

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION**

DERRICK PEARSON,

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PLAINTIFF,

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v.

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Civil Action No.: _____

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**DEPUY SYNTHES SALES, INC. d/b/a
DEPUY SYNTHES JOINT
RECONSTRUCTION;
DEPUY ORTHOPAEDICS, INC.;
MEDICAL DEVICE BUSINESS
SERVICES, INC.; DEPUY SYNTHES
PRODUCTS, INC.; and DEPUY
IRELAND UNLIMITED COMPANY,**

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JURY TRIAL DEMAND

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DEFENDANTS.

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COMPLAINT

Plaintiff Derrick Pearson, by and through the undersigned counsel, brings this Complaint against Defendants DePuy Synthes Sales, Inc. d/b/a DePuy Synthes Joint Reconstruction; DePuy Orthopaedics, Inc.; Medical Device Business Services, Inc.; DePuy Synthes Products, Inc.; and DePuy Ireland Unlimited Company (hereinafter collectively “Defendants”) and states as follows:

PARTIES, JURISDICTION, AND VENUE

1. Plaintiff Derrick Pearson is an adult resident of Dallas, Texas.
2. Defendant DePuy Synthes Sales, Inc. d/b/a DePuy Synthes Joint Reconstruction (“DSS”) is a Massachusetts corporation with its principal place of business located at 325 Paramount Drive, Raynham, Massachusetts 02767, which is located in Bristol County. At all relevant times, Defendant DePuy Synthes Sales, Inc. d/b/a DePuy Synthes Joint Reconstruction regularly conducted business in Texas.

3. Defendant DePuy Orthopaedics, Inc. (“DePuy”) is a corporation organized and existing under the laws of the State of Indiana, with its principal place of business located at 700 Orthopaedic Drive, Warsaw, Indiana 46582, which is located in Kosciusko County. At all relevant times, DePuy regularly conducted business in Texas.

4. Defendant Medical Device Business Services, Inc. (“Device Business Services”) is an Indiana corporation with its principal place of business located at 700 Orthopaedic Drive, Warsaw, Indiana 46582, which is located in Kosciusko County. At all relevant times, Defendant Medical Device Business Services regularly conducted business in Texas.

5. Defendant DePuy Synthes Products, Inc. (“DSP”) is a Delaware corporation with its principal place of business located at 325 Paramount Drive, Raynham, Massachusetts 02767, which is located in Bristol County. At all relevant times, Defendant DePuy Synthes Products, Inc., regularly conducted business in Texas.

6. Defendant DePuy Ireland Unlimited Company (“DePuy Ireland”) is a company organized and existing under the laws of Ireland with its principal place of business located at Loughbeg Industrial Estate, Loughbeg Ringaskiddy, County Cork, Ireland. At all relevant times, Defendant DePuy Ireland Unlimited Company regularly conducted business in Texas.

7. At all times relevant, Defendants were the representatives, agents, employees, co-conspirators, servants, employees, partners, joint-venturers, franchisees, or alter egos of the other Defendants and were acting within the scope of such authority in such conspiracy, service, agency, employment, partnership, joint venture and/or franchise.

8. Each Defendant was involved, either directly or as described in paragraph eight, 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 DePuy Attune Knee System, as well as monitoring and reporting adverse events.

9. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332, because the amount in controversy exceeds \$75,000.00, exclusive of interest and costs, and because Defendants are incorporated and have their principal places of business in states other than the state in which Mr. Pearson resides.

10. Venue is proper in this Court pursuant to 28 U.S.C. § 1391 because a substantial part of the events giving rise to Mr. Pearson's claims occurred, in part, in this District, and because Defendants conducted regular business in this District.

11. Mr. Pearson resides in Dallas, Texas which is in the Dallas Division of the United States District Court for the Northern District of Texas.

BACKGROUND AND FACTUAL ALLEGATIONS

12. 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.

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

14. 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.

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

HISTORY OF DEPUY KNEES AND THE ATTUNE SYSTEM

16. According to Defendants, the Attune Knee System “builds on the LCS Complete Knee System and the Sigma Rotating Platform Knee,” both of which are also Defendants’ products.

17. In 1977, Defendants 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).

18. Defendants 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.

19. Based on this clinical success, according to DePuy, the company introduced the DePuy Synthes P.F.C. SIGMA System (“SIGMA system”) in 1996.

20. The SIGMA system 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 system has demonstrated excellent survivorship with 99.6% at 7 years.

21. Notwithstanding DePuy's alleged success with the SIGMA system, as reported by DePuy, the company began to tinker with the SIGMA system design in an effort to replicate the total flexion of the natural knee and maintain a competitive position in the market. This new project—one that Defendants boasted as their largest research and development project ever, carrying a price tag of approximately \$200 million—resulted in the DePuy Attune Knee System (“ATTUNE system”).

A. 510(k) Approval of the ATTUNE System and Regulatory History

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

23. The resulting ATTUNE 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. Defendants sought FDA clearance for the new ATTUNE system through the “510(k)” process.

24. Section 510(k) of the Food, Drug and Cosmetic Act provides a mechanism for device manufacturers to obtain accelerated FDA clearance for products that are shown to be “substantially equivalent” to a product that has previously received FDA approval. The process requires device manufacturers to notify FDA of their intent to market a medical device at least 90

days in advance of introduction to the market. This is known as Premarket Notification – also called PMN or 510(k). This approval process allows the FDA to determine whether the device is substantially equivalent to a device already approved for marketing.

25. By 2010, DePuy was ready to take the ATTUNE system to market. In December 2010, DePuy received FDA clearance of the ATTUNE System under the “510k” notification process. The basis for FDA clearance was substantial similarity to several prior devices, including, but not limited to, the P.F.C. SIGMA Knee System. Consequently, Defendants received FDA 510(k) approval of the components of the ATTUNE system in 2010 and 2011 with only very limited, if any, testing of the new ATTUNE system.

26. The ATTUNE system includes the Attune Tibial Base (510K Number K101433), also called the tibial tray, which, as compared to the SIGMA system, 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.

27. The design and composition of the ATTUNE system, especially the tibial baseplate, is defective and failed resulting in harm to Derrick Pearson.

B. Launch of the DePuy Attune Knee System

28. In March 2013, Defendants introduced its ATTUNE system, including procedures for implantation, to surgeons and consumers. On March 20, 2013, Defendants issued a press release widely introducing its “latest innovation in total knee replacement—the ATTUNE Knee System—at the 2013 American Academy of Orthopedic Surgeons (AAOS) annual meeting in Chicago.”

29. According to the Press release, the ATTUNE system 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 Defendants, its “proprietary technologies include: ... SOFCAM™ Contact: An S-curve design that provides a smooth engagement for stability through flexion, while reducing stresses placed on the implant.”

30. Defendants’ 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. Defendants claimed the following features of the ATTUNE system: “the largest clinical program at DePuy,” “improves value of TKA,” “compares favorably in joint registries,” and “significantly less symptomatic crepitus, primarily Sigma PS.”

31. The most notable improvement Defendants purported to make between the SIGMA and ATTUNE system 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.

32. However, the ATTUNE system did not deliver on these promises, resulting in significantly higher failure rates than previous Defendant knee counterparts due to the debonding of the tibial baseplate. As a result, thousands of knee replacement patients implanted with ATTUNE systems 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 system.

33. Since the initial launch, Defendants have continued to expand the ATTUNE system product line based on claims it would provide a more life-like knee to patients who were “expecting

to maintain an active lifestyle.” Defendants have aggressively marketed the ATTUNE system and has become the dominant player in the knee market, upon information and belief, selling approximately 400,000 ATTUNE systems worldwide.

FAILURES OF THE ATTUNE SYSTEM

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

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

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

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

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

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

40. Beginning in 2013 and 2014, Defendants became aware of safety issues with the ATTUNE system. 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 system design elements which caused loosening and/or debonding at the tibial baseplate cement/implant interface. These MAUDE reports detail an extremely high incidence of aseptic loosening at the tibial baseplate of the ATTUNE system resulting in subsequent revision surgeries.

41. 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.

42. 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 Revision Knee System ("ATTUNE Revised system"), which included the Attune Revision Fixed Bearing Tibial Base and a 14 x 50 mm Cemented Stem.

43. Ostensibly, noticing the alarming rate of failure and subsequent revisions related to the ATTUNE system, on March 10, 2016, Defendants submitted a Section 510(k) premarket notice of intent to market the ATTUNE Revised system, which included a new stem, with added length

and a keel for additional stability and recessed cement pockets intended to promote cement fixation. The stem of the ATTUNE Revised system was designed with a cylindrical or tapered body geometry with a blasted and fluted fixation surface.

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

45. 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 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.

46. 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.

47. Additionally, according to Defendants, 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 Defendants, the “ATTUNE S+ Technology finishing process increases the surface roughness compared with other, DePuy Synthes clinically proven, tibial tray designs that were tested.” *See* DePuy Synthes PowerPoint, “ATTUNE S+ Technology.”

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

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

50. Although Defendants knew about the high number of ATTUNE system failures resulting in revision surgeries, Defendants 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 Mr. Pearson and his physician.

51. In fact, beginning in December 2016, Defendants began openly admitting, in its responses in the MAUDE failure reports, that the ATTUNE systems were failing. Although

Defendants 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, Defendants 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.

52. In January 2017, the *Journal of Arthroplasty* published a study, led by Dr. Raymond H. Kim and other surgeons at Colorado Joint Replacement, Department of Orthopedic Surgery, and OrthoCarolina, Department of Orthopaedic Surgery entitled, Tibial Tray Thickness Significantly Increases Medial Tibial Bone Resorption in Cobalt-Chromium Total Knee Arthroplasty Implants. The study reported that the thicker cobalt-chromium baseplate of the ATTUNE system was associated with significantly more tibial bone loss.

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

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

55. As part of this study, 164 patients underwent a total knee replacement with the ATTUNE system 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%.

56. 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.

57. In 2017, the alarming rate of failure associated with the ATTUNE system due to debonding of the tibial baseplate was discussed in a paper written by Dr. Peter M. Bonutti and colleagues, entitled Unusually High Rate of Early Failure of Tibial Component in ATTUNE Total Knee Arthroplasty System at Implant-Cement Interface. The article presented compelling evidence that the design and/or composition of the ATTUNE system, and particularly the tibial baseplate component, contribute greatly to debonding at the interface between the cement and the tibial baseplate, resulting in high rates of failure and revision surgery.

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

59. The authors of the Bonutti study concluded that high rates of ATTUNE system 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.

60. Despite Defendants' claim that the ATTUNE system 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 system's defects, which Defendants knew existed Pearson ago.

DEFENDANTS' MARKETING OF ATTUNE SYSTEMS

61. According to Defendants, the ATTUNE system 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 system 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.

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

63. 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 systems to be placed into the stream of commerce throughout the United States, including Texas.

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

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

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

67. Upon information and belief, Defendants downplayed the health risks associated with the ATTUNE system through promotional literature and communications with orthopedic surgeons. Defendants deceived doctors, including Mr. Pearson's surgeon, and potential users of the ATTUNE system by relaying positive information, while concealing the nature and extent of the known adverse and serious health effects of the ATTUNE system.

68. 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 system was prone to fail. Mr. Pearson alleges that the ATTUNE system is defective and unreasonably dangerous.

CASE SPECIFIC FACTUAL ALLEGATIONS

69. On or about March 7, 2016, Plaintiff Derrick Pearson underwent a right-sided total knee replacement surgery performed by Dr. Michael H. Huo at UT Southwestern Medical Center in Dallas, Texas. Mr. Pearson was implanted with an ATTUNE system, including a fixed tibial

insert and a fixed tibial baseplate, which was designed, manufactured, marketed, distributed, labeled, marketed and sold throughout the United States by Defendants. The ATTUNE system was purchased by Mr. Pearson, and this action relates to the ATTUNE system.

70. After the ATTUNE system was implanted, Mr. Pearson began experiencing severe and persistent pain, discomfort, instability, and difficulty ambulating caused by aseptic loosening of the defective ATTUNE tibial baseplate.

71. On or about October 18, 2016, Dr. Huo took and viewed radiographs which showed loosening and debonding of the tibial tray. He noted this was unfortunately seen in some of the Attune systems.

72. On or about March 21, 2017, Dr. Huo explained the concerns with the Attune tibial tray and discussed the plan for revision.

73. On May 25, 2017, Mr. Pearson underwent revision surgery due to loosening of the components of the defective ATTUNE system implanted in his right knee. This surgery was performed by Dr. Huo at UT Southwestern Medical Center in Dallas, Texas. Dr. Huo noted the “tibial tray was completely loose and it was removed with hand only without any instruments. There was complete separation of the cement with the tray which is essentially the observation I have had in all the revision I have done with the series of this particular instrumentation system.”

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

75. As a direct and proximate result of Defendants placing the defective ATTUNE system in the stream of commerce, Mr. Pearson has suffered and continues to suffer both injuries and damages, including, but not limited to: past, present, and future physical and mental pain and

suffering; and past, present, and future medical, hospital, rehabilitative, monitoring, and pharmaceutical expenses, economic damages, severe and possibly permanent injuries, and other related damages.

76. All of the injuries and complications suffered by Mr. Pearson were caused by the defective design, warnings, construction, and unreasonably dangerous character of the ATTUNE system that was implanted in him. Had Defendants not concealed the known defects, the early failure rate, the known complications, and the unreasonable risks associated with the use of the ATTUNE system, Mr. Pearson would not have consented to the ATTUNE system being used in his total knee arthroplasty.

COUNT I
STRICT PRODUCTS LIABILITY – DESIGN DEFECT

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

78. At all times herein mentioned, Defendants are the researchers, designers, manufacturers, testers, advertisers, promoters, marketers, packagers, labelers, sellers, and/or distributors of the ATTUNE system, which is defective and unreasonably dangerous.

79. The ATTUNE system is defective in its design or formulation in that it is not reasonably fit, suitable, or safe for its intended purpose and/or its foreseeable risks exceed the benefits associated with its design. The ATTUNE system is defective in design in that it lacks efficacy, has a high failure rate, poses a greater likelihood of injury, and is more dangerous than other available devices indicated for the same conditions and uses. If the design defects were known at the time of manufacture, a reasonable person would have concluded that the utility of the ATTUNE system did not outweigh its risks.

80. At or before time the ATTUNE system was released on the market and/or sold to Mr. Pearson, Defendants could have designed the ATTUNE system to make it less prone to debonding and loosening, and there was a practical, technically feasible safer alternative design that would have prevented the harm Mr. Pearson suffered without substantially impairing the function of the device.

81. The defective condition of the ATTUNE system rendered it unreasonably dangerous and/or not reasonably safe, and the ATTUNE system was in this defective condition at the time it left the hands of Defendants. The ATTUNE system was expected to and did reach Mr. Pearson and his physician without substantial change in the condition in which it was designed, manufactured, labeled, sold, distributed, marketed, promoted, supplied, and otherwise released into the stream of commerce.

82. Mr. Pearson was unaware of the significant hazards and defects in the ATTUNE system. The ATTUNE system was unreasonably dangerous and/or not reasonably safe in that it was more dangerous than would be reasonably contemplated by the ordinary patient or physician. During the period that Mr. Pearson used the ATTUNE system, it was being utilized in a manner that was intended by Defendants. At the time Mr. Pearson had the ATTUNE system implanted, it was represented to be safe and free from latent defects.

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

84. Defendants are liable to Mr. Pearson for designing, manufacturing, and placing into the stream of commerce the ATTUNE system, which was unreasonably dangerous for its reasonably foreseeable use because of its design defects.

85. Defendants knew or should have known of the danger associated with the use of the ATTUNE system, as well as the defective nature of the ATTUNE system, but continued to design, manufacture, sell distribute, market, promote, and/or supply the ATTUNE system so as to maximize sales and profits at the expense of the public health and safety, in conscious disregard of the foreseeable harm caused by the ATTUNE system.

86. As a direct and proximate result of Defendants' conduct, Mr. Pearson has suffered and continues to suffer serious and permanent non-economic and economic injuries, and Defendants are liable to Mr. Pearson in an amount to be determined at trial.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly and severally, and requests compensatory damages, together with costs and interest, and any further relief as the Court deems proper, as well as a trial by jury of all issues.

COUNT II
STRICT PRODUCTS LIABILITY- MANUFACTURING DEFECT

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

88. At all times material hereto, Defendants manufactured, designed, tested, marketed, distributed, sold, and/or supplied the ATTUNE system and placed it in the stream of commerce in a condition which rendered it unreasonably dangerous due to its propensity to result in early debonding and failure of the device. The subject product was unreasonably dangerous in construction or composition.

89. Alternatively, the ATTUNE system purchased and implanted in Mr. Pearson was defective because it varied from Defendants' intended design and contained unreasonably dangerous conditions.

90. As a direct and proximate result of Defendants placing the defective ATTUNE system into the stream of commerce, Plaintiff suffered serious physical and mental injury, harm, and damages will continue to suffer such harm and damages in the future.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, and severally, and requests compensatory damages, together with costs and interest, and any further relief as the Court deems proper.

COUNT III
STRICT PRODUCTS LIABILITY – FAILURE TO WARN

91. Plaintiff incorporates by reference all the forgoing language of this Complaint as if fully set forth herein and further states as follows:

92. At all times material hereto, Defendants researched, tested, developed, designed, licensed, manufactured, packaged, labeled, marketed, sold to patients, and/or introduced the ATTUNE system into the stream of commerce knowing the devices would then be implanted in patients in need of a knee prosthesis. In the course of the same, Defendants directly advertised and/or marketed the product to health care professionals and consumers, including Mr. Pearson and Mr. Pearson's physicians, and therefore had a duty to warn of the risks associated with the use of the ATTUNE system. Defendants breached this duty.

93. The ATTUNE system was not accompanied by proper warnings and instructions to physicians and the public regarding potential adverse side effects associated with the implantation of the ATTUNE system and the comparative severity and duration of such adverse side effects.

94. The warnings, instructions, and information provided to the medical community and the public did not accurately reflect the symptoms, scope, or severity of potential side effects, specifically the risk of early debonding of the tibial plate.

95. Defendants failed to perform adequate testing which would have demonstrated that the ATTUNE system had potentially serious side effects about which Defendants should have provided full and proper warnings.

96. The ATTUNE system was defective due to inadequate warnings, information, and instructions that failed to convey to physicians and the public accurate information about the scope and severity of potential side effects.

97. Had Defendants reasonably and properly provided adequate warnings, such warnings would have been heeded and no healthcare professional, including Mr. Pearson's physicians, would have used the ATTUNE device, and no consumer, including Mr. Pearson, would have purchased and/or used the ATTUNE device.

98. As a direct and proximate result of Defendants' conduct, Mr. Pearson has suffered and continues to suffer serious and permanent non-economic injuries and economic injuries and Defendants are liable to Mr. Pearson in an amount to be determined at trial.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly and severally, and requests compensatory damages, together with costs and interest, and any further relief as the court deems proper.

COUNT IV
BREACH OF EXPRESS WARRANTY

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

100. Defendants expressly warranted to Mr. Pearson by and through Defendants and/or their authorized agents or sales representatives, in publications, package inserts, the internet, and other communications intended for physicians, patients, Mr. Pearson, and the general public, that the ATTUNE system was safe, effective, fit and proper for its intended use.

101. The ATTUNE device does not conform to those express representations because the ATTUNE system is defective, is not safe, and has serious side effects.

102. Mr. Pearson and/or Mr. Pearson's physicians justifiably relied on Defendants' representations regarding the safety of the ATTUNE device, and Defendants' representations became part of the basis of the bargain.

103. Defendants breached their warranty of mechanical soundness of the ATTUNE system by continuing sales and marketing campaigns highlighting the safety and efficacy of their product, while they knew of the defects and risk of product failure and resulting patient injuries.

104. As a direct and proximate result of Defendants' conduct, Mr. Pearson has suffered and continues to suffer serious and permanent non-economic and economic injuries.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly and severally, and requests compensatory damages, together with costs and interest, and any further relief as the court deems proper.

COUNT V
BREACH OF IMPLIED WARRANTY

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

106. Defendants were the sellers of the ATTUNE device and sold the ATTUNE to Mr. Pearson and/or Mr. Pearson's physician to be used in Mr. Pearson's knee implantation surgery.

107. When the ATTUNE device was used by Mr. Pearson's physician, the product was being used for the ordinary purpose for which it was intended.

108. The ATTUNE device sold to Mr. Pearson was not merchantable because it was not fit for its ordinary purpose to function as a long-lasting, safe and stable prosthetic knee.

109. The ATTUNE device would not pass without objection in the trade; is not of fair average quality; is not fit for its ordinary purposes for which the product is used; was not adequately contained, packaged and labeled; and fails to conform to the promises or affirmations of fact made on the container or label.

110. Defendants have been put on notice that the ATTUNE device is not fit for its ordinary purpose.

111. Defendants breach of their implied warranties resulted in the implantation of an unreasonably dangerous and defective product in Mr. Pearson's body, which placed his health and safety at risk.

112. As a direct and proximate result of Defendants' conduct, Mr. Pearson has suffered and continues to suffer serious physical and mental injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly and severally, and requests compensatory damages, together with costs and interest, and any further relief as the court deems proper.

COUNT VI
NEGLIGENCE

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

114. Defendants had a duty to exercise reasonable and ordinary care in designing, researching, testing, manufacturing, marketing, supplying, promoting, distributing, approving, and selling of the ATTUNE device.

115. Defendants failed to exercise ordinary care in designing, researching, testing, manufacturing, marketing, supplying, promoting, distributing, approving, and selling of the

ATTUNE system into interstate commerce in that Defendants knew or should have known that this product created a high risk of unreasonable, dangerous side effects, including the loosening and debonding at the tibial plate, thereby breaching their duty to consumers, including Mr. Pearson.

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

(a) Negligently designing the ATTUNE system in a manner which was dangerous to those individuals who had the device surgically implanted;

(b) Designing, manufacturing, producing, creating and/or promoting the ATTUNE system without adequately, sufficiently, or thoroughly testing it;

(c) Failing to adequately and correctly warn Mr. Pearson and his physicians, hospitals, and/or healthcare providers of the dangers of the ATTUNE system;

(d) Failing to recall their dangerous and defective ATTUNE system at the earliest date that it became known that the device was, in fact, dangerous and defective;

(e) Advertising and/or marketing the use of the ATTUNE system despite the fact that Defendants knew or should have known of its defects;

(f) Representing that the ATTUNE system was safe for its intended purpose when, in fact, it was unsafe;

(g) Manufacturing the ATTUNE system in a manner which was dangerous to those individuals who had it implanted; and

(h) Under-reporting, underestimating, and/or downplaying the serious danger of the ATTUNE system.

117. Upon information and belief, Defendants continued to market, manufacture, distribute and/or sell the ATTUNE system to consumers, including Mr. Pearson, despite the fact that Defendants knew or should have known that the ATTUNE system caused unreasonable, dangerous defects, including a defective tibial plate design leading to early debonding and early failures, when there were safer alternative designs available.

118. Defendants knew or should have known that consumers such as Mr. Pearson would suffer foreseeable injuries as a result of Defendants' failure to exercise ordinary care as described above.

119. At all material times, Defendants knew of the defective nature of the ATTUNE system as set forth herein, and continued to design, manufacture, market and sell it so as to maximize sales and profits at the expense of public health and safety, and as such Defendants' conduct exhibited a wanton and reckless disregard for human life.

120. As a direct and proximate result of Defendants' conduct, Mr. Pearson has suffered and continues to suffer serious and permanent non-economic and economic injuries.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly and severally, and requests compensatory damages, together with costs and interest, and any further relief as the court deems proper.

PRAYER FOR RELIEF

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

- (a) Trial by jury;
- (b) Judgment against Defendants for all compensatory damages allowable to Mr. Pearson;

- (c) Judgment against Defendants for all other relief sought by Mr. Pearson under this Complaint;
- (d) For reasonable attorneys' fees and costs;
- (e) For pre-judgment interest; and
- (f) For such further and other relief the Court deems just and equitable.

DEMAND FOR JURY TRIAL

Plaintiff demands a trial by jury on all counts and as to all issues.

Dated: August 7, 2018

Respectfully Submitted,

**THE LAW OFFICES REYNOLDS AND
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Counsel for Plaintiff

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

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

(c) Attorneys (Firm Name, Address, and Telephone Number)

DEFENDANTS

County of Residence of First Listed Defendant (IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys (If Known)

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

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

III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)

Table with columns for Plaintiff (PTF) and Defendant (DEF) citizenship: Citizen of This State, Citizen of Another State, Citizen or Subject of a Foreign Country, Incorporated or Principal Place of Business In This State, Incorporated and Principal Place of Business In Another State, Foreign Nation.

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

Large table with categories: CONTRACT, REAL PROPERTY, CIVIL RIGHTS, PRISONER PETITIONS, TORTS, PERSONAL INJURY, FORFEITURE/PENALTY, LABOR, IMMIGRATION, BANKRUPTCY, SOCIAL SECURITY, FEDERAL TAX SUITS, OTHER STATUTES.

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

- 1 Original Proceeding, 2 Removed from State Court, 3 Remanded from Appellate Court, 4 Reinstated or Reopened, 5 Transferred from Another District, 6 Multidistrict Litigation - Transfer, 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing (Do not cite jurisdictional statutes unless diversity):
Brief description of cause:

VII. REQUESTED IN COMPLAINT:

CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.Cv.P. DEMAND \$ CHECK YES only if demanded in complaint: JURY DEMAND: Yes No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE DOCKET NUMBER

DATE SIGNATURE OF ATTORNEY OF RECORD

FOR OFFICE USE ONLY

RECEIPT # AMOUNT APPLYING IFP JUDGE MAG. JUDGE

Case 3:18-cv-02073-B Document 1-1 Filed 08/09/18 Page 2 of 2 PageID 28
INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

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

- I.(a) Plaintiffs-Defendants.** Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.
- (b) County of Residence.** For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)
- (c) Attorneys.** Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".
- II. Jurisdiction.** The basis of jurisdiction is set forth under Rule 8(a), F.R.Cv.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.
 United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.
 United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.
 Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.
 Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below; **NOTE: federal question actions take precedence over diversity cases.**)
- III. Residence (citizenship) of Principal Parties.** This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.
- IV. Nature of Suit.** Place an "X" in the appropriate box. If there are multiple nature of suit codes associated with the case, pick the nature of suit code that is most applicable. Click here for: [Nature of Suit Code Descriptions](#).
- V. Origin.** Place an "X" in one of the seven boxes.
 Original Proceedings. (1) Cases which originate in the United States district courts.
 Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441. When the petition for removal is granted, check this box.
 Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.
 Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.
 Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.
 Multidistrict Litigation – Transfer. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407.
 Multidistrict Litigation – Direct File. (8) Check this box when a multidistrict case is filed in the same district as the Master MDL docket.
PLEASE NOTE THAT THERE IS NOT AN ORIGIN CODE 7. Origin Code 7 was used for historical records and is no longer relevant due to changes in statute.
- 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 a related case exists, whether pending or closed, insert the docket numbers and the corresponding judge names for such cases. A case is related to this filing if the case: 1) involves some or all of the same parties and is based on the same or similar claim; 2) involves the same property, transaction, or event; 3) involves substantially similar issues of law and fact; and/or 4) involves the same estate in a bankruptcy appeal.

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