withdrawal	<b>3</b> 76 Qui Tam (31 USC	
<ul> <li>130 Miller Act</li> <li>140 Negotiable Instrument</li> </ul>	315 Airplane Product Liability	Product Liability 367 Health Care/	□ 69	0 Other	28 USC 157	3729(a)) □ 400 State Reapportionment	
□ 150 Recovery of Overpayment	□ 320 Assault, Libel &	Pharmaceutical			PROPERTY RIGHTS	□ 410 Antitrust	
& Enforcement of Judgment	Slander	Personal Injury			□ 820 Copyrights	430 Banks and Banking	
□ 151 Medicare Act	□ 330 Federal Employers'	Product Liability			□ 830 Patent	□ 450 Commerce	
152 Recovery of Defaulted Student Loans	Liability <b>340</b> Marine	368 Asbestos Personal Injury Product			835 Patent - Abbreviated New Drug Application	<ul> <li>460 Deportation</li> <li>470 Racketeer Influenced and</li> </ul>	
(Excludes Veterans)	□ 345 Marine Product	Liability			□ 840 Trademark	Corrupt Organizations	
□ 153 Recovery of Overpayment	Liability	PERSONAL PROPER		LABOR	SOCIAL SECURITY	□ 480 Consumer Credit	
of Veteran's Benefits <ul> <li>160 Stockholders' Suits</li> </ul>	<ul> <li>350 Motor Vehicle</li> <li>355 Motor Vehicle</li> </ul>	<ul> <li>370 Other Fraud</li> <li>371 Truth in Lending</li> </ul>	<b>1</b> 71	0 Fair Labor Standards Act	<ul> <li>861 HIA (1395ff)</li> <li>862 Black Lung (923)</li> </ul>	<ul> <li>490 Cable/Sat TV</li> <li>850 Securities/Commodities/</li> </ul>	
□ 190 Other Contract	Product Liability	□ 380 Other Personal	<b>1</b> 72	0 Labor/Management	□ 863 DIWC/DIWW (405(g))	Exchange	
195 Contract Product Liability	360 Other Personal	Property Damage		Relations	□ 864 SSID Title XVI	890 Other Statutory Actions	
□ 196 Franchise	Injury 362 Personal Injury -	385 Property Damage Product Liability		0 Railway Labor Act 1 Family and Medical	□ 865 RSI (405(g))	<ul> <li>891 Agricultural Acts</li> <li>893 Environmental Matters</li> </ul>	
	Medical Malpractice	Product Liability	LI 73	Leave Act		□ 895 Environmental Matters □ 895 Freedom of Information	
REAL PROPERTY	CIVIL RIGHTS	PRISONER PETITION	NS 🗖 79	0 Other Labor Litigation	FEDERAL TAX SUITS	Act	
□ 210 Land Condemnation	440 Other Civil Rights	Habeas Corpus:	<b>1</b> 79	1 Employee Retirement	870 Taxes (U.S. Plaintiff	□ 896 Arbitration	
<ul> <li>220 Foreclosure</li> <li>230 Rent Lease &amp; Ejectment</li> </ul>	<ul> <li>441 Voting</li> <li>442 Employment</li> </ul>	<ul> <li>463 Alien Detainee</li> <li>510 Motions to Vacate</li> </ul>		Income Security Act	or Defendant) 871 IRS—Third Party	899 Administrative Procedure Act/Review or Appeal of	
□ 240 Torts to Land	□ 443 Housing/	Sentence	, 		26 USC 7609	Agency Decision	
245 Tort Product Liability	Accommodations	□ 530 General				950 Constitutionality of	
290 All Other Real Property	445 Amer. w/Disabilities - Employment	535 Death Penalty Other:	17.46	IMMIGRATION 2 Naturalization Application		State Statutes	
	□ 446 Amer. w/Disabilities -	□ 540 Mandamus & Oth		5 Other Immigration			
	Other	550 Civil Rights		Actions			
	□ 448 Education	□ 555 Prison Condition □ 560 Civil Detainee -					
		Conditions of					
		Confinement					
V. ORIGIN (Place an "X" i	n One Box Only)						
37		Remanded from	J 4 Rein	stated or 🗇 5 Transfe	erred from 🛛 6 Multidisti	rict 🛛 8 Multidistrict	
	ate Court	Appellate Court	Reop	pened Anothe	r District Litigation	- Litigation -	
	Cite the U.C. Civil St			(specify)		Direct File	
	28 U.S.C. Sect	ion 1332	re ming (I	Do not cite jurisdictional stat	utes unless alversity):		
VI. CAUSE OF ACTION	ON Brief description of ca						
	I I						
VII. REQUESTED IN	CHECK IF THIS	IS A CLASS ACTION	D D	EMAND \$	CHECK YES only	if demanded in complaint:	
COMPLAINT:	UNDER RULE 2				JURY DEMAND:	: ¥x Yes □No	
VIII. RELATED CAS	F(S)					~ `	
IF ANY	(See instructions):						
		JUDGE			DOCKET NUMBER		
DATE		SIGNATURE OF ATT	FORNEY C	OF RECORD			
09/04/2018		/s/ Jeffrey Kunt	Z				
FOR OFFICE USE ONLY		· · · · · ·					
RECEIPT # Al	Case 4:18-cv-00	)695-4RP2YING The	iment	1-1 FileND00/	)4/18 Page <sup>™</sup> @f <sup>u</sup> 2	GE	
			annont	<u> </u>	$r_{\rm m} \pm 0$ r uyc $\pm 012$	•	

#### **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: <u>Nature of Suit Code Descriptions</u>.
- 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.