

1 Steve H. Patience  
2 State Bar No. 009537  
3 SKOUSEN, GULBRANDSEN  
4 & PATIENCE, PLC  
5 414 East Southern Avenue  
6 Mesa, AZ 85204  
7 Telephone: 480-833-8800  
8 Email: [shp@sgplaw.com](mailto:shp@sgplaw.com)  
9 Attorneys for Plaintiffs

10 **IN THE UNITED STATES DISTRICT COURT**  
11 **FOR THE DISTRICT OF ARIZONA**  
12 **FLAGSTAFF DIVISION**

13 ELAINE SHUBIN and PATRICK  
14 SHUBIN, her husband,

15 Plaintiffs,

16 v.

17 WRIGHT MEDICAL  
18 TECHNOLOGY, INC., a Delaware  
19 corporation; WRIGHT MEDICAL  
20 GROUP, INC., a Delaware  
21 corporation; and MICROPORT  
22 ORTHOPEDICS, INC., a Delaware  
23 corporation.

24 Defendants.

Case No.:

**COMPLAINT**

**COMPLAINT**

25 COMES NOW the Plaintiffs, Elaine Shubin and Patrick Shubin  
26 (“Plaintiffs”), by and through their undersigned attorneys, and files this their  
27  
28

1 Complaint for damages against Defendants, Wright Medical Technology, Inc., a  
2 Delaware corporation; Wright Medical Group, Inc., a Delaware corporation; and  
3 MicroPort Orthopedics, Inc., a Delaware corporation, and allege the following  
4 causes of action against Defendants, and each of them, as follows:  
5

6 **NATURE OF THE ACTION**  
7

8 1. Defendants have long known that their device design has an  
9 unacceptable tendency to fret and corrode at the location of the modular neck-  
10 stem-body junction during even low to moderate physical activity. Defendants  
11 have known for years that their hip replacement device – the PROFEMUR<sup>®</sup> Total  
12 Hip System with PROFEMUR<sup>®</sup> Stem (“Stem”) and PROFEMUR<sup>®</sup> Modular  
13 Neck (“Modular Neck”) (collectively “the PROFEMUR<sup>®</sup> Total Hip System” or  
14 “the Device” – was prone to fail within a few years of implantation causing severe  
15 debilitating tissue destruction. Significantly, consequent to reports of fretting-  
16 corrosion and fracture at the Stem and Modular Neck junction, Defendant  
17 MicroPort issued a recall and ceased marketing the Device. As a result of the  
18 Device’s defects and Defendants’ tortious acts/omissions, Plaintiff Elaine Shubin,  
19 and many other patients who received these devices, endured unnecessary pain and  
20 suffering; debilitating lack of mobility; and a subsequent more difficult revision  
21 surgery to replace the defective Device, giving rise to more pain and suffering,  
22  
23  
24  
25  
26  
27  
28

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

3  
4 2. This is an action for strict products liability, negligence, breach of  
5 express and implied warranties, fraudulent misrepresentation, fraudulent  
6 concealment, negligent misrepresentation, loss of consortium, and punitive  
7 damages brought by Plaintiffs Elaine Shubin and Patrick Shubin for injuries arising  
8 out of the failure of the PROFEMUR<sup>®</sup> Total Hip System, Plaintiff Elaine Shubin  
9 received as part of her total hip replacement surgery.  
10  
11

12 **PARTIES**

13 3. Plaintiffs Elaine Shubin and Patrick Shubin at all times relevant hereto  
14 were residents of Flagstaff, Coconino County, State of Arizona. Plaintiff Elaine  
15 Shubin underwent a left total hip arthroplasty surgery performed by Michelle  
16 Ward, M.D. at San Antonio Regional Hospital on October 30, 2015. At that time,  
17 the PROFEMUR<sup>®</sup> Total Hip System manufactured, designed, distributed, labeled,  
18 marketed, and warranted by Defendants was implanted into Plaintiff Elaine  
19 Shubin. Plaintiff Elaine Shubin's surgeon, medical staff, and other healthcare  
20 providers met or exceeded the standard of care applicable to the hip replacement  
21 surgery. The PROFEMUR<sup>®</sup> Total Hip System implanted on Plaintiff's left side  
22 subsequently failed, and necessitated revision surgery. At the time of Plaintiff's  
23  
24  
25  
26  
27  
28

1 index and revision surgery, Defendant MicroPort Orthopedics, Inc. marketed,  
2 promoted and distributed the PROFEMUR<sup>®</sup> Total Hip System.

3  
4 4. Defendant Wright Medical Technology, Inc. (“WMT”) is a  
5 corporation organized under the laws of the State of Delaware, with its principal  
6 place of business located in Memphis, Tennessee, and as such is a citizen of both  
7 the State of Tennessee and the State of Delaware. Defendant WMT is registered to  
8 do business in the State of Arizona and may be served with process by serving its  
9 registered agent for service, Corporation Service Company, at 2338 W. Royal  
10 Palm Road, Suite J, Phoenix, Arizona 85021. At all times relevant hereto,  
11 Defendant WMT conducted regular and sustained business in the State of Arizona  
12 by selling and distributing its products in Arizona and engaged in substantial  
13 commerce and business activity in the County of Coconino.  
14  
15  
16  
17

18 5. Defendant Wright Medical Group, Inc. (“WMG”) is a corporation  
19 organized under the laws of the State of Delaware, with its principal place of  
20 business located in Memphis, Tennessee, and as such is a citizen of both the State  
21 of Tennessee and the State of Delaware. Defendant WMG may be served with  
22 process by serving its registered agent for service, Corporation Service Company,  
23 at 2908 Poston Avenue, Nashville, Tennessee 37203-1312. At all times relevant  
24 hereto, Defendant WMG conducted regular and sustained business in the State of  
25  
26  
27  
28

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

3  
4 6. Defendant MicroPort Orthopedics, Inc. (“MicroPort”) is a corporation  
5 organized under the laws of the State of Delaware, with its headquarters and  
6 principal place of business located in Arlington, Tennessee, and as such is a citizen  
7 of the State of Tennessee and the State of Delaware. Defendant MicroPort is  
8 registered to do business in the State of Arizona and may be served with process by  
9 serving its registered agent for service, the CT Corporation System, at 3800 N.  
10 Central Avenue, Suite 460, Phoenix Arizona 85012. At all times relevant hereto,  
11 Defendant MicroPort conducted regular and substantial business in the State of  
12 Arizona by selling and distributing its products in Arizona, and engaged in  
13 substantial commerce and business activity in the County of Coconino.  
14  
15  
16  
17

### 18 **FACTUAL ALLEGATIONS**

19 7. PROFEMUR<sup>®</sup> modular necks were first marketed by Cremascoli  
20 Ortho (“Cremascoli”), a European medical device manufacturer in 1986.

21  
22 8. In December 1999, WMT and WMG (collectively “Wright”) acquired  
23 Cremascoli, its product lines, documents, and manufacturing facilities, including  
24 the Profemur<sup>®</sup> line of hip products.  
25

26 9. After the acquisition of Cremascoli, Wright re-designed the  
27 Profemur<sup>®</sup> modular artificial hip stem and modular neck, expanded the product line  
28

1 to include additional titanium models or versions of Profemur<sup>®</sup> stems and  
2 Profemur<sup>®</sup> modular necks, and rebranded the Cremascoli titanium modular neck  
3 product line, and compatible titanium artificial hip stems, as the Wright Profemur<sup>®</sup>  
4 Total Hip System.  
5

6 10. By way of what is known as Section 510(k) premarket notification  
7 process, on December 13, 2000, Wright received clearance from the U.S. Food and  
8 Drug Administration (FDA) to distribute in the United States its first titanium  
9 modular neck and stem artificial hips.  
10  
11

12 11. The FDA never approved the safety or effectiveness of Wright's  
13 newly rebranded hip implant system and product line of modular necks, but instead  
14 merely accepted Wright's assertion that the Profemur<sup>®</sup> Hip System was  
15 substantially equivalent to an already legally marketed device (i.e., the Cremascoli  
16 modular neck component acquired by Wright in December 1999).  
17  
18

19 12. The 510(k)-clearance process is distinct from the FDA pre-market  
20 approval (PMA) process in that clearance does not require clinical confirmation of  
21 safety and effectiveness and as such the manufacturer retains all liability for the  
22 assertions of safety and effectiveness.  
23  
24

25 13. Sometime after December 13, 2000, Wright began to manufacture,  
26 label, market, promote, distribute and sell in the United States the hip implant  
27  
28

1 devices branded as “Profemur<sup>®</sup> Total Hip System” under the 510(k) clearance,  
2 which included titanium stems and titanium modular necks.

3  
4 14. The Wright Medical Profemur<sup>®</sup> modular necks that were distributed  
5 by Wright after December 13, 2000, and before August 25, 2009, were all made of  
6 the titanium-aluminum-vanadium alloy known as Ti6Al4V.  
7

8 15. In the year 2000 and in all years thereafter to the present, Ti6Al4V  
9 was an alloy generally available for use in manufacturing implantable medical  
10 devices.  
11

12 16. In the year 2000 and in all years thereafter to the present, monoblock  
13 hip implant stems without modular neck-stem junctions were readily available in  
14 the market.  
15

16 17. In various marketing and promotional material published and  
17 distributed by Wright from approximately the year 2002, and into the year 2005,  
18 and available to Wright’s sales representatives and distributors, surgeons, patients  
19 and the general public, Wright made the following representations, statements,  
20 claims and guarantees about its Profemur<sup>®</sup> modular necks:  
21

22  
23 The modular neck used with the Profemur<sup>®</sup> hip has been employed by  
24 Wright Cremascoli for over fifteen years. The necks were designed in 1985  
25 and have been successfully implanted in over 50,000 patients requiring both  
26 primary and revision hip procedures. The necks are used in other Wright  
27 Cremascoli hip systems besides the Profemur<sup>®</sup> hip. None of the necks has  
experienced a clinical failure since their inception [emphasis added].  
28

1 and

2 The modular neck system, designed by Cremascoli in 1985 (U.S. Patent No.  
3 4,957,510), has now been successfully implanted in over 50,000 patients  
4 requiring both primary and revision hip arthroplasty. Extensive laboratory  
5 tests have proven that the coupling between the modular neck and femoral  
6 implant guarantees:

- 7 • Structural reliability
- 8 • Absence of significant micromovement
- 9 • Absence of fretting corrosion

10 [emphasis added].

11 [Wright Medical Technology Monograph MH688-102<sup>©</sup> 2004].

12 18. On or about April 19, 2005, Wright first reported to the FDA a  
13 Profemur<sup>®</sup> modular neck clinical failure where a Ti6Al4V modular neck implanted  
14 in a patient experienced a catastrophic fracture (i.e., breaking into two pieces) due  
15 to fretting and corrosion at the oblong tapered distal end where the neck is seated  
16 in the stem.  
17

18 19. After receiving notice of the first modular neck fracture, Wright  
19 received notice of additional modular neck clinical failures from corrosion based  
20 fractures of the modular necks.  
21

22 20. The number of Profemur<sup>®</sup> Ti6Al4V modular neck clinical corrosion  
23 based fractures has continued to increase over time, and continues to increase to  
24 the present day, now numbering more than 800 such clinical failures.  
25  
26  
27  
28



1           21. As the number of reported Wright Ti6Al4V modular neck fractures  
2 continued to increase and the FDA became aware of its dismal clinical  
3 performance, case studies appeared in medical journals reporting the fracture of  
4 Wright titanium Profemur<sup>®</sup> modular necks and identifying micromotion and  
5 fretting corrosion at the neck-stem junction as the cause and mode of failure.  
6  
7

8           22. At some point in time prior to August 25, 2009, Wright had notice  
9 that a higher than normal rate of early failure of its Profemur<sup>®</sup> line of hip implant  
10 devices were failing by fracture at the modular neck junction secondary to  
11 micromotion, fretting and corrosion.  
12

13           23. As the number of reported Wright Ti6Al4V Profemur<sup>®</sup> modular neck  
14 fractures continued to increase, Wright, rather than redesigning its hip implant  
15 system to eliminate the modular neck-stem junction and thereby eliminate  
16 micromotion and fretting-corrosion, instead began to design and develop a  
17 Profemur<sup>®</sup> modular neck made of a cobalt chrome (CoCr) metal alloy utilizing the  
18 same taper design as the titanium modular necks and the same Profemur<sup>®</sup> stems.  
19  
20  
21

22           24. On April 16, 2009, Wright submitted a Section 510(k) premarket  
23 notification of intent to market a device generally identified as Profemur<sup>®</sup> hip  
24 system modular necks made of a cobalt chrome alloy to the FDA to be coupled  
25 with existing Profemur<sup>®</sup> stems.  
26  
27  
28

1           25. On or about August 25, 2009, Wright began to market and offer for  
2 distribution and sale in the United States Profemur<sup>®</sup> modular Necks made of cobalt  
3 chromium alloy, and Wright simultaneously began withdrawing from the market  
4 its Profemur<sup>®</sup> modular necks comprised of Ti6Al4V titanium alloy.  
5

6           26. Wright could have eliminated the potential for fretting and corrosion  
7 at the modular neck junction of its Profemur<sup>®</sup> hip implants by redesigning and/or  
8 abandoning modularity and manufacturing, designing, and marketing monoblock  
9 stems, but it chose not to do so because Wright did not want to lose its investment  
10 in the market share for the use of its modular stems in primary hip implant  
11 arthroplasties.  
12  
13

14           27. In promoting its Profemur<sup>®</sup> CoCr modular Necks, Wright claimed that  
15 the cobalt chrome modular Necks would result in less fretting than occurred with  
16 Ti6Al4V modular necks.  
17  
18

19           28. The design of the Profemur<sup>®</sup> CoCr modular Neck, when coupled with  
20 the design of the titanium Profemur<sup>®</sup> hip Stems, is such that it in fact promotes the  
21 process of fretting corrosion of more harmful metal particles at the modular Neck-  
22 Stem junction.  
23

24           29. The Profemur<sup>®</sup> CoCr modular Necks that Wright designed and  
25 manufactured were designed to be used with most, if not all, of the same femoral  
26  
27  
28

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

3  
4 30. While promoting its Profemur<sup>®</sup> CoCr modular Necks Wright Medical  
5 stated, “[p]roduct complaint data reported to Wright to date does not indicate an  
6 increased risk, as compared to traditional titanium necks, of adverse events due to  
7 taper junction fretting and corrosion or fractures for Profemur<sup>®</sup> CoCr modular  
8 Necks.” [See Profemur<sup>®</sup> CoCr Modular Necks Frequently Asked Questions,  
9 Wright Medical publication MH 1619-812.]  
10  
11

12 31. Wright’s statement in its promotional materials that “[p]roduct  
13 complaint data reported to Wright to date does not indicate an increased risk, as  
14 compared to traditional titanium necks, of adverse events due to taper junction  
15 fretting and corrosion or fractures for Profemur<sup>®</sup> CoCr modular Necks,” was not  
16 supported by unbiased sound scientific testing.  
17  
18

19 32. The claim by Wright that “[p]roduct complaint data reported to  
20 Wright to date does not indicate an increased risk, as compared to traditional  
21 titanium necks, of adverse events due to taper junction fretting and corrosion or  
22 fractures for Profemur<sup>®</sup> CoCr modular Necks” was false and/or misleading.  
23  
24

25 33. While promoting its Profemur<sup>®</sup> CoCr modular Necks, Wright claimed  
26 that its CoCr modular Necks would result in less fretting than occurred with  
27 titanium modular necks.  
28

1           34. Claims by Wright that its CoCr modular Necks would result in less  
2 fretting than occurred with titanium (Ti6Al4V) modular necks were not supported  
3 by unbiased, sound scientific testing.  
4

5           35. Claims by Wright that its CoCr modular Necks would result in less  
6 fretting than occurred with titanium (Ti6Al4V) modular necks were false and/or  
7 misleading.  
8

9           36. The design of the Profemur<sup>®</sup> CoCr modular Neck, when coupled with  
10 the design of the titanium (Ti6Al4V) Profemur<sup>®</sup> hip Stems, is such that it in fact  
11 encourages the process of fretting corrosion at the modular Neck-Stem junction.  
12

13           37. Prior to offering its Profemur<sup>®</sup> CoCr modular Necks for distribution  
14 or sale in the United States, Wright nor MicroPort adequately tested the design of  
15 CoCr Profemur<sup>®</sup> modular Necks for fretting corrosion or the biological effects of  
16 cobalt and chromium corrosion, metal debris and metal ions on the body of  
17 patients.  
18

19           38. Prior to offering its Profemur<sup>®</sup> CoCr modular Necks for distribution  
20 or sale in the United States, Wright nor MicroPort adequately tested the design of  
21 the CoCr Profemur<sup>®</sup> modular Necks for corrosion or the biological effect of  
22 corrosion on the body after implantation in patients.  
23  
24  
25  
26  
27  
28

1           39. Wright rushed the Profemur<sup>®</sup> CoCr modular Necks to market without  
2 adequately testing it for in vivo performance, including, but not limited to,  
3 resistance to fretting and corrosion or the effects of corrosion on human tissue.  
4

5           40. Wright rushed the Profemur<sup>®</sup> CoCr modular Necks to market in order  
6 to preserve market share and its profits from the sale of its failing Profemur<sup>®</sup> hip  
7 implant products.  
8

9           41. Years before Plaintiff Elaine Shubin was implanted with the Device,  
10 Wright had been informed that the Profemur<sup>®</sup> CoCr modular Necks were corroding  
11 in patients to the extent that revision surgeries were necessary to remove the  
12 Profemur<sup>®</sup> CoCr modular Necks.  
13

14           42. In January of 2014, Wright sold the OrthoRecon Division, Wright's  
15 operating unit for the manufacture and sale of Wright's hip and knee implants, to  
16 MicroPort.  
17

18           43. MicroPort and Wright knew or should have known that as of October  
19 30, 2015, the date Plaintiff Elaine Shubin received her Wright Profemur<sup>®</sup> Total  
20 Hip System that:  
21

22           (a) Wright and MicroPort had not adequately tested the Profemur<sup>®</sup>  
23 CoCr modular Necks to simulate in vivo performance for resistance to  
24 fretting-corrosion;  
25  
26  
27  
28

1 (b) MicroPort had not adequately tested the Profemur<sup>®</sup> Total Hip  
2 System;

3 (c) Wright and MicroPort had not adequately tested the Profemur<sup>®</sup>  
4 CoCr modular Necks to simulate in vivo performance for resistance to  
5 corrosion;  
6

7 (d) The Profemur<sup>®</sup> CoCr modular Necks would be subject to  
8 fretting-corrosion;  
9

10 (e) There was an increased risk of fretting-corrosion at the Neck-  
11 Stem junction;  
12

13 (f) There was an increased risk of corrosion at the Neck-Stem  
14 junction;  
15

16 and

17 (g) There was a substantial risk that patients' bodies would be  
18 adversely affected by the exposure to corrosion, metal debris and metal ions  
19 secondary to cobalt and chromium fretting and corrosion.  
20

21 44. The Neck-Stem junctions of the Profemur<sup>®</sup> CoCr modular Neck,  
22 coupled with a Profemur<sup>®</sup> titanium hip stem, are subject to significant movement  
23 which results in fretting-corrosion, pitting corrosion, metal debris cast off and  
24 metal ion release.  
25  
26  
27  
28

1           45. Product complaint data reported to Wright and MicroPort prior to  
2 October 30, 2015 indicated an increased risk of adverse events due to tissue  
3 exposure to metal debris and ion cast off from taper junction fretting and corrosion  
4 of the Profemur<sup>®</sup> CoCr modular Necks when coupled with Profemur<sup>®</sup> titanium hip  
5 Stems, as compared to traditional titanium necks or monoblock stems.  
6  
7

8           46. Product complaint data reported to Wright and MicroPort prior to  
9 October 30, 2015 indicated an increased risk of adverse events due to corrosion, as  
10 compared to traditional monoblock stems or titanium necks when coupled with the  
11 Profemur<sup>®</sup> hip stems.  
12

13           47. Based upon what Wright and MicroPort knew or should have known  
14 before October 30, 2015, Wright and MicroPort should have informed orthopedic  
15 surgeons using the Profemur<sup>®</sup> Total Hip Systems that there was an increased risk  
16 of fretting and corrosion for Profemur<sup>®</sup> CoCr modular Necks when coupled with  
17 Profemur<sup>®</sup> titanium hip stems.  
18  
19

20           48. The Profemur<sup>®</sup> CoCr modular Neck, Profemur<sup>®</sup> titanium modular  
21 Stem and the Profemur<sup>®</sup> Total Hip System are defective and unreasonably  
22 dangerous because of their design defects in that the harmful characteristics or  
23 consequences inherent in the product's use for hip replacement, when weighed  
24 against the utility or benefit derived from the product, outweigh the benefits which  
25 might have been gained by placing the said defective devices product in the body  
26  
27  
28

1 of Plaintiff Elaine Shubin. Further, the said devices were defective and  
2 unreasonably dangerous in that they failed to perform as safely as an ordinary  
3 consumer would expect when they were used in a reasonably foreseeable manner.  
4

5 49. Additionally, the Profemur<sup>®</sup> CoCr modular Neck, Profemur<sup>®</sup> titanium  
6 modular Stem and the Profemur<sup>®</sup> Total Hip System implanted in Plaintiff Elaine  
7 Shubin were defective in manufacture, as Wright manufactured same such that the  
8 tolerances between the Stem and Neck components did not comply with Wright's  
9 design specifications.  
10  
11

12 50. Based upon the facts and allegations set forth above, the Profemur<sup>®</sup>  
13 CoCr modular Neck, Profemur<sup>®</sup> titanium Stem, and the Profemur<sup>®</sup> Total Hip  
14 System are defective and unreasonably dangerous in labeling in that they do not  
15 provide adequate warnings of the dangers or information of said risks when the  
16 device is used in a reasonably foreseeable manner.  
17  
18

19 51. Based upon the facts and allegations set forth above, the Profemur<sup>®</sup>  
20 CoCr modular Necks, Profemur<sup>®</sup> titanium modular Stem, and the Profemur<sup>®</sup> Total  
21 Hip System are defective and unreasonably dangerous in that the risks that were  
22 inherent in the product being used for hip replacement, when weighed against the  
23 alleged utility or benefit derived from the product's use, outweigh the benefit.  
24  
25

26 52. Defendants WMT, WMG, and MicroPort were negligent and / or  
27 strictly liable in design, manufacture, distribution, sale, marketing, promotion, and  
28



1 labeling of the Profemur<sup>®</sup> CoCr modular Neck, Profemur<sup>®</sup> titanium modular Stem,  
2 and the Profemur<sup>®</sup> Total Hip System.

3  
4 53. Defendants were negligent and / or strictly liable in the failure to warn  
5 patients and/or surgeons that it had received product complaint data that indicated  
6 an increased risk of adverse events due to taper junction fretting and cobalt  
7 chromium corrosion, as compared to other available safe alternative devices.  
8

9 54. Defendants were negligent and / or strictly liable in failing to warn  
10 patients and surgeons that they had received product complaint data that indicated  
11 an increased risk of adverse events due to corrosion, as compared to other available  
12 safe alternative devices.  
13  
14

15 **PLAINTIFF'S INJURIES AND DAMAGES**

16 **PLAINTIFF ELAINE SHUBIN'S PROFEMUR<sup>®</sup> HIP**

17  
18 55. On or about October 30, 2015, Plaintiff Elaine Shubin had a  
19 Profemur<sup>®</sup> Total Hip System implanted in her left hip ("Index Surgery") in a  
20 procedure known as a total hip arthroplasty (or "THA").  
21

22 56. Orthopedic surgeon Michelle Ward, M.D. ("Dr. Ward") performed the  
23 Index Surgery during which she implanted the Profemur<sup>®</sup> Total Hip System in  
24 Plaintiff Elaine Shubin.  
25

26 57. Plaintiff Elaine Shubin's Index Surgery was performed at San  
27 Antonio Regional Hospital in Upland, California.  
28

1           58. Dr. Ward did not breach any generally accepted standard of care in  
2 the field of orthopedic surgery in her care and treatment of Plaintiff Elaine Shubin  
3 or negligently cause any injury to Plaintiff in any of the following respects:  
4

5           (a) In the care or treatment that she provided to Plaintiff Elaine  
6 Shubin prior to beginning the hip implant surgery;  
7

8           (b) In the hip implant surgery, she performed on Plaintiff Elaine  
9 Shubin;  
10

11           or

12           (c) In the care or treatment that she provided to Plaintiff Elaine  
13 Shubin subsequent to Plaintiff's hip implant surgery.  
14

15           59. Based upon the patient population that Wright and MicroPort intended  
16 the Device to be implanted in, at the time of Plaintiff Elaine Shubin's Index  
17 Surgery, she was an appropriate patient to be implanted with the Profemur<sup>®</sup> Total  
18 Hip System.  
19

20           60. Dr. Ward recommended the Profemur Total Hip System to Plaintiff  
21 Elaine Shubin and indicated that the Device was appropriate for her.  
22

23           61. Plaintiff Elaine Shubin reasonably relied upon Dr. Ward in deciding  
24 to proceed with hip replacement surgery and have the Profemur<sup>®</sup> Total Hip System  
25 implanted.  
26  
27  
28

1           62. Before or during the course of Plaintiff Elaine Shubin’s Index  
2 Surgery, Defendants MicroPort and/or Wright arranged for the Profemur<sup>®</sup> Total  
3 Hip System that was implanted in Plaintiff to be delivered to San Antonio Regional  
4 Hospital and/or Dr. Ward for implantation in Plaintiff Elaine Shubin.  
5

6           63. Defendants, directly or through their subsidiaries or affiliates,  
7 designed, manufactured, distributed, marketed, delivered and sold in the United  
8 States various prosthetic orthopedic devices, including the Profemur<sup>®</sup> Total Hip  
9 System implanted in Plaintiff Elaine Shubin during the Index Surgery.  
10

11           64. At the Index Surgery, each of the components of Plaintiff Elaine  
12 Shubin’s Profemur<sup>®</sup> Total Hip System was in substantially the same condition in  
13 all relevant respects as when they left Defendants’ control.  
14

15           65. At all times relevant hereto, Plaintiff Elaine Shubin used the  
16 Profemur<sup>®</sup> Total Hip System implanted during the Index Surgery in a normal and  
17 reasonably foreseeable manner.  
18

19           66. On or about March 9, 2020, Plaintiff Elaine Shubin reported to Dr.  
20 Amber Randall (“Dr. Randall”) for revision surgery of her failed hip prosthesis  
21 (“Revision Surgery”). Dr. Randall recommended the revision surgery after  
22 Plaintiff Elaine Shubin presented with elevated cobalt ion level, severe pain, and  
23 lack of mobility.  
24  
25  
26  
27  
28

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

3  
4           68. But for the fact that the CoCr modular Neck of Plaintiff Elaine  
5 Shubin's Device had corroded causing it to fail and injure Plaintiff, Plaintiff's  
6 Device was not otherwise in need of revision.

7  
8           69. On or about March 9, 2020, it was discovered that the Device failed  
9 due to corrosion of the oblong taper of the Profemur<sup>®</sup> CoCr modular Neck where it  
10 seated in the pocket of the Profemur<sup>®</sup> titanium Stem, which caused continuing and  
11 otherwise irreversible physical injury to Plaintiff Elaine Shubin.

12  
13           70. On or about March 9, 2020, the Profemur<sup>®</sup> Total Hip System  
14 implanted in Plaintiff Elaine Shubin's left hip was discovered to have failed as a  
15 direct and proximate result of the actions, conduct, negligence, and breach of  
16 duties of the Defendants, as alleged in this Complaint.

17  
18           71. The Profemur<sup>®</sup> Total Hip System (and its components), to include the  
19 Device implanted in Plaintiff Elaine Shubin was not merchantable, but was  
20 defective and unreasonably dangerous for its intended and/or reasonably  
21 foreseeable uses in that:

22  
23  
24 (a) it was and is defective and unreasonably dangerous under Arizona's product  
25 liability law as a result of one or more or a combination of the following:  
26  
27  
28

1 (i) the Neck was manufactured/designed in such a manner as to be subjected to  
2 excessive micromotion and fretting corrosion, thereby increasing the potential for  
3 failure;  
4

5 (ii) the Neck was manufactured/designed in such a manner as to be subjected to  
6 excessive micromotion, fretting and corrosion, thereby increasing the potential for  
7 injury and failure;  
8

9 (iii) the surface of the section of the Neck that was inserted into the modular  
10 Stem was manufactured/designed in such a manner as to increase the potential for  
11 fretting and corrosion, thereby increasing the potential for injury and failure;  
12

13 (iv) the portion of the Neck that was inserted into the modular Stem was in a  
14 narrow, confined space, thereby increasing the potential for fretting, corrosion,  
15 injury and failure;  
16

17 (v) the components were manufactured/designed in such a way as to make the  
18 modular Neck component susceptible to micromotion, fretting and corrosion,  
19 thereby increasing the potential for injury and failure;  
20

21 (vi) the components were manufactured/designed in such a way as to cause  
22 dissimilar metals (i.e., a CoCr modular Neck and titanium modular Stem) to mate  
23 by insertion into a narrow, confined space, thereby increasing the potential for  
24 corrosion; and  
25  
26  
27  
28

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28

(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.

1           74. The Device was not tested for the FDA Section 510(k) Premarket  
2 Notification Process under conditions that were known would be encountered in  
3 the normal in vivo patient environment.  
4

5           75. The testing performed by Wright and MicroPort of the Device did not  
6 adhere to or meet FDA guidance.  
7

8           76. The Device's design was known by Defendants to be failing from  
9 fretting and corrosion of the modular Neck-Stem junction prior to the day of its  
10 FDA 510(k) Premarket Notification Application.  
11

12           77. The Device was known by Defendants to be failing at higher than  
13 expected rates from micromotion, fretting and corrosion of the modular Neck-Stem  
14 junction prior to the date of its implantation in Plaintiff Elaine Shubin during the  
15 Index Surgery.  
16

17           78. The Device's design was known by Defendants to be failing at higher  
18 than expected rates due to fretting and corrosion prior to the date of Plaintiff Elaine  
19 Shubin's Revision Surgery, during which the Device was discovered to be  
20 corroded at the Neck-Stem junction.  
21

22           79. Prior to the Index Surgery, Defendants did not warn patients,  
23 surgeons, customers, or their sales representatives/distributors that the Device was  
24 known to be failing from corrosion at higher than expected rates.  
25  
26  
27  
28

1           80. On or about March 9, 2020, Plaintiff Elaine Shubin discovered the  
2 Device implanted in her left side failed due to corrosion as a result of one or more  
3 or a combination of the foregoing unreasonably dangerous conditions.  
4

5           81. As a direct and proximate result of the failure of the Profemur<sup>®</sup> Total  
6 Hip System, Plaintiff Elaine Shubin has sustained injuries and damages, including,  
7 but not limited to:  
8

9 (a) undergoing surgery to remove and replace the failed prosthesis and repair  
10 the damage that failure caused;  
11

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

13 (c) permanent diminishment of her ability to participate in and enjoy the affairs  
14 of life;  
15

16 (d) medical bills associated with the revision surgery, rehabilitation, and  
17 recovery therefrom;  
18

19 (e) future medical expenses;

20 (f) disfigurement; and  
21

22 (g) permanent physical impairment.

23 (h) serious and permanent physical injuries to bone, muscle, tendons, tissues and  
24 nerves in her hip and pelvis;  
25

26 (i) loss of earnings and any decrease in earning power or capacity in the future.  
27  
28



1                   **FEDERAL STATUTORY AND REGULATORY REQUIREMENTS**

2                   82. Pursuant to federal law, a medical device is deemed to be adulterated  
3 if, among other things, it fails to meet established performance standards, or if the  
4 methods, facilities or controls used for its manufacture, packing, storage or  
5 installation are not in conformity with federal requirements. 21 U.S.C. § 351.  
6  
7

8                   83. Pursuant to federal law, a device is deemed to be misbranded if,  
9 among other things, its labeling is false or misleading in any particular, or if it is  
10 dangerous to health when used in the manner prescribed, recommended or  
11 suggested in the labeling thereof. 21 U.S.C. § 352.  
12

13                   84. Pursuant to federal law, manufacturers are required to comply with  
14 FDA regulation of medical devices, including FDA requirements for records and  
15 reports, in order to prohibit introduction of medical devices that are adulterated or  
16 misbranded, and to assure the safety and effectiveness of medical devices. In  
17 particular, manufacturers must keep records and make reports if any medical  
18 device may have caused or contributed to death or serious injury, or if the device  
19 has malfunctioned in a manner likely to cause or contribute to death or serious  
20 injury. Federal law also mandates that the FDA establish regulations requiring a  
21 manufacturer of a medical device to report promptly to FDA any correction or  
22 removal of a device undertaken to reduce a risk to health posed by the device, or to  
23  
24  
25  
26  
27  
28

1 remedy a violation of federal law by which a device may present a risk to health.  
2 21 U.S.C. § 360(i).

3  
4 85. Pursuant to federal law, the Secretary of Health and Human Services  
5 may prescribe regulations requiring that the methods used in, and the facilities and  
6 controls used for, the manufacture, pre-production design validation (including a  
7 process to assess the performance of a device, but not including an evaluation of  
8 the safety or effectiveness of a device), packaging, storage and installation of a  
9 device conform to current good manufacturing practice, as prescribed in such  
10 regulations, to assure that the device will be safe and effective and otherwise in  
11 compliance with federal law.  
12  
13  
14

15 86. The regulations requiring conformance to good manufacturing  
16 practices are set forth in 21 C.F.R. § 820, *et seq.* As explained in the Federal  
17 Register, because the Current Good Manufacturing Practice (CGMP) regulations  
18 must apply to a variety of medical devices, the regulations do not prescribe the  
19 details for how a manufacturer must produce a device. Rather, the quality system  
20 regulations provide a framework of basic requirements for each manufacturer to  
21 use in establishing a quality system appropriate to the devices designed and  
22 manufactured and the manufacturing processes employed. Manufacturers must  
23 adopt current and effective methods and procedures for each device they design  
24  
25  
26  
27  
28

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

3  
4 87. Pursuant to 21 C.F.R. § 820.1(c), the failure to comply with any  
5 applicable provision in Part 820 renders a device adulterated under section 501(h)  
6 of the Federal Drug & Cosmetic Act (“the Act”). 21 U.S.C. § 351.  
7

8 88. Pursuant to 21 C.F.R. § 820.5, each manufacturer shall establish and  
9 maintain a quality system that is appropriate for the specific medical device  
10 designed or manufactured. “Quality system” means the organizational structure,  
11 responsibilities, procedures, processes and resources for implementing quality  
12 management. 21 C.F.R. § 820.3(v).  
13  
14

15 89. Pursuant to 21 C.F.R. § 820.22, each manufacturer shall establish  
16 procedures for quality audits and conduct such audits to assure that the quality  
17 system is in compliance with the established quality system requirements and to  
18 determine the effectiveness of the quality system.  
19

20 90. Pursuant to 21 C.F.R. § 820.30(a), each manufacturer shall establish  
21 and maintain procedures to control the design of the device in order to ensure that  
22 specified design requirements are met.  
23

24 91. Pursuant to 21 C.F.R. § 820.30(d), each manufacturer shall establish  
25 and maintain procedures for defining and documenting design output in terms that  
26 allow an adequate evaluation of conformance to design input requirements.  
27  
28

1           92. Pursuant to 21 C.F.R. § 820.30(e), each manufacturer shall establish  
2 and maintain procedures to ensure that formal documented reviews of the design  
3 results are planned and conducted at appropriate stages of the device's design  
4 development.  
5

6           93. Pursuant to 21 C.F.R. § 820.30(f), each manufacturer shall establish  
7 and maintain procedures for verifying the device design to confirm that the device  
8 design output meets the design input requirements.  
9

10           94. Pursuant to 21 C.F.R. § 820.30(g), each manufacturer shall establish  
11 and maintain procedures for validating the device design. Design validation shall  
12 be performed under defined operating conditions on initial production units, lots or  
13 batches, or their equivalents. Design validations shall ensure that devices conform  
14 to defined user needs and intended uses and shall include testing of production  
15 units under actual or simulated use conditions.  
16  
17

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

22           96. Pursuant to 21 C.F.R. § 820.30(i), each manufacturer shall establish  
23 and maintain procedures for the identification, documentation, validation or where  
24 appropriate verification, review and approval of design changes before their  
25 implementation.  
26  
27  
28

1           97. Pursuant to 21 C.F.R. § 820.70(a), each manufacturer shall develop,  
2 conduct, control and monitor production processes to ensure that a device  
3 conforms to its specifications. Where deviations from device specifications could  
4 occur as a result of the manufacturing process, the manufacturer shall establish and  
5 maintain process control procedures that describe any process controls necessary to  
6 ensure conformance to specifications. Such process controls shall include:  
7

8 (a) documented instructions, standard operating procedures (SOPs) and methods  
9 that define and control the manner of production;  
10

11 (b) monitoring and control of process parameters and component and device  
12 characteristics during production;  
13

14                   (c) compliance with specified reference standards or codes;

15                   (d) the approval of processes and process equipment; and  
16

17 (e) criteria for workmanship which shall be expressed in documented standards  
18 or by means of identified and approved representative samples.  
19

20           98. Pursuant to 21 C.F.R. § 820.70(b), each manufacturer shall establish  
21 and maintain procedures for changes to a specification, method, process or  
22 procedure.  
23

24           99. Pursuant to 21 C.F.R. § 820.70(c), each manufacturer shall establish  
25 and maintain procedures to adequately control environmental conditions that could  
26 reasonably be expected to have an adverse effect on product quality, including  
27  
28

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

3  
4 100. Pursuant to 21 C.F.R. § 820.70(e), each manufacturer shall establish  
5 and maintain procedures to prevent contamination of equipment or product by  
6 substances that could reasonably be expected to have an adverse effect on product  
7 quality.  
8

9 101. Pursuant to 21 C.F.R. § 820.70(g), each manufacturer shall ensure that  
10 all equipment used in the manufacturing process meets specified requirement and  
11 is appropriately designed, constructed, placed and installed to facilitate  
12 maintenance, adjustment, cleaning an use.  
13

14  
15 102. Pursuant to 21 C.F.R. § 820.70(h), each manufacturer shall establish  
16 and maintain procedures for the use and removal of manufacturing material which  
17 could reasonably be expected to have an adverse effect on product quality to  
18 ensure that it is removed or limited to an amount that does not adversely affect the  
19 device's quality.  
20

21  
22 103. Pursuant to 21 C.F.R. § 820.70(i), when computers or automated data  
23 processing systems are used as part of production or the quality system, the  
24 manufacturer shall validate computer software for its intended use according to an  
25 established protocol.  
26  
27  
28

1           104. Pursuant to 21 C.F.R. § 820.72, each manufacturer shall ensure that  
2 all inspection, measuring and test equipment, including mechanical, automated or  
3 electronic inspection and test equipment, is suitable for its intended purposes and is  
4 capable of producing valid results. Each manufacturer shall establish and maintain  
5 procedures to ensure that equipment is routinely calibrated, inspected, checked and  
6 maintained.  
7  
8

9           105. Pursuant to 21 C.F.R. § 820.75(a), where the results of a process  
10 cannot be fully verified by subsequent inspection and test, the process shall be  
11 validated with a high degree of assurance and approved according to established  
12 procedures. “Process validation” means establishing by objective evidence that a  
13 process consistently produces a result or product meeting its predetermined  
14 specifications. *See* 21 C.F.R. § 820.3(z)(1).  
15  
16  
17

18           106. Pursuant to 21 C.F.R. § 820.75(b), each manufacturer shall establish  
19 and maintain procedures for monitoring and control of process parameters for  
20 validated processes to ensure that the specified requirements continue to be met.  
21 Each manufacturer shall ensure that validated processes are performed by qualified  
22 individuals.  
23  
24

25           107. Pursuant to 21 C.F.R. § 820.90, each manufacturer shall establish and  
26 maintain procedures to control product that does not conform to specified  
27 requirements.  
28

1           108. Pursuant to 21 C.F.R. § 820.100, each manufacturer shall establish  
2 and maintain procedures for implementing corrective and preventive action. The  
3 procedures shall include requirements for:  
4

5           (a) analyzing processes, work operations, concessions, quality  
6 audit reports, quality records, service records, complaints, returned product,  
7 and other sources of quality data to identify existing and potential causes of  
8 nonconforming product or other quality problems;  
9

10           (b) investigating the cause of nonconformities relating to product,  
11 processes and the quality system;  
12

13           (c) identifying the action(s) needed to correct and prevent  
14 recurrence of nonconforming product and other quality problems;  
15

16           (d) verifying or validating the corrective and preventative action to  
17 ensure that such action is effective and does not adversely affect the finished  
18 device;  
19

20           (e) implementing and recording changes in methods and  
21 procedures needed to correct and prevent identified quality problems;  
22

23           (f) ensuring that information related to quality problems or  
24 nonconforming product is disseminated to those directly responsible for  
25 assuring the quality of such product or the prevention of such problems; and  
26  
27  
28



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

3  
4 109. Upon information and belief, the Profemur<sup>®</sup> Total Hip System is  
5 adulterated pursuant to 21 U.S.C. § 351 because, among other things, it failed to  
6 meet established performance standards and/or the methods, facilities or controls  
7 used for its manufacture, packing, storage or installation are not in conformity with  
8 federal requirements. *See* 21 U.S.C. § 351.

9  
10  
11 110. Upon information and belief, the Profemur<sup>®</sup> Total Hip System is  
12 misbranded because, among other things, it is dangerous to health when used in the  
13 manner prescribed, recommended or suggested in the labeling thereof. *See* 21  
14 U.S.C. § 352.

15  
16 111. Upon information and belief, the Profemur<sup>®</sup> Total Hip System is  
17 adulterated pursuant to 21 U.S.C. § 351 because Wright and/or MicroPort failed to  
18 establish and maintain CGMP for the Profemur<sup>®</sup> Total Hip System, including  
19 components, in accordance with 21 C.F.R. § 820, *et seq.*, as set forth above.

20  
21  
22 112. Upon information and belief, Wright and/or MicroPort failed to  
23 establish and maintain CGMP with respect to the quality audits, quality testing and  
24 process validation for the Profemur<sup>®</sup> Total Hip System, including its components.  
25  
26  
27  
28

1           113. As a result of Wright's and/or MicroPort's failure to establish and  
2 maintain CGMP as set forth above, the Profemur<sup>®</sup> Total Hip System was defective  
3 and failed, resulting in injuries and damages to Plaintiff Elaine Shubin.  
4

5           114. If Wright and/or MicroPort had complied with the federal  
6 requirements regarding CGMP, the Profemur<sup>®</sup> Total Hip System would have been  
7 manufactured and/or designed properly such that it would not have resulted in  
8 injuries and damages to Plaintiff Elaine Shubin.  
9

10           115. Plaintiff Elaine Shubin's injuries and damages were both factually and  
11 proximately caused by the defective Profemur<sup>®</sup> Total Hip System.  
12

13           116. Plaintiff Elaine Shubin's injuries and damages were both factually and  
14 proximately caused by the unreasonably dangerous Profemur<sup>®</sup> Total Hip System.  
15

16           117. Plaintiff Elaine Shubin further shows that she is entitled to recover for  
17 all noneconomic and compensatory damages allowed by law, including, but not  
18 limited to, pain and suffering for all pain and suffering that she has incurred as a  
19 result of the defective product, the follow-up surgery, rehabilitation, and constant  
20 pain that occurs as a result of the failure of the Device.  
21  
22  
23  
24  
25  
26  
27  
28

**FIRST CAUSE OF ACTION**

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

1  
2  
3  
4 118. Plaintiffs hereby reallege and incorporate by reference all of the  
5  
6 allegations and statements contained in Paragraphs 1 through 117, inclusive, as  
7  
8 though fully set forth herein.

9 119. At all times relevant hereto, Defendants Wright and Microport  
10  
11 designed, manufactured, distributed, sold, marketed and/or promoted the  
12 Profemur<sup>®</sup> Total Hip System, including the 1) Profemur<sup>®</sup> PHA00270 Plasma Z  
13  
14 Stem, 2) Profemur<sup>®</sup> PHAC1232 8° var/val CoCr Modular Femoral Neck, 3)  
15  
16 26000010 Ceramic Femoral Head that were implanted in Plaintiff Elaine Shubin  
17  
18 on October 30, 2015.

19 120. At all times relevant hereto, the Profemur<sup>®</sup> Total Hip System was  
20  
21 expected to, and did, reach prescribing physicians and consumers, including  
22  
23 Plaintiff Elaine Shubin and Plaintiff's physician, without a substantial change in  
24  
25 the condition in which it was sold.

26 121. At all times relevant hereto, Plaintiff and Plaintiff's healthcare  
27  
28 providers used the Profemur<sup>®</sup> Total Hip System for its intended or reasonably  
foreseeable purpose.

1           122. At all times relevant hereto, the Profemur<sup>®</sup> Total Hip System was  
2 defective and unreasonably dangerous. Such defects included, but were not limited  
3 to, a tendency to (a) generate dangerous and harmful metal debris in the patient's  
4 body; (b) corrode; (c) cause pain; (d) inhibit mobility; (e) require revision surgery;  
5 and (f) fracture.  
6  
7

8           123. Plaintiffs are informed and believe, and thereupon allege, that the  
9 Profemur<sup>®</sup> Total Hip System implanted in Plaintiff, Elaine Shubin, is defective and  
10 unreasonably dangerous because of a manufacturing defect in the alleged device,  
11 as aforesaid, which contain a condition that the manufacturer did not intend and,  
12 as a result, failed to perform as safely as an ordinary consumer would expect when  
13 the product is used in a reasonably foreseeable manner and / or because it differed  
14 from the manufacturer's design and specifications, or from typical units of the  
15 same product line.  
16  
17  
18

19           124. As a direct, legal, proximate and producing result of the defective  
20 manufacture of the Profemur<sup>®</sup> Total Hip System implanted in Plaintiff, Elaine  
21 Shubin, Plaintiffs sustained injuries and damages as set forth above, for which the  
22 said defendants are strictly liable.  
23

24           125. The dangerous, unsafe and defective manufacturing of the Profemur<sup>®</sup>  
25 Total Hip System implanted in Plaintiff, Elaine Shubin was a substantial factor in  
26  
27  
28

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

3  
4 **SECOND CAUSE OF ACTION**

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

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

10  
11 127. The Profemur<sup>®</sup> Total Hip System was defective and unreasonably  
12 dangerous when it left the possession of Defendants in that it failed to provide  
13 adequate warnings to alert the medical community and patients, including  
14 Plaintiffs and Plaintiff's healthcare providers, to the dangerous risks associated  
15 with the Profemur<sup>®</sup> Total Hip System when used for its intended and reasonable  
16 foreseeable purpose. The dangers and risks included, but were not limited to, a  
17 tendency to (a) generate dangerous and harmful metal debris in the patient's body;  
18 (b) cause injury and pain; (c) inhibit mobility; (d) require revision surgery; and (e)  
19 fracture.  
20  
21  
22  
23

24 128. At all times relevant hereto, Plaintiffs and Plaintiff's healthcare  
25 providers used the Profemur<sup>®</sup> Total Hip System for its intended or reasonably  
26 foreseeable purpose.  
27  
28

1           129. Plaintiffs and Plaintiff's healthcare providers could not have  
2 discovered any defect in the Profemur<sup>®</sup> Total Hip System through the exercise of  
3 due care.  
4

5           130. Defendants knew or should have known, through complaint data and  
6 knowledge of the design's history, by the use of generally recognized and  
7 prevailing scientific/ technical/ medical knowledge available at the time of the said  
8 product's distribution, that a foreseeable use of the product may be unreasonably  
9 dangerous without adequate warnings of the danger(s) posed by potential risks and  
10 side effects associated with the Profemur<sup>®</sup> Total Hip System. Defendants knew or  
11 should have known of the defective condition, characteristics, and risks associated  
12 with the Device as previously set forth herein.  
13  
14  
15

16           131. The warnings and instructions provided with the Profemur<sup>®</sup> Total Hip  
17 System by Defendants did not adequately warn of the potential risks and side  
18 effects of the Profemur<sup>®</sup> Total Hip System, which risks were known or  
19 scientifically knowable to Defendants.  
20  
21

22           132. Defendants had a continuing duty to warn the medical community and  
23 public, including Plaintiff and Plaintiff's healthcare providers, of the potential risks  
24 and increased failure rate associated with the Profemur<sup>®</sup> Total Hip System.  
25  
26  
27  
28

1           133. As a direct, legal, proximate and producing result of Defendants'  
2 failure to warn, Plaintiff sustained the injuries and damages as set forth above, for  
3 which said defendants are strictly liable.  
4

5           134. Defendants' failure to adequately warn of the potential risks and side  
6 effects of the Profemur® Total Hip System was a substantial factor in causing  
7 Plaintiff's injuries and damages as set forth above, for which said defendants are  
8 strictly liable.  
9

10  
11                                   **THIRD CAUSE OF ACTION**

12                   **(STRICT PRODUCTS LIABILITY – UNREASONABLY DANGEROUS**  
13                                   **DESIGN)**  
14                                   **(As to All Defendants)**

15           135. Plaintiffs repeat, reallege and hereby incorporate by reference all of  
16 the allegations and statements contained in Paragraphs 1 through 117, inclusive, as  
17 though fully set forth herein.  
18

19           136. At all times relevant hereto, Defendants designed, manufactured,  
20 distributed, sold, marketed and/or promoted the Profemur® Total Hip System,  
21 including the 1) Profemur® PHA00270 Plasma Z Stem, 2) Profemur® PHAC1232  
22 8° var/val CoCr Modular Femoral Neck, 3) 26000010 Ceramic Femoral Head that  
23 were implanted in Plaintiff Elaine Shubin on October 30, 2015.  
24  
25

26           137. At all times relevant hereto, the Profemur® Total Hip System was  
27 expected to, and did, reach prescribing physicians and consumers, including  
28

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

3  
4 138. At all times relevant hereto, Plaintiff and Plaintiff's healthcare  
5 providers used the Profemur<sup>®</sup> Total Hip System for its intended or reasonably  
6 foreseeable purpose.

7  
8 139. At all times relevant hereto, the Profemur<sup>®</sup> Total Hip System was  
9 defective and unreasonably dangerous because of a design defect, as aforesaid in  
10 this complaint. Such defects included, but were not limited to, a tendency to (a)  
11 generate dangerous and harmful metal debris in the patient's body; (b) corrode; (c)  
12 cause injury and pain; (d) inhibit mobility; (e) require revision surgery; and (f)  
13 fracture.

14  
15  
16 140. Defendants knew or should have known of the unreasonably  
17 dangerous and serious risks associated with the design of the Profemur<sup>®</sup> Total Hip  
18 System. Such risks were historically and scientifically knowable to Defendants.  
19 However, Defendants performed inadequate evaluation and testing of the  
20 Profemur<sup>®</sup> Total Hip System design.

21  
22  
23 141. As a direct, legal, proximate and producing result of the defective  
24 design of the Profemur<sup>®</sup> Total Hip System implanted in Plaintiff, Plaintiff  
25 sustained injuries and damages as set forth above, for which said defendants are  
26 strictly liable.  
27  
28





1 and evaluation of the Profemur<sup>®</sup> Total Hip System's safety and performance prior  
2 to placing the Profemur<sup>®</sup> Total Hip System into the stream of commerce.

3  
4 146. At all times relevant hereto, Defendants knew or should have known  
5 of the serious complications and high failure rate associated with the Profemur<sup>®</sup>  
6 Total Hip System. Despite receiving hundreds of reports of serious complications  
7 from healthcare providers, Defendants chose (1) not to discontinue or redesign the  
8 Device; (2) not to perform any additional testing of the Profemur<sup>®</sup> Total Hip  
9 System; (3) not to investigate other potential causes of the reported complications; (4)  
10 suspend sales or distribution; or (5) warn physicians and patients of the propensity  
11 of the Profemur<sup>®</sup> Total Hip System to generate dangerous and harmful metal  
12 debris in the patient's body; cause pain; inhibit mobility; fracture; and require  
13 revision surgery.  
14  
15  
16  
17

18 147. As a direct, legal, proximate and producing result of the Defendants'  
19 negligent design, warning, labeling, testing, manufacturing, marketing selling and  
20 promoting the Profemur<sup>®</sup> Total Hip System, Plaintiff sustained injuries as set forth  
21 above.  
22

23 148. Defendants' negligent design, warning, labeling, testing,  
24 manufacturing, marketing, selling and promoting of the Profemur<sup>®</sup> Total Hip  
25 System implanted in Plaintiff, Elaine Shubin was a substantial factor in Plaintiff's  
26 injuries and damages as set forth above.  
27  
28

**FIFTH CAUSE OF ACTION**

**(NEGLIGENCE – FAILURE TO RECALL/RETROFIT)**

**(As to all Defendants)**

1  
2  
3  
4 149. Plaintiffs hereby reallege and incorporate by reference all of the  
5  
6 allegations and statements contained in Paragraphs 1 through 117, inclusive, as  
7  
8 though fully set forth herein.

9 150. At all times relevant hereto, Defendants Wright and MicroPort knew  
10  
11 or should have known that the design of the Profemur<sup>®</sup> Total Hip System and its  
12  
13 warnings were dangerous or were likely to be dangerous when used in an intended  
14  
15 or reasonably foreseeable manner.

16 151. Despite the severity and number of complaints Defendants Wright and  
17  
18 MicroPort received, Defendants failed to recall, retrofit or warn patients or  
19  
20 physicians about the danger of the Profemur<sup>®</sup> Total Hip System.

21 152. As a direct, legal, proximate and producing result of the Defendants’  
22  
23 failure to recall the Profemur<sup>®</sup> Total Hip System, Plaintiffs suffered injuries and  
24  
25 damages as set forth above.

26 153. Defendants’ failure to recall the Profemur<sup>®</sup> Total Hip System  
27  
28 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)**

1  
2  
3  
4 154. Plaintiffs repeat, reallege and hereby incorporate by reference all of  
5 the allegations and statements contained in Paragraphs 1 through 117 above,  
6 inclusive, as though fully set forth herein.  
7

8  
9 155. Defendants had a duty to truthfully represent to the medical  
10 community, and to Plaintiffs, Plaintiff's healthcare providers and the FDA, that the  
11 Profemur<sup>®</sup> Total Hip System had not been properly tested and not found to be safe  
12 and effective for its intended use.  
13

14 156. Defendants knew or should have known that their representations that  
15 the Device was safe and effective were false and the representations regarding the  
16 safety and performance of the Profemur<sup>®</sup> Total Hip System was in fact, false.  
17

18 157. Defendants failed to exercise ordinary care in determining the truth or  
19 falsity of their representations, and by misrepresenting the safety and performance  
20 of the Profemur<sup>®</sup> Total Hip System.  
21

22 158. Defendants breached their duty to present truthful representations by  
23 knowingly, or by want of ordinary care, misrepresenting the safety and  
24 performance of the Profemur<sup>®</sup> Total Hip System.  
25  
26  
27  
28



1           163. Defendants had a duty to inform, but fraudulently concealed from the  
2 medical community, implanting orthopedic surgeon Dr. Ward, Plaintiff, and the  
3 public that the Wright Medical Profemur CoCr Modular Neck coupled with the  
4 Wright Medical Profemur titanium modular stem in the Wright Medical Profemur  
5 Total Hip System had an unreasonable and dangerous risk of corroding, fretting,  
6 and causing bodily injury.  
7  
8

9           164. Through the reporting of adverse events to Wright and MicroPort, and  
10 by reports from experts in metallurgy and biomechanics retained by Wright and  
11 MicroPort, Defendants knew of the risk of corrosion and subsequent adverse tissue  
12 reaction and resulting bodily injury present in the device implanted in Plaintiff but  
13 did not disclose this information. Neither Plaintiff nor Plaintiff's surgeon had this  
14 information, nor could they have discovered this information through reasonable  
15 diligence.  
16  
17  
18

19           165. The Defendants had a duty to communicate the increased risk and  
20 known failures associated with the device implanted in Plaintiff to Plaintiff and  
21 Plaintiff's surgeon.  
22

23           166. Plaintiff and Plaintiff's surgeon justifiably relied upon Defendants to  
24 communicate known risks and failures when making both the decision to implant  
25 the device and the appropriate course of treatment following Plaintiff's index  
26 surgery.  
27  
28



1           171. Defendants, as manufacturers and distributors of the Profemur<sup>®</sup> Total  
2 Hip System armed with superior knowledge regarding the latent defects and failure  
3 rates associated with the Device, had a duty to accurately and truthfully represent  
4 to the public, the medical community, Plaintiff, and Plaintiff's surgeon, the  
5 material facts that it knew regarding the risks of the Profemur CoCr Modular Neck  
6 coupled with the Wright Medical Profemur titanium modular stem as part of the  
7 Profemur<sup>®</sup> Total Hip System.  
8

9  
10           172. Defendants made false representations of material fact to Plaintiff  
11 and/or her healthcare providers as to the safety and efficacy of the Profemur CoCr  
12 Modular Neck coupled with the Wright Medical Profemur titanium modular neck  
13 in the Profemur Total Hip System. Instead of disclosing the heightened risks of  
14 corrosion, fretting, fracture, failure, and permanent injury, Defendnats represented:  
15  
16

- 17           a) that there was no indication of an increased risk of adverse events  
18           due to taper junction fretting and corrosion,  
19  
20           b) that lab testing guaranteed structural reliability and the  
21           absence of significant micromovement and absence of  
22           fretting corrosion;  
23  
24           c) that product complaint data did not indicate an increased risk of  
25           corrosion for Profemur CoCr Modular Necks when coupled with  
26           Profemur titanium hip stems;  
27  
28



- 1 d) that, “[u]tilized in both primary and revision applications, the  
2 current [Profemur modular] neck design has been successfully  
3 employed to improve surgical outcomes with no reported failures”;  
4  
5 e) that Profemur<sup>®</sup> cobalt-chromium modular necks would result in  
6 less fretting than occurred with titanium modular necks;  
7  
8 f) that Profemur<sup>®</sup> cobalt-chromium modular Necks coupled with  
9 Profemur<sup>®</sup> stems showed a total absence of corrosion in an in vivo  
10 environment; and  
11  
12 g) that the Profemur Total Hip System, including its component parts,  
13 were safe and effective, and were safer and more effective than  
14 other treatments for hip replacements.  
15

16 173. Defendants knew that the above representations alleged in paragraph  
17 172 were false, yet Defendants willfully, wantonly, and recklessly disregarded the  
18 inaccuracies in these representations.  
19

20 21 174. Defendants made these false representations with the intent of  
22 defrauding and deceiving the medical community (including implanting surgeon  
23 Dr. Ward), Plaintiff, and the public, and to induce the medical community,  
24 Plaintiff’s implanting surgeon, Plaintiff, and the public to utilize the Profemur  
25 CoCr Modular Neck coupled with the Profemur titanium modular stem as part of  
26 the Profemur Total Hip System. Doing so constituted a callous, reckless, willful,  
27  
28

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

3  
4 175. Plaintiff and her implanting orthopedic surgeon Dr. Ward justifiably  
5 relied upon Defendants' false representations of material fact in deciding to utilize  
6 the Profemur Hip System, including the CoCr modular neck and titanium modular  
7 stem.  
8

9  
10 176. Had Plaintiff or her healthcare providers known the true facts about  
11 the dangers and health risks of the Profemur CoCr Modular Neck coupled with the  
12 Profemur titanium modular stem as components of the Profemur Total Hip System,  
13 they would not have utilized these products.  
14

15 177. As a direct and proximate result of Defendants' fraudulent conduct,  
16 Plaintiff has experienced significant mental and physical pain and suffering, has  
17 sustained permanent injury, has undergone medical treatment and will likely  
18 undergo further medical treatment and procedures, has suffered financial or  
19 economic loss, including, but not limited to, obligations for medical services and  
20 expenses, and other damages.  
21  
22

23 **NINTH CAUSE OF ACTION**

24 **(LOSS OF CONSORTIUM)**  
25 **(As to All Defendants)**  
26  
27  
28



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

3  
4 184. The willful and wanton conduct and evil minds of Defendants was  
5 conduct either purposefully committed or Defendants acted to serve defendants'  
6 own interests, having reason to know and consciously disregarding a substantial  
7 risk that its conduct might significantly injure the rights and safety of others, or  
8 defendant consciously pursued a course of conduct knowing that it created a  
9 substantial risk of significant harm to the rights and safety of others, particularly  
10 Elaine Shubin.  
11

12  
13 185. Defendants, when they had the opportunity to do so, repeatedly failed  
14 to warn or to correct a known unreasonably dangerous condition regarding their  
15 medical device at issue.  
16

17  
18 186. Defendants knew or should have known, in light of the surrounding  
19 circumstances that its conduct would naturally and probably result in injury or  
20 damage and continued the conduct with malice or in reckless disregard of the  
21 consequences, from which malice may be inferred. Accordingly, Plaintiff is  
22 entitled to an award of punitive damages.  
23

24  
25  
26  
27 ///  
28

**PRAYER FOR RELIEF**

1  
2 WHEREFORE, Plaintiffs pray for judgment against Defendants, jointly  
3 and/or severally, as follows:  
4

- 5 1. For general damages for personal injuries to Plaintiffs, according to  
6 proof;  
7  
8 2. For all past, current and future medical and incidental expenses,  
9 according to proof;  
10  
11 3. For punitive damages, according to proof;  
12  
13 4. For loss of consortium, according to proof;  
14  
15 5. For prejudgment interest, as provided by law;  
16  
17 6. For costs of litigation; and  
18  
19 7. For such other and further relief as this Court may deem just and proper.  
20  
21 8. loss of earnings and any decrease in earning power or capacity in the  
22 future.  
23

24 Respectfully submitted, this 5<sup>th</sup> day of June, 2020.  
25

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

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28

**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*