Steve H. Patience
State Bar No. 009537
SKOUSEN, GULBRANDSEN
& PATIENCE, PLC
414 East Southern Avenue
Mesa, AZ 85204
Telephone: 480-833-8800
Email: shp@sgplaw.com
Attorneys for Plaintiffs

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA
FLAGSTAFF DIVISION

ELAINE SHUBIN and PATRICK SHUBIN, her husband, Plaintiffs, v. WRIGHT MEDICAL TECHNOLOGY, INC., a Delaware corporation; WRIGHT MEDICAL GROUP, INC., a Delaware corporation; and MICROPORT ORTHOPEDICS, INC., a Delaware corporation. Defendants.	Case No.: **COMPLAINT**

COMPLAINT

COMES NOW the Plaintiffs, Elaine Shubin and Patrick Shubin ("Plaintiffs"), by and through their undersigned attorneys, and files this their

Complaint for damages against Defendants, Wright Medical Technology, Inc., a Delaware corporation; Wright Medical Group, Inc., a Delaware corporation; and MicroPort Orthopedics, Inc., a Delaware corporation, and allege the following causes of action against Defendants, and each of them, as follows:

NATURE OF THE ACTION

1. Defendants have long known that their device design has an unacceptable tendency to fret and corrode at the location of the modular neck-stem-body junction during even low to moderate physical activity. Defendants have known for years that their hip replacement device – the PROFEMUR® Total Hip System with PROFEMUR® Stem ("Stem") and PROFEMUR® Modular Neck ("Modular Neck") (collectively "the PROFEMUR® Total Hip System" or "the Device" – was prone to fail within a few years of implantation causing severe debilitating tissue destruction. Significantly, consequent to reports of fretting-corrosion and fracture at the Stem and Modular Neck junction, Defendant MicroPort issued a recall and ceased marketing the Device. As a result of the Device's defects and Defendants' tortious acts/omissions, Plaintiff Elaine Shubin, and many other patients who received these devices, endured unnecessary pain and suffering; debilitating lack of mobility; and a subsequent more difficult revision surgery to replace the defective Device, giving rise to more pain and suffering,

prolonged recovery time, and increased risk of complications and death from surgery.

2. This is an action for strict products liability, negligence, breach of express and implied warranties, fraudulent misrepresentation, fraudulent concealment, negligent misrepresentation, loss of consortium, and punitive damages brought by Plaintiffs Elaine Shubin and Patrick Shubin for injuries arising out of the failure of the PROFEMUR® Total Hip System, Plaintiff Elaine Shubin received as part of her total hip replacement surgery.

PARTIES

3. Plaintiffs Elaine Shubin and Patrick Shubin at all times relevant hereto were residents of Flagstaff, Coconino County, State of Arizona. Plaintiff Elaine Shubin underwent a left total hip arthroplasty surgery performed by Michelle Ward, M.D. at San Antonio Regional Hospital on October 30, 2015. At that time, the PROFEMUR® Total Hip System manufactured, designed, distributed, labeled, marketed, and warranted by Defendants was implanted into Plaintiff Elaine Shubin. Plaintiff Elaine Shubin's surgeon, medical staff, and other healthcare providers met or exceeded the standard of care applicable to the hip replacement surgery. The PROFEMUR® Total Hip System implanted on Plaintiff's left side subsequently failed, and necessitated revision surgery. At the time of Plaintiff's

index and revision surgery, Defendant MicroPort Orthopedics, Inc. marketed, promoted and distributed the PROFEMUR® Total Hip System.

4. Defendant Wright Medical Technology, Inc. ("WMT") is a corporation organized under the laws of the State of Delaware, with its principal place of business located in Memphis, Tennessee, and as such is a citizen of both the State of Tennessee and the State of Delaware. Defendant WMT is registered to do business in the State of Arizona and may be served with process by serving its registered agent for service, Corporation Service Company, at 2338 W. Royal Palm Road, Suite J, Phoenix, Arizona 85021. At all times relevant hereto, Defendant WMT conducted regular and sustained business in the State of Arizona by selling and distributing its products in Arizona and engaged in substantial commerce and business activity in the County of Coconino.

5. Defendant Wright Medical Group, Inc. ("WMG") is a corporation organized under the laws of the State of Delaware, with its principal place of business located in Memphis, Tennessee, and as such is a citizen of both the State of Tennessee and the State of Delaware. Defendant WMG may be served with process by serving its registered agent for service, Corporation Service Company, at 2908 Poston Avenue, Nashville, Tennessee 37203-1312. At all times relevant hereto, Defendant WMG conducted regular and sustained business in the State of

Arizona by selling and distributing its products in Arizona and engaged in substantial commerce and business activity in the County of Coconino.

6. Defendant MicroPort Orthopedics, Inc. ("MicroPort") is a corporation organized under the laws of the State of Delaware, with its headquarters and principal place of business located in Arlington, Tennessee, and as such is a citizen of the State of Tennessee and the State of Delaware. Defendant MicroPort is registered to do business in the State of Arizona and may be served with process by serving its registered agent for service, the CT Corporation System, at 3800 N. Central Avenue, Suite 460, Phoenix Arizona 85012. At all times relevant hereto, Defendant MicroPort conducted regular and substantial business in the State of Arizona by selling and distributing its products in Arizona, and engaged in substantial commerce and business activity in the County of Coconino.

FACTUAL ALLEGATIONS

7. PROFEMUR® modular necks were first marketed by Cremascoli Ortho ("Cremascoli"), a European medical device manufacturer in 1986.

8. In December 1999, WMT and WMG (collectively "Wright") acquired Cremascoli, its product lines, documents, and manufacturing facilities, including the Profemur® line of hip products.

9. After the acquisition of Cremascoli, Wright re-designed the Profemur® modular artificial hip stem and modular neck, expanded the product line

to include additional titanium models or versions of Profemur® stems and Profemur® modular necks, and rebranded the Cremascoli titanium modular neck product line, and compatible titanium artificial hip stems, as the Wright Profemur® Total Hip System.

10. By way of what is known as Section 510(k) premarket notification process, on December 13, 2000, Wright received clearance from the U.S. Food and Drug Administration (FDA) to distribute in the United States its first titanium modular neck and stem artificial hips.

11. The FDA never approved the safety or effectiveness of Wright's newly rebranded hip implant system and product line of modular necks, but instead merely accepted Wright's assertion that the Profemur® Hip System was substantially equivalent to an already legally marketed device (i.e., the Cremascoli modular neck component acquired by Wright in December 1999).

12. The 510(k)-clearance process is distinct from the FDA pre-market approval (PMA) process in that clearance does not require clinical confirmation of safety and effectiveness and as such the manufacturer retains all liability for the assertions of safety and effectiveness.

13. Sometime after December 13, 2000, Wright began to manufacture, label, market, promote, distribute and sell in the United States the hip implant

devices branded as "Profemur® Total Hip System" under the 510(k) clearance, which included titanium stems and titanium modular necks.

14. The Wright Medical Profemur® modular necks that were distributed by Wright after December 13, 2000, and before August 25, 2009, were all made of the titanium-aluminum-vanadium alloy known as Ti6Al4V.

15. In the year 2000 and in all years thereafter to the present, Ti6Al4V was an alloy generally available for use in manufacturing implantable medical devices.

16. In the year 2000 and in all years thereafter to the present, monoblock hip implant stems without modular neck-stem junctions were readily available in the market.

17. In various marketing and promotional material published and distributed by Wright from approximately the year 2002, and into the year 2005, and available to Wright's sales representatives and distributors, surgeons, patients and the general public, Wright made the following representations, statements, claims and guarantees about its Profemur® modular necks:

> The modular neck used with the Profemur® hip has been employed by Wright Cremascoli for over fifteen years. The necks were designed in 1985 and have been successfully implanted in over 50,000 patients requiring both primary and revision hip procedures. The necks are used in other Wright Cremascoli hip systems besides the Profemur® hip. None of the necks has experienced a clinical failure since their inception [emphasis added].

and

The modular neck system, designed by Cremascoli in 1985 (U.S. Patent No. 4,957,510), has now been successfully implanted in over 50,000 patients requiring both primary and revision hip arthroplasty. Extensive laboratory tests have proven that the coupling between the modular neck and femoral implant guarantees:

- Structural reliability
- Absence of significant micromovement
- Absence of fretting corrosion

[emphasis added].

[Wright Medical Technology Monograph MH688-102© 2004].

18. On or about April 19, 2005, Wright first reported to the FDA a Profemur® modular neck clinical failure where a Ti6Al4V modular neck implanted in a patient experienced a catastrophic fracture (i.e., breaking into two pieces) due to fretting and corrosion at the oblong tapered distal end where the neck is seated in the stem.

19. After receiving notice of the first modular neck fracture, Wright received notice of additional modular neck clinical failures from corrosion based fractures of the modular necks.

20. The number of Profemur® Ti6Al4V modular neck clinical corrosion based fractures has continued to increase over time, and continues to increase to the present day, now numbering more than 800 such clinical failures.

21. As the number of reported Wright Ti6Al4V modular neck fractures continued to increase and the FDA became aware of its dismal clinical performance, case studies appeared in medical journals reporting the fracture of Wright titanium Profemur® modular necks and identifying micromotion and fretting corrosion at the neck-stem junction as the cause and mode of failure.

22. At some point in time prior to August 25, 2009, Wright had notice that a higher than normal rate of early failure of its Profemur® line of hip implant devices were failing by fracture at the modular neck junction secondary to micromotion, fretting and corrosion.

23. As the number of reported Wright Ti6Al4V Profemur® modular neck fractures continued to increase, Wright, rather than redesigning its hip implant system to eliminate the modular neck-stem junction and thereby eliminate micromotion and fretting-corrosion, instead began to design and develop a Profemur® modular neck made of a cobalt chrome (CoCr) metal alloy utilizing the same taper design as the titanium modular necks and the same Profemur® stems.

24. On April 16, 2009, Wright submitted a Section 510(k) premarket notification of intent to market a device generally identified as Profemur® hip system modular necks made of a cobalt chrome alloy to the FDA to be coupled with existing Profemur® stems.

25. On or about August 25, 2009, Wright began to market and offer for distribution and sale in the United States Profemur® modular Necks made of cobalt chromium alloy, and Wright simultaneously began withdrawing from the market its Profemur® modular necks comprised of Ti6Al4V titanium alloy.

26. Wright could have eliminated the potential for fretting and corrosion at the modular neck junction of its Profemur® hip implants by redesigning and/or abandoning modularity and manufacturing, designing, and marketing monoblock stems, but it chose not to do so because Wright did not want to lose its investment in the market share for the use of its modular stems in primary hip implant arthroplasties.

27. In promoting its Profemur® CoCr modular Necks, Wright claimed that the cobalt chrome modular Necks would result in less fretting than occurred with Ti6Al4V modular necks.

28. The design of the Profemur® CoCr modular Neck, when coupled with the design of the titanium Profemur® hip Stems, is such that it in fact promotes the process of fretting corrosion of more harmful metal particles at the modular Neck-Stem junction.

29. The Profemur® CoCr modular Necks that Wright designed and manufactured were designed to be used with most, if not all, of the same femoral

heads and most, if not all, of the same Profemur® titanium hip Stems as were its titanium (Ti6Al4V) Profemur® modular necks.

30. While promoting its Profemur® CoCr modular Necks Wright Medical stated, "[p]roduct complaint data reported to Wright to date does not indicate an increased risk, as compared to traditional titanium necks, of adverse events due to taper junction fretting and corrosion or fractures for Profemur® CoCr modular Necks." [See Profemur® CoCr Modular Necks Frequently Asked Questions, Wright Medical publication MH 1619-812.]

31. Wright's statement in its promotional materials that "[p]roduct complaint data reported to Wright to date does not indicate an increased risk, as compared to traditional titanium necks, of adverse events due to taper junction fretting and corrosion or fractures for Profemur® CoCr modular Necks," was not supported by unbiased sound scientific testing.

32. The claim by Wright that "[p]roduct complaint data reported to Wright to date does not indicate an increased risk, as compared to traditional titanium necks, of adverse events due to taper junction fretting and corrosion or fractures for Profemur® CoCr modular Necks" was false and/or misleading.

33. While promoting its Profemur® CoCr modular Necks, Wright claimed that its CoCr modular Necks would result in less fretting than occurred with titanium modular necks.

34. Claims by Wright that its CoCr modular Necks would result in less fretting than occurred with titanium (Ti6Al4V) modular necks were not supported by unbiased, sound scientific testing.

35. Claims by Wright that its CoCr modular Necks would result in less fretting than occurred with titanium (Ti6Al4V) modular necks were false and/or misleading.

36. The design of the Profemur® CoCr modular Neck, when coupled with the design of the titanium (Ti6Al4V) Profemur® hip Stems, is such that it in fact encourages the process of fretting corrosion at the modular Neck-Stem junction.

37. Prior to offering its Profemur® CoCr modular Necks for distribution or sale in the United States, Wright nor MicroPort adequately tested the design of CoCr Profemur® modular Necks for fretting corrosion or the biological effects of cobalt and chromium corrosion, metal debris and metal ions on the body of patients.

38. Prior to offering its Profemur® CoCr modular Necks for distribution or sale in the United States, Wright nor MicroPort adequately tested the design of the CoCr Profemur® modular Necks for corrosion or the biological effect of corrosion on the body after implantation in patients.

39. Wright rushed the Profemur® CoCr modular Necks to market without adequately testing it for in vivo performance, including, but not limited to, resistance to fretting and corrosion or the effects of corrosion on human tissue.

40. Wright rushed the Profemur® CoCr modular Necks to market in order to preserve market share and its profits from the sale of its failing Profemur® hip implant products.

41. Years before Plaintiff Elaine Shubin was implanted with the Device, Wright had been informed that the Profemur® CoCr modular Necks were corroding in patients to the extent that revision surgeries were necessary to remove the Profemur® CoCr modular Necks.

42. In January of 2014, Wright sold the OrthoRecon Division, Wright's operating unit for the manufacture and sale of Wright's hip and knee implants, to MicroPort.

43. MicroPort and Wright knew or should have known that as of October 30, 2015, the date Plaintiff Elaine Shubin received her Wright Profemur® Total Hip System that:

(a) Wright and MicroPort had not adequately tested the Profemur® CoCr modular Necks to simulate in vivo performance for resistance to fretting-corrosion;

(b) MicroPort had not adequately tested the Profemur® Total Hip System;

(c) Wright and MicroPort had not adequately tested the Profemur® CoCr modular Necks to simulate in vivo performance for resistance to corrosion;

(d) The Profemur® CoCr modular Necks would be subject to fretting-corrosion;

(e) There was an increased risk of fretting-corrosion at the Neck-Stem junction;

(f) There was an increased risk of corrosion at the Neck-Stem junction;

and

(g) There was a substantial risk that patients' bodies would be adversely affected by the exposure to corrosion, metal debris and metal ions secondary to cobalt and chromium fretting and corrosion.

44. The Neck-Stem junctions of the Profemur® CoCr modular Neck, coupled with a Profemur® titanium hip stem, are subject to significant movement which results in fretting-corrosion, pitting corrosion, metal debris cast off and metal ion release.

45. Product complaint data reported to Wright and MicroPort prior to October 30, 2015 indicated an increased risk of adverse events due to tissue exposure to metal debris and ion cast off from taper junction fretting and corrosion of the Profemur® CoCr modular Necks when coupled with Profemur® titanium hip Stems, as compared to traditional titanium necks or monoblock stems.

46. Product complaint data reported to Wright and MicroPort prior to October 30, 2015 indicated an increased risk of adverse events due to corrosion, as compared to traditional monoblock stems or titanium necks when coupled with the Profemur® hip stems.

47. Based upon what Wright and MicroPort knew or should have known before October 30, 2015, Wright and MicroPort should have informed orthopedic surgeons using the Profemur® Total Hip Systems that there was an increased risk of fretting and corrosion for Profemur® CoCr modular Necks when coupled with Profemur® titanium hip stems.

48. The Profemur® CoCr modular Neck, Profemur® titanium modular Stem and the Profemur® Total Hip System are defective and unreasonably dangerous because of their design defects in that the harmful characteristics or consequences inherent in the product's use for hip replacement, when weighed against the utility or benefit derived from the product, outweigh the benefits which might have been gained by placing the said defective devices product in the body

of Plaintiff Elaine Shubin. Further, the said devices were defective and unreasonably dangerous in that they failed to perform as safely as an ordinary consumer would expect when they were used in a reasonably foreseeable manner.

49. Additionally, the Profemur® CoCr modular Neck, Profemur® titanium modular Stem and the Profemur® Total Hip System implanted in Plaintiff Elaine Shubin were defective in manufacture, as Wright manufactured same such that the tolerances between the Stem and Neck components did not comply with Wright's design specifications.

50. Based upon the facts and allegations set forth above, the Profemur® CoCr modular Neck, Profemur® titanium Stem, and the Profemur® Total Hip System are defective and unreasonably dangerous in labeling in that they do not provide adequate warnings of the dangers or information of said risks when the device is used in a reasonably foreseeable manner.

51. Based upon the facts and allegations set forth above, the Profemur® CoCr modular Necks, Profemur® titanium modular Stem, and the Profemur® Total Hip System are defective and unreasonably dangerous in that the risks that were inherent in the product being used for hip replacement, when weighed against the alleged utility or benefit derived from the product's use, outweigh the benefit.

52. Defendants WMT, WMG, and MicroPort were negligent and / or strictly liable in design, manufacture, distribution, sale, marketing, promotion, and

labeling of the Profemur® CoCr modular Neck, Profemur® titanium modular Stem, and the Profemur® Total Hip System.

53. Defendants were negligent and / or strictly liable in the failure to warn patients and/or surgeons that it had received product complaint data that indicated an increased risk of adverse events due to taper junction fretting and cobalt chromium corrosion, as compared to other available safe alternative devices.

54. Defendants were negligent and / or strictly liable in failing to warn patients and surgeons that they had received product complaint data that indicated an increased risk of adverse events due to corrosion, as compared to other available safe alternative devices.

PLAINTIFF'S INJURIES AND DAMAGES

PLAINTIFF ELAINE SHUBIN'S PROFEMUR® HIP

55. On or about October 30, 2015, Plaintiff Elaine Shubin had a Profemur® Total Hip System implanted in her left hip ("Index Surgery") in a procedure known as a total hip arthroplasty (or "THA").

56. Orthopedic surgeon Michelle Ward, M.D. ("Dr. Ward") performed the Index Surgery during which she implanted the Profemur® Total Hip System in Plaintiff Elaine Shubin.

57. Plaintiff Elaine Shubin's Index Surgery was performed at San Antonio Regional Hospital in Upland, California.

58. Dr. Ward did not breach any generally accepted standard of care in the field of orthopedic surgery in her care and treatment of Plaintiff Elaine Shubin or negligently cause any injury to Plaintiff in any of the following respects:

(a) In the care or treatment that she provided to Plaintiff Elaine Shubin prior to beginning the hip implant surgery;

(b) In the hip implant surgery, she performed on Plaintiff Elaine Shubin;

or

(c) In the care or treatment that she provided to Plaintiff Elaine Shubin subsequent to Plaintiff's hip implant surgery.

59. Based upon the patient population that Wright and MicroPort intended the Device to be implanted in, at the time of Plaintiff Elaine Shubin's Index Surgery, she was an appropriate patient to be implanted with the Profemur® Total Hip System.

60. Dr. Ward recommended the Profemur Total Hip System to Plaintiff Elaine Shubin and indicated that the Device was appropriate for her.

61. Plaintiff Elaine Shubin reasonably relied upon Dr. Ward in deciding to proceed with hip replacement surgery and have the Profemur® Total Hip System implanted.

62. Before or during the course of Plaintiff Elaine Shubin's Index Surgery, Defendants MicroPort and/or Wright arranged for the Profemur® Total Hip System that was implanted in Plaintiff to be delivered to San Antonio Regional Hospital and/or Dr. Ward for implantation in Plaintiff Elaine Shubin.

63. Defendants, directly or through their subsidiaries or affiliates, designed, manufactured, distributed, marketed, delivered and sold in the United States various prosthetic orthopedic devices, including the Profemur® Total Hip System implanted in Plaintiff Elaine Shubin during the Index Surgery.

64. At the Index Surgery, each of the components of Plaintiff Elaine Shubin's Profemur® Total Hip System was in substantially the same condition in all relevant respects as when they left Defendants' control.

65. At all times relevant hereto, Plaintiff Elaine Shubin used the Profemur® Total Hip System implanted during the Index Surgery in a normal and reasonably foreseeable manner.

66. On or about March 9, 2020, Plaintiff Elaine Shubin reported to Dr. Amber Randall ("Dr. Randall") for revision surgery of her failed hip prosthesis ("Revision Surgery"). Dr. Randall recommended the revision surgery after Plaintiff Elaine Shubin presented with elevated cobalt ion level, severe pain, and lack of mobility.

67. Plaintiff Elaine Shubin's Revision Surgery was necessary because the Device failed due to corrosion at the Neck-Stem junction of the Device.

68. But for the fact that the CoCr modular Neck of Plaintiff Elaine Shubin's Device had corroded causing it to fail and injure Plaintiff, Plaintiff's Device was not otherwise in need of revision.

69. On or about March 9, 2020, it was discovered that the Device failed due to corrosion of the oblong taper of the Profemur® CoCr modular Neck where it seated in the pocket of the Profemur® titanium Stem, which caused continuing and otherwise irreversible physical injury to Plaintiff Elaine Shubin.

70. On or about March 9, 2020, the Profemur® Total Hip System implanted in Plaintiff Elaine Shubin's left hip was discovered to have failed as a direct and proximate result of the actions, conduct, negligence, and breach of duties of the Defendants, as alleged in this Complaint.

71. The Profemur® Total Hip System (and its components), to include the Device implanted in Plaintiff Elaine Shubin was not merchantable, but was defective and unreasonably dangerous for its intended and/or reasonably foreseeable uses in that:

(a) it was and is defective and unreasonably dangerous under Arizona's product liability law as a result of one or more or a combination of the following:

(i) the Neck was manufactured/designed in such a manner as to be subjected to excessive micromotion and fretting corrosion, thereby increasing the potential for failure;

(ii) the Neck was manufactured/designed in such a manner as to be subjected to excessive micromotion, fretting and corrosion, thereby increasing the potential for injury and failure;

(iii) the surface of the section of the Neck that was inserted into the modular Stem was manufactured/designed in such a manner as to increase the potential for fretting and corrosion, thereby increasing the potential for injury and failure;

(iv) the portion of the Neck that was inserted into the modular Stem was in a narrow, confined space, thereby increasing the potential for fretting, corrosion, injury and failure;

(v) the components were manufactured/designed in such a way as to make the modular Neck component susceptible to micromotion, fretting and corrosion, thereby increasing the potential for injury and failure;

(vi) the components were manufactured/designed in such a way as to cause dissimilar metals (i.e., a CoCr modular Neck and titanium modular Stem) to mate by insertion into a narrow, confined space, thereby increasing the potential for corrosion; and

(vii) there may be other conditions or defects yet to be determined.

(b) it was also defective and unreasonably dangerous in that the said devices failed to perform as safely as an ordinary consumer would expect or was dangerous to an extent beyond which could be contemplated by the ordinary consumer with the ordinary knowledge common to the community as to its characteristics in that:

(i) the ordinary consumer would not contemplate that the Device would become so corroded that premature revision surgery would become necessary less than 5 years after implantation; and

(ii) the ordinary consumer would not contemplate that the ordinary activities of daily living would result in the Device releasing harmful metal ions and metal debris in the consumer's body that caused adverse tissue reactions and other medical complications.

72. The Device was not tested in design and development under conditions that were known would be encountered in the normal in vivo patient environment over reasonable periods of time.

73. The Device was not tested in design and development under the normal in vivo patient environmental conditions that were known would be encountered during normal use of the Device.

74. The Device was not tested for the FDA Section 510(k) Premarket Notification Process under conditions that were known would be encountered in the normal in vivo patient environment.

75. The testing performed by Wright and MicroPort of the Device did not adhere to or meet FDA guidance.

76. The Device's design was known by Defendants to be failing from fretting and corrosion of the modular Neck-Stem junction prior to the day of its FDA 510(k) Premarket Notification Application.

77. The Device was known by Defendants to be failing at higher than expected rates from micromotion, fretting and corrosion of the modular Neck-Stem junction prior to the date of its implantation in Plaintiff Elaine Shubin during the Index Surgery.

78. The Device's design was known by Defendants to be failing at higher than expected rates due to fretting and corrosion prior to the date of Plaintiff Elaine Shubin's Revision Surgery, during which the Device was discovered to be corroded at the Neck-Stem junction.

79. Prior to the Index Surgery, Defendants did not warn patients, surgeons, customers, or their sales representatives/distributors that the Device was known to be failing from corrosion at higher than expected rates.

80. On or about March 9, 2020, Plaintiff Elaine Shubin discovered the Device implanted in her left side failed due to corrosion as a result of one or more or a combination of the foregoing unreasonably dangerous conditions.

81. As a direct and proximate result of the failure of the Profemur® Total Hip System, Plaintiff Elaine Shubin has sustained injuries and damages, including, but not limited to:

(a) undergoing surgery to remove and replace the failed prosthesis and repair the damage that failure caused;

(b) past and future pain, suffering, and anguish, both in mind and in body;

(c) permanent diminishment of her ability to participate in and enjoy the affairs of life;

(d) medical bills associated with the revision surgery, rehabilitation, and recovery therefrom;

(e) future medical expenses;

(f) disfigurement; and

(g) permanent physical impairment.

(h) serious and permanent physical injuries to bone, muscle, tendons, tissues and nerves in her hip and pelvis;

(i) loss of earnings and any decrease in earning power or capacity in the future.

FEDERAL STATUTORY AND REGULATORY REQUIREMENTS

82. Pursuant to federal law, a medical device is deemed to be adulterated if, among other things, it fails to meet established performance standards, or if the methods, facilities or controls used for its manufacture, packing, storage or installation are not in conformity with federal requirements. 21 U.S.C. § 351.

83. Pursuant to federal law, a device is deemed to be misbranded if, among other things, its labeling is false or misleading in any particular, or if it is dangerous to health when used in the manner prescribed, recommended or suggested in the labeling thereof. 21 U.S.C. § 352.

84. Pursuant to federal law, manufacturers are required to comply with FDA regulation of medical devices, including FDA requirements for records and reports, in order to prohibit introduction of medical devices that are adulterated or misbranded, and to assure the safety and effectiveness of medical devices. In particular, manufacturers must keep records and make reports if any medical device may have caused or contributed to death or serious injury, or if the device has malfunctioned in a manner likely to cause or contribute to death or serious injury. Federal law also mandates that the FDA establish regulations requiring a manufacturer of a medical device to report promptly to FDA any correction or removal of a device undertaken to reduce a risk to health posed by the device, or to

remedy a violation of federal law by which a device may present a risk to health. 21 U.S.C. § 360(i).

85. Pursuant to federal law, the Secretary of Health and Human Services may prescribe regulations requiring that the methods used in, and the facilities and controls used for, the manufacture, pre-production design validation (including a process to assess the performance of a device, but not including an evaluation of the safety or effectiveness of a device), packaging, storage and installation of a device conform to current good manufacturing practice, as prescribed in such regulations, to assure that the device will be safe and effective and otherwise in compliance with federal law.

86. The regulations requiring conformance to good manufacturing practices are set forth in 21 C.F.R. § 820, *et seq.* As explained in the Federal Register, because the Current Good Manufacturing Practice (CGMP) regulations must apply to a variety of medical devices, the regulations do not prescribe the details for how a manufacturer must produce a device. Rather, the quality system regulations provide a framework of basic requirements for each manufacturer to use in establishing a quality system appropriate to the devices designed and manufactured and the manufacturing processes employed. Manufacturers must adopt current and effective methods and procedures for each device they design

and manufacture to comply with and implement the basic requirements set forth in the quality system regulations.

87. Pursuant to 21 C.F.R. § 820.1(c), the failure to comply with any applicable provision in Part 820 renders a device adulterated under section 501(h) of the Federal Drug & Cosmetic Act ("the Act"). 21 U.S.C. § 351.

88. Pursuant to 21 C.F.R. § 820.5, each manufacturer shall establish and maintain a quality system that is appropriate for the specific medical device designed or manufactured. "Quality system" means the organizational structure, responsibilities, procedures, processes and resources for implementing quality management. 21 C.F.R. § 820.3(v).

89. Pursuant to 21 C.F.R. § 820.22, each manufacturer shall establish procedures for quality audits and conduct such audits to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system.

90. Pursuant to 21 C.F.R. § 820.30(a), each manufacturer shall establish and maintain procedures to control the design of the device in order to ensure that specified design requirements are met.

91. Pursuant to 21 C.F.R. § 820.30(d), each manufacturer shall establish and maintain procedures for defining and documenting design output in terms that allow an adequate evaluation of conformance to design input requirements.

92. Pursuant to 21 C.F.R. § 820.30(e), each manufacturer shall establish and maintain procedures to ensure that formal documented reviews of the design results are planned and conducted at appropriate stages of the device's design development.

93. Pursuant to 21 C.F.R. § 820.30(f), each manufacturer shall establish and maintain procedures for verifying the device design to confirm that the device design output meets the design input requirements.

94. Pursuant to 21 C.F.R. § 820.30(g), each manufacturer shall establish and maintain procedures for validating the device design. Design validation shall be performed under defined operating conditions on initial production units, lots or batches, or their equivalents. Design validations shall ensure that devices conform to defined user needs and intended uses and shall include testing of production units under actual or simulated use conditions.

95. Pursuant to 21 C.F.R. § 820.30(h), each manufacturer shall establish and maintain procedures to ensure that the device design is correctly translated into production specifications.

96. Pursuant to 21 C.F.R. § 820.30(i), each manufacturer shall establish and maintain procedures for the identification, documentation, validation or where appropriate verification, review and approval of design changes before their implementation.

97. Pursuant to 21 C.F.R. § 820.70(a), each manufacturer shall develop, conduct, control and monitor production processes to ensure that a device conforms to its specifications. Where deviations from device specifications could occur as a result of the manufacturing process, the manufacturer shall establish and maintain process control procedures that describe any process controls necessary to ensure conformance to specifications. Such process controls shall include:

(a) documented instructions, standard operating procedures (SOPs) and methods that define and control the manner of production;

(b) monitoring and control of process parameters and component and device characteristics during production;

(c) compliance with specified reference standards or codes;

(d) the approval of processes and process equipment; and

(e) criteria for workmanship which shall be expressed in documented standards or by means of identified and approved representative samples.

98. Pursuant to 21 C.F.R. § 820.70(b), each manufacturer shall establish and maintain procedures for changes to a specification, method, process or procedure.

99. Pursuant to 21 C.F.R. § 820.70(c), each manufacturer shall establish and maintain procedures to adequately control environmental conditions that could reasonably be expected to have an adverse effect on product quality, including

periodic inspection of environmental control system(s) to verify that the system, including necessary equipment, is adequate and functioning properly.

100. Pursuant to 21 C.F.R. § 820.70(e), each manufacturer shall establish and maintain procedures to prevent contamination of equipment or product by substances that could reasonably be expected to have an adverse effect on product quality.

101. Pursuant to 21 C.F.R. § 820.70(g), each manufacturer shall ensure that all equipment used in the manufacturing process meets specified requirement and is appropriately designed, constructed, placed and installed to facilitate maintenance, adjustment, cleaning an use.

102. Pursuant to 21 C.F.R. § 820.70(h), each manufacturer shall establish and maintain procedures for the use and removal of manufacturing material which could reasonably be expected to have an adverse effect on product quality to ensure that it is removed or limited to an amount that does not adversely affect the device's quality.

103. Pursuant to 21 C.F.R. § 820.70(i), when computers or automated data processing systems are used as part of production or the quality system, the manufacturer shall validate computer software for its intended use according to an established protocol.

104. Pursuant to 21 C.F.R. § 820.72, each manufacturer shall ensure that all inspection, measuring and test equipment, including mechanical, automated or electronic inspection and test equipment, is suitable for its intended purposes and is capable of producing valid results. Each manufacturer shall establish and maintain procedures to ensure that equipment is routinely calibrated, inspected, checked and maintained.

105. Pursuant to 21 C.F.R. § 820.75(a), where the results of a process cannot be fully verified by subsequent inspection and test, the process shall be validated with a high degree of assurance and approved according to established procedures. "Process validation" means establishing by objective evidence that a process consistently produces a result or product meeting its predetermined specifications. *See* 21 C.F.R. § 820.3(z)(1).

106. Pursuant to 21 C.F.R. § 820.75(b), each manufacturer shall establish and maintain procedures for monitoring and control of process parameters for validated processes to ensure that the specified requirements continue to be met. Each manufacturer shall ensure that validated processes are performed by qualified individuals.

107. Pursuant to 21 C.F.R. § 820.90, each manufacturer shall establish and maintain procedures to control product that does not conform to specified requirements.

108. Pursuant to 21 C.F.R. § 820.100, each manufacturer shall establish and maintain procedures for implementing corrective and preventive action. The procedures shall include requirements for:

(a) analyzing processes, work operations, concessions, quality audit reports, quality records, service records, complaints, returned product, and other sources of quality data to identify existing and potential causes of nonconforming product or other quality problems;

(b) investigating the cause of nonconformities relating to product, processes and the quality system;

(c) identifying the action(s) needed to correct and prevent recurrence of nonconforming product and other quality problems;

(d) verifying or validating the corrective and preventative action to ensure that such action is effective and does not adversely affect the finished device;

(e) implementing and recording changes in methods and procedures needed to correct and prevent identified quality problems;

(f) ensuring that information related to quality problems or nonconforming product is disseminated to those directly responsible for assuring the quality of such product or the prevention of such problems; and

(g) submitting relevant information on identified quality problems, as well as corrective and preventative actions, for management review.

109. Upon information and belief, the Profemur® Total Hip System is adulterated pursuant to 21 U.S.C. § 351 because, among other things, it failed to meet established performance standards and/or the methods, facilities or controls used for its manufacture, packing, storage or installation are not in conformity with federal requirements. *See* 21 U.S.C. § 351.

110. Upon information and belief, the Profemur® Total Hip System is misbranded because, among other things, it is dangerous to health when used in the manner prescribed, recommended or suggested in the labeling thereof. *See* 21 U.S.C. § 352.

111. Upon information and belief, the Profemur® Total Hip System is adulterated pursuant to 21 U.S.C. § 351 because Wright and/or MicroPort failed to establish and maintain CGMP for the Profemur® Total Hip System, including components, in accordance with 21 C.F.R. § 820, *et seq.*, as set forth above.

112. Upon information and belief, Wright and/or MicroPort failed to establish and maintain CGMP with respect to the quality audits, quality testing and process validation for the Profemur® Total Hip System, including its components.

113. As a result of Wright's and/or MicroPort's failure to establish and maintain CGMP as set forth above, the Profemur® Total Hip System was defective and failed, resulting in injuries and damages to Plaintiff Elaine Shubin.

114. If Wright and/or MicroPort had complied with the federal requirements regarding CGMP, the Profemur® Total Hip System would have been manufactured and/or designed properly such that it would not have resulted in injuries and damages to Plaintiff Elaine Shubin.

115. Plaintiff Elaine Shubin's injuries and damages were both factually and proximately caused by the defective Profemur® Total Hip System.

116. Plaintiff Elaine Shubin's injuries and damages were both factually and proximately caused by the unreasonably dangerous Profemur® Total Hip System.

117. Plaintiff Elaine Shubin further shows that she is entitled to recover for all noneconomic and compensatory damages allowed by law, including, but not limited to, pain and suffering for all pain and suffering that she has incurred as a result of the defective product, the follow-up surgery, rehabilitation, and constant pain that occurs as a result of the failure of the Device.

FIRST CAUSE OF ACTION

(STRICT PRODUCTS LIABILITY – MANUFACTURING DEFECT)
(As to all Defendants)

118. Plaintiffs hereby reallege and incorporate by reference all of the allegations and statements contained in Paragraphs 1 through 117, inclusive, as though fully set forth herein.

119. At all times relevant hereto, Defendants Wright and Microport designed, manufactured, distributed, sold, marketed and/or promoted the Profemur® Total Hip System, including the 1) Profemur® PHA00270 Plasma Z Stem, 2) Profemur® PHAC1232 8° var/val CoCr Modular Femoral Neck, 3) 26000010 Ceramic Femoral Head that were implanted in Plaintiff Elaine Shubin on October 30, 2015.

120. At all times relevant hereto, the Profemur® Total Hip System was expected to, and did, reach prescribing physicians and consumers, including Plaintiff Elaine Shubin and Plaintiff's physician, without a substantial change in the condition in which it was sold.

121. At all times relevant hereto, Plaintiff and Plaintiff's healthcare providers used the Profemur® Total Hip System for its intended or reasonably foreseeable purpose.

122. At all times relevant hereto, the Profemur® Total Hip System was defective and unreasonably dangerous. Such defects included, but were not limited to, a tendency to (a) generate dangerous and harmful metal debris in the patient's body; (b) corrode; (c) cause pain; (d) inhibit mobility; (e) require revision surgery; and (f) fracture.

123. Plaintiffs are informed and believe, and thereupon allege, that the Profemur® Total Hip System implanted in Plaintiff, Elaine Shubin, is defective and unreasonably dangerous because of a manufacturing defect in the alleged device, as aforesaid, which contain a condition that the manufacturer did not intend and, as a result, failed to perform as safely as an ordinary consumer would expect when the product is used in a reasonably foreseeable manner and / or because it differed from the manufacturer's design and specifications, or from typical units of the same product line.

124. As a direct, legal, proximate and producing result of the defective manufacture of the Profemur® Total Hip System implanted in Plaintiff, Elaine Shubin, Plaintiffs sustained injuries and damages as set forth above, for which the said defendants are strictly liable.

125. The dangerous, unsafe and defective manufacturing of the Profemur® Total Hip System implanted in Plaintiff, Elaine Shubin was a substantial factor in

causing Plaintiff's injuries and damages as set forth above, for which the said defendants are strictly liable.

SECOND CAUSE OF ACTION

STRICT PRODUCTS LIABILITY – FAILURE TO WARN
(As to All Defendants)

126. Plaintiffs repeat, reallege and hereby incorporate by reference all of the allegations and statements contained in Paragraphs 1 through 117 above, inclusive, as though fully set forth herein.

127. The Profemur® Total Hip System was defective and unreasonably dangerous when it left the possession of Defendants in that it failed to provide adequate warnings to alert the medical community and patients, including Plaintiffs and Plaintiff's healthcare providers, to the dangerous risks associated with the Profemur® Total Hip System when used for its intended and reasonable foreseeable purpose. The dangers and risks included, but were not limited to, a tendency to (a) generate dangerous and harmful metal debris in the patient's body; (b) cause injury and pain; (c) inhibit mobility; (d) require revision surgery; and (e) fracture.

128. At all times relevant hereto, Plaintiffs and Plaintiff's healthcare providers used the Profemur® Total Hip System for its intended or reasonably foreseeable purpose.

129. Plaintiffs and Plaintiff's healthcare providers could not have discovered any defect in the Profemur® Total Hip System through the exercise of due care.

130. Defendants knew or should have known, through complaint data and knowledge of the design's history, by the use of generally recognized and prevailing scientific/ technical/ medical knowledge available at the time of the said product's distribution, that a foreseeable use of the product may be unreasonably dangerous without adequate warnings of the danger(s) posed by potential risks and side effects associated with the Profemur® Total Hip System. Defendants knew or should have known of the defective condition, characteristics, and risks associated with the Device as previously set forth herein.

131. The warnings and instructions provided with the Profemur® Total Hip System by Defendants did not adequately warn of the potential risks and side effects of the Profemur® Total Hip System, which risks were known or scientifically knowable to Defendants.

132. Defendants had a continuing duty to warn the medical community and public, including Plaintiff and Plaintiff's healthcare providers, of the potential risks and increased failure rate associated with the Profemur® Total Hip System.

133. As a direct, legal, proximate and producing result of Defendants' failure to warn, Plaintiff sustained the injuries and damages as set forth above, for which said defendants are strictly liable.

134. Defendants' failure to adequately warn of the potential risks and side effects of the Profemur® Total Hip System was a substantial factor in causing Plaintiff's injuries and damages as set forth above, for which said defendants are strictly liable.

THIRD CAUSE OF ACTION

(STRICT PRODUCTS LIABILITY – UNREASONABLY DANGEROUS DESIGN)
(As to All Defendants)

135. Plaintiffs repeat, reallege and hereby incorporate by reference all of the allegations and statements contained in Paragraphs 1 through 117, inclusive, as though fully set forth herein.

136. At all times relevant hereto, Defendants designed, manufactured, distributed, sold, marketed and/or promoted the Profemur® Total Hip System, including the 1) Profemur® PHA00270 Plasma Z Stem, 2) Profemur® PHAC1232 8° var/val CoCr Modular Femoral Neck, 3) 26000010 Ceramic Femoral Head that were implanted in Plaintiff Elaine Shubin on October 30, 2015.

137. At all times relevant hereto, the Profemur® Total Hip System was expected to, and did, reach prescribing physicians and consumers, including

Plaintiff and Plaintiff's physician, without a substantial change in the condition in which it was sold.

138. At all times relevant hereto, Plaintiff and Plaintiff's healthcare providers used the Profemur® Total Hip System for its intended or reasonably foreseeable purpose.

139. At all times relevant hereto, the Profemur® Total Hip System was defective and unreasonably dangerous because of a design defect, as aforesaid in this complaint. Such defects included, but were not limited to, a tendency to (a) generate dangerous and harmful metal debris in the patient's body; (b) corrode; (c) cause injury and pain; (d) inhibit mobility; (e) require revision surgery; and (f) fracture.

140. Defendants knew or should have known of the unreasonably dangerous and serious risks associated with the design of the Profemur® Total Hip System. Such risks were historically and scientifically knowable to Defendants. However, Defendants performed inadequate evaluation and testing of the Profemur® Total Hip System design.

141. As a direct, legal, proximate and producing result of the defective design of the Profemur® Total Hip System implanted in Plaintiff, Plaintiff sustained injuries and damages as set forth above, for which said defendants are strictly liable.

142. Defendants' dangerous design and failure to adequately test the safety of the Profemur® Total Hip System was a substantial factor in causing Plaintiff's injuries and damages as set forth above, for which said defendants are strictly liable.

FOURTH CAUSE OF ACTION

(NEGLIGENCE)
(As to All Defendants)

143. Plaintiffs hereby reallege and incorporate by reference all of the allegations and statements contained in Paragraphs 1 through 117, inclusive, as though fully set forth herein.

144. At all times relevant hereto, Defendants designed, manufactured, distributed, sold, marketed and/or promoted the Profemur® Total Hip System for implantation into customers, such as Plaintiff, Elaine Shubin by physicians and surgeons in the U.S.

145. At all times relevant hereto, Defendants knew or should have known that the history and novel design of the Profemur® Total Hip System necessitated clinical trials and other pre-marketing evaluations of risk and efficacy. Such testing would have revealed the increased risk of failure and complications associated with the Profemur® Total Hip System. A reasonable manufacturer under the same or similar circumstances would have conducted additional testing

and evaluation of the Profemur® Total Hip System's safety and performance prior to placing the Profemur® Total Hip System into the stream of commerce.

146. At all times relevant hereto, Defendants knew or should have known of the serious complications and high failure rate associated with the Profemur® Total Hip System. Despite receiving hundreds of reports of serious complications from healthcare providers, Defendants chose (1) not to discontinue or redesign the Device; (2) not to perform any additional testing of the Profemur® Total Hip System; (3) not investigate other potential causes of the reported complications; (4) suspend sales or distribution; or (5) warn physicians and patients of the propensity of the Profemur® Total Hip System to generate dangerous and harmful metal debris in the patient's body; cause pain; inhibit mobility; fracture; and require revision surgery.

147. As a direct, legal, proximate and producing result of the Defendants' negligent design, warning, labeling, testing, manufacturing, marketing selling and promoting the Profemur® Total Hip System, Plaintiff sustained injuries as set forth above.

148. Defendants' negligent design, warning, labeling, testing, manufacturing, marketing, selling and promoting of the Profemur® Total Hip System implanted in Plaintiff, Elaine Shubin was a substantial factor in Plaintiff's injuries and damages as set forth above.

FIFTH CAUSE OF ACTION

(NEGLIGENCE – FAILURE TO RECALL/RETROFIT)
(As to all Defendants)

149. Plaintiffs hereby reallege and incorporate by reference all of the allegations and statements contained in Paragraphs 1 through 117, inclusive, as though fully set forth herein.

150. At all times relevant hereto, Defendants Wright and MicroPort knew or should have known that the design of the Profemur® Total Hip System and its warnings were dangerous or were likely to be dangerous when used in an intended or reasonably foreseeable manner.

151. Despite the severity and number of complaints Defendants Wright and MicroPort received, Defendants failed to recall, retrofit or warn patients or physicians about the danger of the Profemur® Total Hip System.

152. As a direct, legal, proximate and producing result of the Defendants' failure to recall the Profemur® Total Hip System, Plaintiffs suffered injuries and damages as set forth above.

153. Defendants' failure to recall the Profemur® Total Hip System implanted in Plaintiff, Elaine Shubin was a substantial factor in Plaintiff's injuries and damages as set forth above.

SIXTH CAUSE OF ACTION

(NEGLIGENT MISREPRESENTATION)
(As to All Defendants)

154. Plaintiffs repeat, reallege and hereby incorporate by reference all of the allegations and statements contained in Paragraphs 1 through 117 above, inclusive, as though fully set forth herein.

155. Defendants had a duty to truthfully represent to the medical community, and to Plaintiffs, Plaintiff's healthcare providers and the FDA, that the Profemur® Total Hip System had not been properly tested and not found to be safe and effective for its intended use.

156. Defendants knew or should have known that their representations that the Device was safe and effective were false and the representations regarding the safety and performance of the Profemur® Total Hip System was in fact, false.

157. Defendants failed to exercise ordinary care in determining the truth or falsity of their representations, and by misrepresenting the safety and performance of the Profemur® Total Hip System.

158. Defendants breached their duty to present truthful representations by knowingly, or by want of ordinary care, misrepresenting the safety and performance of the Profemur® Total Hip System.

159. As a direct, legal, proximate and producing result of Defendants' concealment of material facts, Plaintiff has suffered injuries and damages as set forth herein.

SEVENTH CAUSE OF ACTION

(FRAUD BY CONCEALMENT)
(As to All Defendants)

160. Plaintiffs repeat, reallege and hereby incorporate by reference all of the allegations and statements contained in Paragraphs 1 through 117 above, inclusive, as though fully set forth herein.

161. Wright and MicroPort, as manufacturers of the Profemur® Total Hip System, were armed with superior knowledge of the latent dangers associated with the Device (namely corrosion, and fretting) and had a duty to communicate these dangers to Plaintiff and Plaintiff's implanting surgeon.

162. Defendants had a duty to accurately and truthfully represent to the medical community, Plaintiff, and the public that Wright Medical Profemur CoCr Modular Neck, and the Wright Medical Profemur Total Hip System, had not been adequately tested and found to be safe and effective for the treatment of patients requiring a hip replacement. Instead, the Defendant knew, but deliberately failed to communicate this to Plaintiff or Plaintiff's surgeon.

163. Defendants had a duty to inform, but fraudulently concealed from the medical community, implanting orthopedic surgeon Dr. Ward, Plaintiff, and the public that the Wright Medical Profemur CoCr Modular Neck coupled with the Wright Medical Profemur titanium modular stem in the Wright Medical Profemur Total Hip System had an unreasonable and dangerous risk of corroding, fretting, and causing bodily injury.

164. Through the reporting of adverse events to Wright and MicroPort, and by reports from experts in metallurgy and biomechanics retained by Wright and MicroPort, Defendants knew of the risk of corrosion and subsequent adverse tissue reaction and resulting bodily injury present in the device implanted in Plaintiff but did not disclose this information. Neither Plaintiff nor Plaintiff's surgeon had this information, nor could they have discovered this information through reasonable diligence.

165. The Defendants had a duty to communicate the increased risk and known failures associated with the device implanted in Plaintiff to Plaintiff and Plaintiff's surgeon.

166. Plaintiff and Plaintiff's surgeon justifiably relied upon Defendants to communicate known risks and failures when making both the decision to implant the device and the appropriate course of treatment following Plaintiff's index surgery.

167. Had Defendants accurately and truthfully represented to the medical community, Dr. Ward, Plaintiff, and the public the material facts that it knew regarding the risks of the Profemur CoCr Modular Neck coupled with the Profemur titanium modular stem as part of the Profemur Total Hip System, Plaintiff and/or Plaintiff's healthcare provider(s) would not have utilized Defendants' Profemur Total Hip System.

168. Had Defendants not fraudulently concealed the increased risk of corrosion, effects of corrosion, and the known failures of the device from Plaintiff or Plaintiff's surgeon, Plaintiff's injuries would have been avoided or limited.

169. As a direct and proximate result of Defendants' fraudulent concealment, Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and other damages.

EIGHTH CAUSE OF ACTION

(FRAUDULENT MISREPRESENTATION)
(Against All Defendants)

170. Plaintiffs incorporate by reference as if fully set forth herein the facts alleged in paragraphs 1-117 of this Complaint.

171. Defendants, as manufacturers and distributors of the Profemur® Total Hip System armed with superior knowledge regarding the latent defects and failure rates associated with the Device, had a duty to accurately and truthfully represent to the public, the medical community, Plaintiff, and Plaintiff's surgeon, the material facts that it knew regarding the risks of the Profemur CoCr Modular Neck coupled with the Wright Medical Profemur titanium modular stem as part of the Profemur® Total Hip System.

172. Defendants made false representations of material fact to Plaintiff and/or her healthcare providers as to the safety and efficacy of the Profemur CoCr Modular Neck coupled with the Wright Medical Profemur titanium modular neck in the Profemur Total Hip System. Instead of disclosing the heightened risks of corrosion, fretting, fracture, failure, and permanent injury, Defendnats represented:

a) that there was no indication of an increased risk of adverse events due to taper junction fretting and corrosion,

b) that lab testing guaranteed structural reliability and the absence of significant micromovement and absence of fretting corrosion;

c) that product complaint data did not indicate an increased risk of corrosion for Profemur CoCr Modular Necks when coupled with Profemur titanium hip stems;

d) that, "[u]tilized in both primary and revision applications, the current [Profemur modular] neck design has been successfully employed to improve surgical outcomes with no reported failures";

e) that Profemur® cobalt-chromium modular necks would result in less fretting than occurred with titanium modular necks;

f) that Profemur® cobalt-chromium modular Necks coupled with Profemur® stems showed a total absence of corrosion in an in vivo environment; and

g) that the Profemur Total Hip System, including its component parts, were safe and effective, and were safer and more effective than other treatments for hip replacements.

173. Defendants knew that the above representations alleged in paragraph 172 were false, yet Defendants willfully, wantonly, and recklessly disregarded the inaccuracies in these representations.

174. Defendants made these false representations with the intent of defrauding and deceiving the medical community (including implanting surgeon Dr. Ward), Plaintiff, and the public, and to induce the medical community, Plaintiff's implanting surgeon, Plaintiff, and the public to utilize the Profemur CoCr Modular Neck coupled with the Profemur titanium modular stem as part of the Profemur Total Hip System. Doing so constituted a callous, reckless, willful,

and depraved indifference to the health, safety, and welfare of Plaintiff and the public.

175. Plaintiff and her implanting orthopedic surgeon Dr. Ward justifiably relied upon Defendants' false representations of material fact in deciding to utilize the Profemur Hip System, including the CoCr modular neck and titanium modular stem.

176. Had Plaintiff or her healthcare providers known the true facts about the dangers and health risks of the Profemur CoCr Modular Neck coupled with the Profemur titanium modular stem as components of the Profemur Total Hip System, they would not have utilized these products.

177. As a direct and proximate result of Defendants' fraudulent conduct, Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and other damages.

NINTH CAUSE OF ACTION

(LOSS OF CONSORTIUM)
(As to All Defendants)

178. Plaintiffs repeat, reallege and hereby incorporate by reference all of the allegations and statements contained in Paragraphs 1 through 177 above, inclusive, as though fully set forth herein.

179. Plaintiff, Patrick Shubin, was and is the lawful spouse of Plaintiff Elaine Shubin, and as such, was and is entitled to the comfort, enjoyment, society and services of his spouse.

180. As a direct and proximate result of the foregoing, Plaintiff Patrick Shubin was deprived of the comfort and enjoyment of the services and society of his spouse, Elaine Shubin, and has suffered and will continue to suffer economic loss and has otherwise been emotionally and economically injured. The Plaintiff, Patrick Shubin's injuries and damages are permanent and will continue into the future.

181. Plaintiff Patrick Shubin is entitled to recover damages for his loss of consortium in an amount to be proven at trial.

PUNITIVE DAMAGES

(As to All Defendants)

182. Plaintiffs incorporate by reference as if fully set forth herein the facts alleged above in this Complaint.

183. The acts of Defendants, as set forth above, was attended by circumstances of an evil mind, to wit: malice, or willful and wanton conduct,

and/or in reckless disregard of the consequences from which malice may be inferred and showed a total disregard for human life and human suffering.

184. The willful and wanton conduct and evil minds of Defendants was conduct either purposefully committed or Defendants acted to serve defendants' own interests, having reason to know and consciously disregarding a substantial risk that its conduct might significantly injure the rights and safety of others, or defendant consciously pursued a course of conduct knowing that it created a substantial risk of significant harm to the rights and safety of others, particularly Elaine Shubin.

185. Defendants, when they had the opportunity to do so, repeatedly failed to warn or to correct a known unreasonably dangerous condition regarding their medical device at issue.

186. Defendants knew or should have known, in light of the surrounding circumstances that its conduct would naturally and probably result in injury or damage and continued the conduct with malice or in reckless disregard of the consequences, from which malice may be inferred. Accordingly, Plaintiff is entitled to an award of punitive damages.

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PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment against Defendants, jointly and/or severally, as follows:

1. For general damages for personal injuries to Plaintiffs, according to proof;
2. For all past, current and future medical and incidental expenses, according to proof;
3. For punitive damages, according to proof;
4. For loss of consortium, according to proof;
5. For prejudgment interest, as provided by law;
6. For costs of litigation; and
7. For such other and further relief as this Court may deem just and proper.
8. loss of earnings and any decrease in earning power or capacity in the future.

Respectfully submitted, this 5th day of June, 2020.

/s/ Steve H. Patience
Steve H. Patience
SKOUSEN, GULBRANDSEN
& PATIENCE, PLC
414 East Southern Avenue
Mesa, AZ 85204
Attorneys for Plaintiffs

DEMAND FOR TRIAL BY JURY

Plaintiffs hereby demand a trial by jury to the full extent permitted by law.

/s/ Steve H. Patience
Steve H. Patience
SKOUSEN, GULBRANDSEN
& PATIENCE, PLC
414 East Southern Avenue
Mesa, AZ 85204
Attorneys for Plaintiffs